EthxWeb Search Results

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Result=(("18.2".PC.) AND (@YD >= "20040000")) NOT (EDITORIAL OR LETTER OR NEWS)
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Documents: 1 - 325 of 2150

* Book  Document 1
Stark, Laura
BEHIND CLOSED DOORS: IRBs AND THE MAKING OF ETHICAL RESEARCH
Call number: R852.5 .S837 2012

* Article  Document 2
Truong, Tony H; Weeks, Jane C; Cook, E Francis; Joffe, Steven
Outcomes of informed consent among parents of children in cancer clinical trials.
Pediatric blood & cancer 2011 Dec 1; 57(6): 998-1004
Abstract: Clinical trials are central to pediatric oncology, yet the process and outcomes of informed consent are poorly understood. We evaluated correlates of understanding among parents of pediatric trial participants, and explored differences in the process and outcome of informed consent between parents and a comparison group of adult participants.
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* Article  Document 3
Garg, Amit K
Nocebo side-effects in cancer treatment.
The lancet oncology 2011 Dec; 12(13): 1181-2
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* Article  Document 4
Lo, Bernard; Barnes, Mark
Protecting research participants while reducing regulatory burdens.
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* Article  Document 5
Mayor, Susan
Government says that UK does not need an external regulator to oversee research integrity.
BMJ (Clinical research ed.) 2011 October 19; 343: d6798
Document 6
Sheehan, Mark; Parker, Michael; Dunn, Michael
Delia Smith and the ethics committee.
BMJ (Clinical research ed.) 2011 October 12; 343: d6511
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Document 7
Swank, H A; Morton, D G; Meijer, D W; Bemelman, W A;
European Society of Coloproctology Research Committee
The consequences of good clinical practice for investigator-initiated research.
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Document 8
Chi, John H
Exposing conflicts of interest and complications of rhBMP-2.
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Document 9
Hauser, Stephen L; Johnston, S Claiborne
Global clinical trials: challenges ahead.
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Document 10
Thomas, George
Institutional ethics committees: critical gaps.
Indian journal of medical ethics 2011 Oct-Dec; 8(4): 200-1
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Document 11
Bhan, Anant
Ethics in cluster randomised trials: a grey zone.
Indian journal of medical ethics 2011 Oct-Dec; 8(4): 253-4
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Document 12
Patel, Sangita; Baxi, Rajendra K; Patel, Shilpa N; Golin, Carol E
Challenges of collaborative research.
Indian journal of medical ethics 2011 Oct-Dec; 8(4): 262
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Document 13
Fukuda, Haruhiko
[Science and ethics in clinical research].
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Document 14
Wong, Janice C; Bernstein, Mark
Payment of research subjects for more than minimal risk trials is unethical.
The American journal of the medical sciences 2011 Oct; 342(4): 294-6
Abstract: This article explores the ethics of paying research participants for studies involving more than minimal risk using arguments grounded in morality, logic and pragmatism, as well as patient responses from a focused qualitative study. The authors argue that payment of research participants is ethically unacceptable. Balanced against the probability of harmful risks, guaranteed payment to participants represents excessive and undue influence and leads to commodification of human health. Patients range in their opinions on whether payment for research participation is ethical, considering issues of justice and nonmaleficence. From basic assumptions about the correlation between risks, financial need and willingness to participate in studies, the authors demonstrate that payments lead to unjustly influencing patients, especially the financially needy to participate in potentially harmful studies. Previous commentators have offered methods to regulate payment to participants, but these models do not seem feasible or ethically sound.
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Document 15
Halpern, Scott D
Financial incentives for research participation: empirical questions, available answers and the burden of further proof.
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Document 16
Djulbegovic, Benjamin
Uncertainty and equipoise: at interplay between epistemology, decision making and ethics.
Abstract: In recent years, various authors have proposed that the concept of equipoise be abandoned because it conflates the practice of clinical care with clinical research. At the same time, the equipoise opponents acknowledge the necessity of clinical research if there are unresolved uncertainties about the effects of proposed healthcare interventions. As equipoise represents just 1 measure of uncertainty, proposals to abandon equipoise while maintaining a requirement for addressing uncertainties are contradictory and ultimately not valid. As acknowledgment and articulation of uncertainties represent key scientific and moral requirements for human experimentation, the
concept of equipoise remains the most useful framework to link the theory of human experimentation with the theory of rational choice. In this article, I show how uncertainty (equipoise) is at the intersection between epistemology, decision making and ethics of clinical research. In particular, I show how our formulation of responses to uncertainties of hoped-for benefits and unknown harms of testing is a function of the way humans cognitively process information. This approach is based on the view that considerations of ethics and rationality cannot be separated. I analyze the response to uncertainties as it relates to the dual-processing theory, which postulates that rational approach to (clinical research) decision making depends both on analytical, deliberative processes embodied in scientific method (system II), and good human intuition (system I). Ultimately, our choices can only become wiser if we understand a close and intertwined relationship between irreducible uncertainty, inevitable errors and unavoidable injustice.

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**Document 17**
Rehbock, Theda

**Limits of autonomy in biomedical ethics?: conceptual clarifications.**

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**Document 18**
Gearhart, Cami

**Review boards: vital to protect subjects.**
Nature 2011 September 21; 477(7365): 407

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**Document 19**
Slack, Nicholas C

**Review boards: all need closer scrutiny.**
Nature 2011 September 14; 477(7364): 280

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**Document 20**
The Lancet,

**Ethical behaviour in clinical research--a lesson from the past.**
Lancet 2011 Sep 10; 378(9795): 962

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**Document 21**
Wadman, Meredith

**Proposed centralization of trial oversight stirs mixed reaction.**
Nature medicine 2011 September 7; 17(9): 1025

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Document 22

Ilitis, Ana S

Justice, fairness, and membership in a class: conceptual confusions and moral puzzles in the regulation of human subjects research.

Abstract: This essay examines conceptual difficulties with one of the ways in which justice has been understood and applied the ethical and regulatory review of human research. Justice requires the fair distribution of the benefits and burdens of research. Class membership is seen as justifying inclusion in higher hazard-no benefit research from which members of potentially vulnerable classes, such as children, typically would be excluded. I argue that class membership does not do the justificatory work it is thought to do and that the use of class membership to justify inclusion in higher hazard-no benefit research leads to unjustified discrimination of sick children and offers special protections to healthy children.

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Document 23

Klitzman, Robert

Views and experiences of IRBs concerning research integrity.

Abstract: Institutional Review Boards (IRBs) can play vital roles in observing, monitoring, and responding to research integrity (RI) issues among researchers, yet many questions remain concerning whether, when, and in what ways these boards adopt these roles. I contacted 60 IRBs (every fourth one in the list of the top 240 institutions by NIH funding), and interviewed leaders from 34 (response rate=55%), and an additional 12 members and administrators. IRBs become involved in a variety of RI problems, broadly defined, and face challenges in deciding how and when to do so. IRBs vary in how they define, discover, and respond to RI problems, and interact with other institutional offices concerning these issues; and what types of RI violations they encountered. While many institutions establish separate Compliance Offices, the boundaries and relationships between these entities and IRBs vary; and many IRBs discover and monitor RI violations, and struggle with how to respond. Larger questions arise of how IRBs decide whether to trust vs. closely monitor individual PIs. IRBs' roles are often indirect, and not fully systematic, raising questions of whether these functions should be enhanced, and if so, to what degree, and how. These areas require heightened investigation and discussion.

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Document 24

VanderWalde, Ari; Kurzban, Seth

Paying human subjects in research: where are we, how did we get here, and now what?
The Journal of law, medicine & ethics : a journal of the American Society of Law, Medicine & Ethics 2011 Fall; 39(3): 543-58

Abstract: Both international and federal regulations exist to ensure that scientists perform research on human subjects in an environment free of coercion and in which the benefits of the research are commensurate with the risks involved. Ensuring that these conditions hold is difficult, and perhaps even more so when protocols include the issue of monetary compensation of research subjects. The morality of paying human research subjects has been hotly debated for over 40 years, and the grounds for this debate have ranged from discussion of legal rights, economic rights, philosophical principles of vulnerability and altruism to bioethical concepts of consent, best-interest determination, and justice theory. However, the thought surrounding these issues has evolved over time, and the way we think about the role of the human research subject today is markedly different than the way we thought in the past. Society first thought of the research subject as an altruist, necessarily giving of his time to benefit society as a whole. As time progressed, many suggested that the subject should not need to sacrifice himself for research: if something goes wrong, someone should compensate the subject for injuries. The concept of redress evolved into a system in which subjects were offered money as an inducement to participate in research, sometimes merely to
offset the monetary costs of participation, but sometimes even to mitigate the risks of the study. This article examines ethical and legal conversations regarding compensation from the 1960s through today, examining theories of the ethics of compensation both comparatively and critically. In conclusion, we put forward an ethical framework for treating paid research subjects, with an attempt to use this framework as a means of resolving some of the more difficult problems with paying human subjects in research.

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**Document 25**

Bishop, Emily C; Shepherd, Marie L

**Ethical reflections: examining reflexivity through the narrative paradigm.**

Qualitative health research 2011 Sep; 21(9): 1283-94

**Abstract:** Being reflexive and providing these reflections for public scrutiny is often considered a key element of ethical, rigorous qualitative research. Prevalent conceptualizations of reflexivity, however, need interrogating and sharpening. We aim to contribute to this by examining reflexive practice, and in particular researchers' reflexive accounts, through the lens of the narrative paradigm. Our aim is to demonstrate that acknowledging the role of narrative reconstruction in reflexivity creates more ethical research, and that it is therefore crucial for researchers to more explicitly recognize this. Both authors present an analysis of one particular exchange between interviewer and participant. This analysis highlights that despite our best efforts at "doing reflexivity," both immediately following and when reflecting back on an interview, there are influential factors that escape our gaze. Reflections of the past are particularly imperfect. Without fully recognizing this, we are not utilizing all the tools available for ensuring honest, ethical research.

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**Document 26**

Locock, Louise; Smith, Lorraine

**Personal experiences of taking part in clinical trials - a qualitative study.**

Patient education and counseling 2011 Sep; 84(3): 303-9

**Abstract:** To investigate people's experiences of and attitudes to participation in clinical trials.

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**Document 27**

Ibrahim, George M; Chung, Caroline; Bernstein, Mark

**Competing for patients: an ethical framework for recruiting patients with brain tumors into clinical trials.**

Journal of neuro-oncology 2011 Sep; 104(3): 623-7

**Abstract:** With more rapid advances in potential treatments for brain tumours, the number of clinical trials for brain tumour patients is rising. In the context of the challenges of recruitment and enrollment of patients with brain tumors, the dichotomy between the paucity of subjects and abundance of clinical trials creates a unique ethical dilemma, whereby a single patient may be eligible for several studies. Here, we identify and present three approaches for recruiting and enrolling patients who may be eligible for several trials. The ethical implications of the full disclosure, paternalistic, and random approaches are discussed. The full disclosure approach presents information to patients regarding all ongoing concurrent trials, allowing them to make an informed decision, while the paternalistic approach allows the healthcare providers to select the trial for which they believe the patient is most suitable. These introduce the biases into circumstances where equipoise is necessary and risk selection bias in study design. The random approach randomly allocates patients to each trial, which may erode patient autonomy and decrease trial enrollment. Brain tumor patients comprise a vulnerable population and it remains incumbent on healthcare providers to maintain the highest ethical standards when approaching them for clinical research. Changes in clinical trial design are required to mitigate the conflicts created by competition for patients.

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Document 28
Karbwang, Juntra; Torres, Cristina
**Ethical issues related to clinical trials outside the International Conference on Harmonization regions.**
Future medicinal chemistry 2011 Sep; 3(12): 1457-60
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Document 29
Westra, Anna E; De Beaufort, Inez D
**The merits of procedure-level risk-benefit assessment.**
Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 30
Wisner, Katherine L; Conley, Robert R; Taylor, Stephan F; Kosten, Thomas; Rapaport, Mark Hyman; Brown, Lawrence S
**Researcher experiences with IRBs: a survey of members of the American College of Neuropsychopharmacology.**
IRB 2011 Sep-Oct; 33(5): 14-20
Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 31
Steeves, John D; Zariffa, Jose; Kramer, John L K
**Are you "tilting at windmills" or undertaking a valid clinical trial?**
Yonsei medical journal 2011 Sep; 52(5): 701-16
**Abstract:** In this review, several aspects surrounding the choice of a therapeutic intervention and the conduct of clinical trials are discussed. Some of the background for why human studies have evolved to their current state is also included. Specifically, the following questions have been addressed: 1) What criteria should be used to determine whether a scientific discovery or invention is worthy of translation to human application? 2) What recent scientific advance warrants a deeper understanding of clinical trials by everyone? 3) What are the different types and phases of a clinical trial? 4) What characteristics of a human disorder should be noted, tracked, or stratified for a clinical trial and what inclusion/exclusion criteria are important to enrolling appropriate trial subjects? 5) What are the different study designs that can be used in a clinical trial program? 6) What confounding factors can alter the accurate interpretation of clinical trial outcomes? 7) What are the success rates of clinical trials and what can we learn from previous clinical trials? 8) What are the essential principles for the conduct of valid clinical trials?
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Document 32
Umscheid, Craig A; Margolis, David J; Grossman, Craig E
**Key concepts of clinical trials: a narrative review.**
Postgraduate medicine 2011 Sep; 123(5): 194-204
**Abstract:** The recent focus of federal funding on comparative effectiveness research underscores the importance of clinical trials in the practice of evidence-based medicine and health care reform. The impact of clinical trials not only extends to the individual patient by establishing a broader selection of effective therapies, but also to society as a whole by enhancing the value of health care provided. However, clinical trials also have the potential to pose unknown risks to their participants, and biased knowledge extracted from flawed clinical trials may lead to the
inadvertent harm of patients. Although conducting a well-designed clinical trial may appear straightforward, it is founded on rigorous methodology and oversight governed by key ethical principles. In this review, we provide an overview of the ethical foundations of trial design, trial oversight, and the process of obtaining approval of a therapeutic, from its pre-clinical phase to post-marketing surveillance. This narrative review is based on a course in clinical trials developed by one of the authors (DJM), and is supplemented by a PubMed search predating January 2011 using the keywords "randomized controlled trial," "patient/clinical research," "ethics," "phase IV," "data and safety monitoring board," and "surrogate endpoint." With an understanding of the key principles in designing and implementing clinical trials, health care providers can partner with the pharmaceutical industry and regulatory bodies to effectively compare medical therapies and thereby meet one of the essential goals of health care reform.

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Document 33

Mdege, Noreen D; Man, Mei-See; Taylor Nee Brown, Celia A; Torgerson, David J

**Systematic review of stepped wedge cluster randomized trials shows that design is particularly used to evaluate interventions during routine implementation.**

Journal of clinical epidemiology 2011 Sep; 64(9): 936-48

**Abstract:** To describe the application of the stepped wedge cluster randomized controlled trial (CRCT) design.

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Document 34

Beadle, G; Mengersen, K; Moynihan, S; Yates, P

**Perceptions of the ethical conduct of cancer trials by oncology nurses.**


**Abstract:** Informed consent and subject protection are internationally mandated requirements for the ethical conduct of research; however, the monitoring of the day-to-day conduct of research may be insufficient for ensuring consistent compliance with required ethical ideals. Oncology nurses were surveyed about their perceptions of ethical issues relevant to cancer trials research. Utilising an investigator-developed instrument, multi-item scales assessed six ethical domains. Of 192 respondents, 95% or more held definite views in 12 of 15 items about patient understanding of cancer trials, informed consent and the welfare of participants. Approximately 95% perceived that patients consented freely and knew how to withdraw from a trial, and 81% perceived better monitoring of trial than non-trial patients. However, more than 80% of respondents perceived that at times patients had unrealistic expectations of participation, and more than 50% perceived that participants sometimes did not understand the nature and risk of cancer trials. Although the conative attributes of patients place limits on the goals of bioethics, the results of this study show first that oncology nurses have opinions about ethical constructs directly linked to the daily conduct of cancer clinical trials, and second that this link warrants further investigation in order to benchmark trial conduct against the ideals of ethical research.

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Document 35

Cohen, Deborah

**Medtronic submits full data on spinal protein to independent scrutiny.**

BMJ (Clinical research ed.) 2011 August 30; 343: d5484

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Document 36

**Who watches the watchmen?**

Nature 2011 August 10; 476(7359): 125
Qiu, Jane

Chinese academies promise cleaner elections.
Nature 2011 August 10; 476(7359): 139

Katsnelson, Alla

Experimental therapies for Parkinson’s disease: Why fake it?
Nature 2011 August 10; 476(7359): 142-4

Hampton, Tracy

European drug agency under fire: critics charge that trial data are too inaccessible.

Coulehan, Jack

My battle against gonorrhea.
Annals of internal medicine 2011 Aug 2; 155(3): 198-200

Hermos, John A; Spiro, Avron 3rd.

Tripping over the HIPAA hurdle.
Annals of internal medicine 2011 Aug 2; 155(3): 203

Zatz, Marion

A view from the NIH bridge: perspectives of a program officer.
Molecular biology of the cell 2011 Aug 1; 22(15): 2661-3

Abstract: This essay is written from my perspective as a program officer for research and training activities at the National Institute of General Medical Sciences (NIGMS) for almost 27 yr. It gives a bird's-eye view of the job of a program officer, which includes providing advice to applicants and grantees, making funding recommendations, overseeing grantees' progress, facilitating scientific opportunities in specific areas of program responsibility, and
shaping NIGMS and National Institutes of Health (NIH) policy. I have highlighted the numerous rewards of serving as a program officer, as well as some of the difficulties. For those who may be considering a position as an NIH program officer now or in the future, I've also described the qualities and qualifications that are important for such a career choice. Finally, this essay addresses some of the challenges for the NIH and the research community in the years ahead as we simultaneously face exciting scientific opportunities and tighter budgets.

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**Document 43**

Hart, Robert A

**Acknowledging the elephant in the room: conflict of interest in industry-sponsored clinical research.**

The spine journal: official journal of the North American Spine Society 2011 Aug; 11(8): 703-4

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**Document 44**

Woo, Emily Jane

**Re: A critical review of recombinant human bone morphogenetic protein-2 trials in spinal surgery: emerging safety concerns and lessons learned.**


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**Document 45**

Wang, Xiao-yun; Liang, Zhao-hui; Huang, Hui-ling; Liang, Wei-xiong

**Principles of ethics review on traditional medicine and the practice of institute review board in China.**

Chinese journal of integrative medicine 2011 Aug; 17(8): 631-4

**Abstract:** As one of the significant parts of medical science research in China, the research on Chinese medicine (CM) reflects the essence of healthcare tradition in the country both theoretically and clinically, and embodies the values of Chinese culture. Therefore, in the practice of ethics review on CM research protocols, besides abiding by the contemporary prevalent international principles and guidelines on bioethics, which emphasizes the scientific and bioethical value of the study, we should also stress the CM theoretical background and relevant clinical experience in the framework of Chinese culture and values. In this paper, we went over the traits of CM clinical research and the experience from the practice of ethics review by the institution review board for bioethics, and then attempted to summarize the key points for the bioethics review to CM researches in China, so as to serve as reference for the bioethics review to traditional and alternative medicine researches.

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**Document 46**

Field, Clarice J; Robinson, Sam; Mackay, Stuart; Harrison, James D; Marshall, Nathaniel S

**Clinical equipoise in sleep surgery: investigating clinical trial targets.**


**Abstract:** Surgical approaches for alleviating snoring and/or obstructive sleep apnea (OSA) have been questioned because of a lack of evidence from high-quality randomized controlled trials (RCTs). An ethical requirement for RCTs is that they must test questions where community equipoise (i.e., uncertainty) exists as to the correct treatment. We aimed to measure perceived importance, community equipoise, and willingness to enroll patients in 5 potential trial targets among members of the Australian Society for Otolaryngology Head and Neck Surgery (ASOHNS). STUDY DESIGN, SETTING, AND SUBJECTS: All ASOHNS members were surveyed using a multistage mail, email, Internet, and phone-based questionnaire.
Document 47
Bull, Susan; Lindegger, Graham Charles
**Ensuring consent to research is voluntary: how far do we need to go?**

Document 48
Bell, Jennifer; Ho, Anita
**Authenticity as a necessary condition for voluntary choice: a case study in cancer clinical trial participation.**

Document 49
Wessling, Adelheid
**[The difficult relationship of industry and science. Money versus research]. = Über das schwierige Verhältnis von Industrie und Wissenschaft. Geld versus Forschung.**
Pflege Zeitschrift 2011 Aug; 64(8): 454-5

Document 50
Gelling, Leslie
**Why do I have to apply for ethical approval before I can begin my research?**
Nursing times 2011 Aug 2-15; 107(30-31): 23

Document 51
Fortpied, Catherine; Liberatoscioli, Cecilia; Bogaerts, Jan
**Design issues in head and neck clinical trials: a statistician’s perspective.**
Anti-cancer drugs 2011 Aug; 22(7): 682-7

**Abstract:** The purpose of this article is to present some of the challenges the trial statistician meets when designing a clinical trial of the head and neck cancer. In recent years, the field of head and neck cancer has been facing some exciting evolutions, such as the arrival of newly targeted therapies and findings of disease causality and prognosis. These evolutions are accompanied by challenges in trial methodology that continue even today, and will most likely grow in importance in the future. This article focuses essentially on the design of phase III trials and discusses three major topics: should the trial be designed for a broad or a targeted population? Is there a concern for lack of equipoise and if so, how will it affect the trial results? What are the key elements that need to be taken into consideration when choosing, defining, and measuring the primary endpoint?
Document 52
Panichkul, Suthee; Mahaisavariya, Punkae; Morakote, Nimit; Condo, Sumalee; Caengow, Supak; Ketunpanya, Aphronpirom

**Current status of the research ethics committees in Thailand.**
Journal of the Medical Association of Thailand = Chotmaihet thangphaet 2011 Aug; 94(8): 1013-8

**Abstract:** Many research ethics committees (RECs) have been established to review biomedical research involving human subjects in many research institutes. The purpose is “To protect rights and welfare of human research participants”. It is necessary to determine how many research ethics committees have been established in Thailand and whether they have a high enough standard to protect the rights and welfare of human research subjects.

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Document 53
Dunlop, Anne L; Leroy, Zanie C; Logue, Kristi M; Glanz, Karen; Dunlop, Boadie W

**Preconsent education about research processes improved African Americans' willingness to participate in clinical research.**
Journal of clinical epidemiology 2011 Aug; 64(8): 872-7

**Abstract:** To determine whether preconsent education about research processes and protections affects the willingness of African Americans to participate.

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Document 54
Knapp, Peter; Raynor, David K; Silcock, Jonathan; Parkinson, Brian

**Can user testing of a clinical trial patient information sheet make it fit-for-purpose?--a randomized controlled trial.**
BMC medicine 2011 July 21; 9: 89

**Abstract:** The participant information sheet (PIS) provided to potential trial participants is a critical part of the process of valid consent. However, there is long-standing concern that these lengthy and complex documents are not fit-for-purpose. This has been supported recently through the application of a performance-based approach to testing and improving readability called user testing. This method is now widely used to improve patient medicine leaflets—determining whether people can find and understand key facts. This study applied for the first time a controlled design to determine whether a PIS developed through user testing had improved readability over the original, using a sheet from a UK trial in acute myeloid leukemia (AML16).

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Document 55
Labrique, Alain B; Bartlett, Linda A; Merritt, Maria W

**Research enrollment and informed consent.**
JAMA : the journal of the American Medical Association 2011 Jul 20; 306(3): 266; author reply 266

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Document 56
Wadman, Meredith

**Paxil study under fire.**
Nature 2011 July 12; 475(7355): 153
Document 57

Bretthauer, Michael; Haug, Charlotte

[What is established treatment?]. = Hva er etablert behandling?

Tidsskrift for den Norske lægeforening : tidsskrift for praktisk medicin, ny række 2011 Jul 1; 131(13-14): 1275

Document 58

Jesani, Amar

Can ethics committees address society's concerns about standards in research?

Indian journal of medical ethics 2011 Jul-Sep; 8(3): 134-5

Document 59

Blom, Erica; De Vries, Raymond

Towards local participation in the creation of ethical research guidelines.

Indian journal of medical ethics 2011 Jul-Sep; 8(3): 145-7

Abstract: Research ethics committees are entrusted with implementing guidelines to protect both scientists and human subjects of research from harm. These guidelines are often based on western contexts and may not resonate with the local moral traditions of the communities that they seek to protect. In this essay, we discuss how using principles of deliberative democracy with a "local derivation" approach may help in the drafting and implementation of ethical guidelines for research that better serve society.

Document 60

Krastev, Yordanka

Institutionalisation of Bulgarian ethics committees: history and current status.

Indian journal of medical ethics 2011 Jul-Sep; 8(3): 148-51

Abstract: This paper provides an overview of the institutionalisation of the ethics review process in Bulgaria in accordance with the worldwide trend in establishment of ethics committees. Historical and current politico-legal changes influencing the work of ethics committees are analysed. The paper focuses on ethics committees which review biomedical research involving humans, with an emphasis on their composition, functions, training of members, and decision-making processes. Recent positive changes addressing insufficient training of ethics committees' members are highlighted. Recommendations are made for enhancement of the ethics review process and improved transparency.

Document 61

Nadig, Pratibha; Joshi, Medha; Uthappa, Aradhana

Competence of ethics committees in patient protection in clinical research.

Indian journal of medical ethics 2011 Jul-Sep; 8(3): 151-4

Abstract: Research Ethics Committees (RECs) are responsible for the protection of patients' rights and wellbeing. In this paper, we describe the findings of a survey of ethics committee members in a south Indian state. 29 members of 11 RECs responded to a questionnaire of 56 questions on their knowledge of and attitudes towards ethics review
and the practices of the RECs to which they belonged.

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Document 62

Bouësséau, Marie-Charlotte; Reis, Andreas; Ho, W Calvin

**Global summit of national ethics committees: an essential tool for international dialogue and consensus-building.**

Indian journal of medical ethics 2011 Jul-Sep; 8(3): 154-7

**Abstract:** July 2010, important decisions were taken to ensure the continuity Held for the first time in 1996, the Global Summit of National of activities between the Summits. This article intends to briefly Ethics Committees (NECs) is a key platform for dialogue and retrace the history and analyse the role and functioning of the fostering consensus on ethical issues at a global level. At the Global Summit. It also discusses future challenges for international Eighth Global Summit meeting, which took place in Singapore in collaboration of NECs.

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Document 63

Steffen, Christian


Pharmazie in unserer Zeit 2011 Jul; 40(4): 332-7

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Document 64

Heilig, Charles M; Chia, David; El-Sadr, Wafaa M; Hirsch-Movberman, Yael; Kenzie, William R Mac; Saukkonen, Jussi; Villarino, Margarita E; Padayatchi, Nesri

**Justifying research risks in a clinical trial for treatment of multidrug-resistant tuberculosis.**


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Document 65

Krumholz, Samuel D; Egilman, David S; Ross, Joseph S

**Study of neurontin: titrate to effect, profile of safety (STEPS) trial: a narrative account of a gabapentin seeding trial.**

Archives of internal medicine 2011 Jun 27; 171(12): 1100-7

**Abstract:** Seeding trials, clinical studies conducted by pharmaceutical companies for marketing purposes, have rarely been described in detail.

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Document 66

Alexander, G Caleb

**Seeding trials and the subordination of science.**

Archives of internal medicine 2011 Jun 27; 171(12): 1107-8
Document 67

Klitzman, Robert

How local IRBs view central IRBs in the US.
BMC medical ethics 2011 June 23; 12: 13

Abstract: A "centralized review" of a clinical trial by an institutional review board (IRB) has been defined by the US Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) as one that is conducted by a central IRB. A central IRB is one that is not affiliated with a particular site, organization, or study sponsor. This article describes the views of local IRBs on the potential advantages and disadvantages of centralized review. The authors found that local IRBs generally view centralized review as a positive development, but that there are concerns about the potential for cost savings and the need for additional oversight. They also found that local IRBs are concerned about the potential for increased bureaucracy and the need for additional resources.

Document 68

Goozner, Merrill

Duke scandal highlights need for genomics research criteria.
Journal of the National Cancer Institute 2011 Jun 22; 103(12): 916-7

Abstract: The Duke University scandal has highlighted the need for better research criteria for genomics studies. The scandal involved the use of DNA from deceased patients without obtaining informed consent, and raised concerns about the ethical implications of such research. The article discusses the need for better research criteria for genomics studies, including the importance of obtaining informed consent from patients, and the need for more rigorous data management practices.

Document 69

Kurihara, Chieko

Ethical, legal, and social implications (ELSI) of microdose clinical trials.
Advanced drug delivery reviews 2011 Jun 19; 63(7): 503-10

Abstract: A "microdose clinical trial" (microdosing) is one kind of early phase exploratory clinical trial, administering the compound at doses estimated to have no pharmacological or toxicological effects, aimed at screening candidates for further clinical development. This article's objective is to clarify the ethical, legal, and social implications (ELSI) of such an exploratory minimum-risk human trial. The definition and non-clinical study requirements for microdosing have been harmonized among the European Union (EU), United States (US), and Japan. Being conducted according to these regulations, microdosing seems to be ethically well justified in terms of respect for persons, beneficence, justice, human dignity, and animal welfare. Three big projects have been demonstrating the predictability of therapeutic dose pharmacokinetics from microdosing. The article offers suggestions as how microdosing can become a more useful and socially accepted strategy.

Document 70

Mbuagbaw, Lawrence; Thabane, Lehana; Ongolo-Zogo, Pierre; Lang, Trudie

The challenges and opportunities of conducting a clinical trial in a low resource setting: the case of the Cameroon mobile phone SMS (CAMPS) trial, an investigator initiated trial.
Trials 2011 June 9; 12: 145

Abstract: Conducting clinical trials in developing countries often presents significant ethical, organisational, cultural and infrastructural challenges to researchers, pharmaceutical companies, sponsors and regulatory bodies. Globally, these regions are under-represented in research, yet this population stands to gain more from research in these settings as the burdens on health are greater than those in developed resourceful countries. However, developing countries also offer an attractive setting for clinical trials because they often have larger treatment naive populations with higher incidence rates of disease and more advanced stages. These factors can present a reduction in costs and time required to recruit patients. So, balance needs to be found where research can be encouraged and supported in order to bring maximum public health benefits to these communities. The difficulties with such trials arise from problems with obtaining valid informed consent, ethical compensation mechanisms for extremely poor populations, poor health infrastructure and considerable socio-economic and cultural divides. Ethical concerns with trials in developing countries have received attention, even though many other non-ethical issues may arise. Local investigator initiated trials also face a variety of difficulties that have not been adequately reported in literature. This paper uses the example of the Cameroon Mobile Phone SMS trial to describe in detail, the specific difficulties
encountered in an investigator-initiated trial in a developing country. It highlights administrative, ethical, financial and staff related issues, proposes solutions and gives a list of additional documentation to ease the organisational process.

Document 71
Sylvestre, Diana
Perspective: recognizing resistance.
Nature 2011 June 8; 474(7350): S11

Document 72
Rice, Mark J
The institutional review board is an impediment to human research: the result is more animal-based research.
Philosophy, ethics, and humanities in medicine : PEHM 2011 June 7; 6: 12
Abstract: Biomedical research today can be generally classified as human-based or nonhuman animal-based, each with separate and distinct review boards that must approve research protocols. Researchers wishing to work with humans or human tissues have become frustrated by the required burdensome approval panel, the Institutional Review Board. However, scientists have found it is much easier to work with the animal-based research review board, the Institutional Animal Care and Use Committee. Consequently, animals are used for investigations even when scientists believe these studies should be performed with humans or human tissue. This situation deserves attention from society and more specifically the animal protection and patient advocate communities, as neither patients nor animals are well served by the present situation.

Document 73
Robillard, Julie M; Federico, Carole A; Tairyan, Kate; Ivinson, Adrian J; Illes, Judy
Untapped ethical resources for neurodegeneration research.
BMC medical ethics 2011 June 2; 12: 9
Abstract: The research community has a mandate to discover effective treatments for neurodegenerative disorders. The ethics landscape surrounding this mandate is in a constant state of flux, and ongoing challenges place ever greater demands on investigators to be accountable to the public and to answer questions about the implications of their work for health care, society, and policy.

Document 74
Eyelade, O R; Ajuwon, A J; Adebamowo, C A
An appraisal of the process of protocol review by an ethics review committee in a tertiary institution in Ibadan.
Abstract: It is a well established norm that biomedical research involving human participants must conform to acceptable scientific principles and international codes of research ethics. The University of Ibadan/University College Hospital Health Research Ethics Committee (UI/UCH HREC) is the body that plays an oversight role and performs the function of a third party independent review of research protocols submitted by staff and students of the two institutions. A 6-year (2002-2007) retrospective audit of the protocols submitted to the HREC was performed to determine the profile of the lead investigator, sources of funding for the research and the duration for review using a
25 item questionnaire. A total of 752 protocols were submitted, 618 protocols (82%) were approved while 38 protocols were not approved. The principal investigators were mainly postgraduate students (67.1%) while academic staff constituted 21.3%. The average time from submission to approval was approximately 21 weeks (95% CI: 20-23 weeks). The period from submission to approval is significantly affected by the number of revision required and the funding agent (p < 0.05); it took a shorter time to review internationally funded research.

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**Document 75**

Pritchard, Ivor A

**How do IRB members make decisions? A review and research agenda.**


**Abstract**: Many factors have been found to influence the nature and quality of the human research ethics review process. These are reviewed along with discussion of ways in which normal psychological characteristics and group decision-making processes may affect the decisions of institutional review board (IRB) members when reviewing proposed research activities, and may contribute to the acknowledged variability of IRB responses to identical research proposals. Three salient features of human judgment and decision-making illuminated by the existing psychological research literature are used to illustrate this idea: Research findings related to (a) risk perception and acceptance, (b) the standards people use to make decisions, and (c) some nonrational influences on group decision-making suggest how psychological characteristics may affect some outcomes of convened IRB meetings. Recognizing such influences may enable the improvement of IRB decision-making.

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**Document 76**

Tur, Juan; Escudero, Antonio; Iglesias, Lourdes; Alos, Maria; Luque, Lourdes; Burguera, Bartolomé

**[Key points in the start and conduct of a clinical trial. From question to reality in an investigator-initiated clinical trial (I)].** = Puntos clave en la puesta en marcha y desarrollo de un Ensayo Clínico. De la pregunta a la realidad de un Ensayo Clínico investigador iniciado (I).


**Abstract**: Evidence-based clinical practice requires integration of individual professional experience with the best objective data to make the best therapeutic decision. The best degree of scientific evidence derives from controlled, randomized clinical trials and post-marketing drug surveillance studies and meta-analyses. During our clinical activities, we often search unsuccessfully for a clinical trial which answers our scientific questions. It is at those times that we may sometimes consider the conduct of a clinical trial. If you, as a clinical investigator, have a (relevant) scientific question that could potentially require the conduct of a clinical trial to achieve a response and have no support from a pharmaceutical company to perform it, you may find it useful to read this article, in which an attempt has been made to briefly and clearly explain the applicable regulations for planning a clinical trial. Our humble intention is that this publication becomes a useful tool for any independent researcher.

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**Document 77**

Ashton, Carol M; Wray, Nelda P; Jarman, Anna F; Kolman, Jacob M; Wenner, Danielle M; Brody, Baruch A

**A taxonomy of multinational ethical and methodological standards for clinical trials of therapeutic interventions.**


**Abstract**: If trials of therapeutic interventions are to serve society's interests, they must be of high methodological quality and must satisfy moral commitments to human subjects. The authors set out to develop a clinical-trials compendium in which standards for the ethical treatment of human subjects are integrated with standards for research methods.
**Document 78**

Clifford, Vanessa

**The placebo mystique: Implications for clinical trial methodology.**

*Journal of paediatrics and child health* 2011 Jun; 47(6): 361-6

**Abstract:** The World Medical Association Declaration of Helsinki states that the use of a placebo in a clinical trial can only be justified ethically when no proven active treatment is available as a comparison. Despite this, placebos remain a popular choice as controls in clinical trials. Recent literature reviews have suggested that reliance on placebos may, in part, be because of methodological misconceptions about the need for placebos to control for the 'placebo effect'. This study aimed to assess doctors' understanding of the requirements for placebo use in clinical trials.

**Document 79**

Gupta, Yogendra K; Padhy, Biswa M

**India’s growing participation in global clinical trials.**


**Abstract:** Lower operational costs, recent regulatory reforms and several logistic advantages make India an attractive destination for conducting clinical trials. Efforts for maintaining stringent ethical standards and the launch of Pharmacovigilance Program of India are expected to maximize the potential of the country for clinical research.

**Document 80**

Rodrigues, H C M L; Deprest, J; v d Berg, P P

**When referring physicians and researchers disagree on equipoise: the TOTAL trial experience.**


**Abstract:** In this article, we reflect on whether randomized controlled trials (RCTs) are adequate for the clinical evaluation of maternal-fetal surgery for congenital diaphragmatic hæmia (CDH), focusing on the role of patients' preferences in the setting up of research protocols, on the requirement of equipoise and on the concept of therapeutic misconception (TM).

**Document 81**

Wendler, David

**What we worry about when we worry about the ethics of clinical research.**

*Theoretical medicine and bioethics* 2011 Jun; 32(3): 161-80

**Abstract:** Clinical research is thought to be ethically problematic and is subject to extensive regulation and oversight. Despite frequent endorsement of this view, there has been almost no systematic evaluation of why clinical research might be ethically problematic. As a result, it is difficult to determine whether the regulations to which clinical research is subject address the ethical concerns it raises. Commentators who consider this question at all tend to assume that clinical research is ethically problematic because it exposes some individuals to risks for the benefit of others. Yet, many other activities that expose some individuals to risks for the benefit of others are not subject to extensive regulation and oversight. This difference raises the question of whether clinical research is distinct from these activities in normatively relevant ways and, if so, what implications this difference (or differences) has for how clinical research should be regulated and conducted. The present manuscript attempts to answer this question by comparing clinical research to two other activities that expose some individuals to risks for the benefit of others. This comparison highlights an aspect of clinical research which has received relatively little attention,
namely, the active role investigators play in exposing subjects to risks. I argue that this aspect explains much of the ethical concern expressed regarding clinical research. I end by considering the normative significance of this feature and the implications it has for how clinical research should be regulated and conducted.

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Document 82

DeBruin, Debra A; Liaschenko, Joan; Fisher, Anastasia

**How clinical trials really work rethinking research ethics.**

Kennedy Institute of Ethics journal 2011 Jun; 21(2): 121-39

**Abstract:** Despite prevalent concerns about the ethical conduct of clinical trials, little is known about the day-to-day work of trials and the ethical challenges arising in them. This paper reports on a study designed to fill this gap and demonstrates a need to refine the oversight system for trials to reflect an understanding of this day-to-day work. It also illuminates ethical challenges that cannot be addressed by the oversight system and so necessitate a rethinking of the ethics of clinical trials.

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Document 83

Rid, Annette; Wendler, David

**A framework for risk-benefit evaluations in biomedical research.**

Kennedy Institute of Ethics journal 2011 Jun; 21(2): 141-79

**Abstract:** Essentially all guidelines and regulations require that biomedical research studies have an acceptable risk-benefit profile. However, these documents offer little concrete guidance for implementing this requirement and determining when it is satisfied. As a result, those charged with risk-benefit evaluations currently assess the risk-benefit profile of biomedical research studies in unsystematic ways, raising concern that some research participants are not being protected from excessive risks and that some valuable studies involving acceptable risk are being rejected. The present paper aims to address this situation by delineating the first comprehensive framework, which is based on existing guidelines and regulations as well as the relevant literature, for risk-benefit evaluations in biomedical research.

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Document 84

Van Aken, Hugo; Staender, Sven; Mellin-Olsen, Jannicke; Pelosi, Paolo

**Patient safety in anaesthesiology.**


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Document 85

Whitaker, David K; Brattebø, Guttorm; Smith, Andrew F; Staender, Sven E A

**The Helsinki Declaration on Patient Safety in Anaesthesiology: putting words into practice.**


**Abstract:** In June 2010, the European Board of Anaesthesiology (EBA) of the European Union of Medical Specialists (UEMS) and the European Society of Anaesthesiology (ESA) signed the Helsinki Declaration for Patient Safety in Anaesthesiology at the Euroanaesthesia meeting in Helsinki. The document had been jointly prepared by these two principal anaesthesiology organisations in Europe who pledged to improve the safety of patients being cared for by anaesthesiologists working in the medical fields of perioperative care, intensive care medicine, emergency medicine and pain medicine. The declaration stated their current heads of agreement on patient safety and listed a number of principle requirements as thought necessary for anaesthesiologists, anaesthesiology departments and institutions to
introduce to improve patient safety. Good words are only as good as their implementation and this article explains the rationale behind them and expands the recommendations practically so anaesthesiologists caring for patients everywhere can follow the Helsinki Declaration and put the words into practice.

Document 86
Schleppers, Alexander; Prien, Thomas; Van Aken, Hugo
Helsinki Declaration on patient safety in anaesthesiology: putting words into practice - experience in Germany.
Abstract: For years now, the German Society of Anaesthesiology and Intensive Care Medicine and the Professional Association of German Anaesthesiologists have been actively involved in efforts to improve patient safety. To this end, a whole range of activities have been initiated in recent years and, since February 2011, collected together on our home page 'PATSI' (www.patientensicherheit-ains.de). Further, the implementation of syringe labelling (ISO 26825) with additional information on drugs frequently used in intensive care was carried out. Under the item Helsinki Declaration, all decisions and recommendations so far worked out by our speciality have, in structured form, been assigned to individual points and saved as PDF files. This has made it possible for every anaesthesiological department in Germany to integrate all the relevant instructions and conditions of the Helsinki Declaration into their own individual work structures. These systematic solutions represent a major contribution towards reducing the possibility of errors at the workplace. We are certainly still in the early stages of our efforts to achieve a nationwide integration of a cultural change in the way we deal with mistakes in medicine. We have incorporated the item 'learning from mistakes' in our project 'critical incident reporting system for anaesthesia, intensive care medicine, emergency care, and pain therapy, CIRS-AINS', and have brought out a range of relevant illustrative publications. Accepting these 'mistakes' as an opportunity to critically examine ourselves and our work with a view to learning from them and further improving our speciality service is, we believe, a great challenge for future developments in anaesthesia.

Document 87
Standard cooperating procedures.

Document 88
Ledford, Heidi
Therapeutic success stifles medical progress.
Nature 2011 May 26; 473(7348): 433

Document 89
Djulbegovic, Benjamin; Paul, Ash
From efficacy to effectiveness in the face of uncertainty: indication creep and prevention creep.
Binik, Ariella; Weijer, Charles; McRae, Andrew D; Grimshaw, Jeremy M; Boruch, Robert; Brehaut, Jamie C; Donner, Allan; Eccles, Martin P; Saginur, Raphael; Taljaard, Monica; Zwarenstein, Merrick

**Does clinical equipoise apply to cluster randomized trials in health research?**

**Abstract:** This article is part of a series of papers examining ethical issues in cluster randomized trials (CRTs) in health research. In the introductory paper in this series, Weijer and colleagues set out six areas of inquiry that must be addressed if the cluster trial is to be set on a firm ethical foundation. This paper addresses the third of the questions posed, namely, does clinical equipoise apply to CRTs in health research? The ethical principle of beneficence is the moral obligation not to harm needlessly and, when possible, to promote the welfare of research subjects. Two related ethical problems have been discussed in the CRT literature. First, are control groups that receive only usual care unduly disadvantaged? Second, when accumulating data suggests the superiority of one intervention in a trial, is there an ethical obligation to act? In individually randomized trials involving patients, similar questions are addressed by the concept of clinical equipoise, that is, the ethical requirement that, at the start of a trial, there be a state of honest, professional disagreement in the community of expert practitioners as to the preferred treatment. Since CRTs may not involve physician-researchers and patient-subjects, the applicability of clinical equipoise to CRTs is uncertain. Here we argue that clinical equipoise may be usefully grounded in a trust relationship between the state and research subjects, and, as a result, clinical equipoise is applicable to CRTs. Clinical equipoise is used to argue that control groups receiving only usual care are not disadvantaged so long as the evidence supporting the experimental and control interventions is such that experts would disagree as to which is preferred. Further, while data accumulating during the course of a CRT may favor one intervention over another, clinical equipoise supports continuing the trial until the results are likely to be broadly convincing, often coinciding with the planned completion of the trial. Finally, clinical equipoise provides research ethics committees with formal and procedural guidelines that form an important part of the assessment of the benefits and harms of CRTs in health research.

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Taljaard, Monica; McRae, Andrew D; Weijer, Charles; Bennett, Carol; Dixon, Stephanie; Taleban, Julia; Skea, Zoe; Eccles, Martin P; Brehaut, Jamie C; Donner, Allan; Saginur, Raphael; Boruch, Robert F; Grimshaw, Jeremy M

**Inadequate reporting of research ethics review and informed consent in cluster randomised trials: review of random sample of published trials.**

BMJ (Clinical research ed.) 2011 May 11; 342: d2496

**Abstract:** To investigate the extent to which authors of cluster randomised trials adhered to two basic requirements of the World Medical Association's Declaration of Helsinki and the International Committee of Medical Journal Editors' uniform requirements for manuscripts (namely, reporting of research ethics review and informed consent), to determine whether the adequacy of reporting has improved over time, and to identify characteristics of cluster randomised trials associated with reporting of ethics practices.

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Karan, Jay

**Advertisement of "Complan".**

Indian pediatrics 2011 May 7; 48(5): 412-3

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Wu, Xiaoru; Carlsson, Martin
**Detecting data fabrication in clinical trials from cluster analysis perspective.**  
*Pharmaceutical statistics* 2011 May; 10(3): 257-64

**Abstract:** Detecting data fabrication is of great importance in clinical trials. As the role of statisticians in detecting abnormal data patterns has grown, a large number of statistical procedures have been developed, most of which are based on descriptive statistics. Based upon the fact that substantial data fabrication cases have certain clustering structures, this paper discusses the potential for the use of statistical clustering method in fraud detection. Three clustering patterns, angular, neighborhood and repeated measurements clustering, are identified and explored. Correspondingly, simple and efficient test statistics are proposed and randomization tests are carried out. The proposed methods are applied to a 12-week multi-center study for illustration. Extensive simulations are conducted to validate the effectiveness of the procedures.

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**Leslie, Gavin D**  
Re: **Explicit declaration of ethical approval for clinical research.**  
*Australian critical care : official journal of the Confederation of Australian Critical Care Nurses* 2011 May; 24(2): 90

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**Eastwood, Glenn M**  
**Explicit declaration of ethical approval for clinical research.**  
*Australian critical care : official journal of the Confederation of Australian Critical Care Nurses* 2011 May; 24(2): 89

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**Wiederhold, Brenda K**  
**What will it take to get IRB reform?**  
*Cyberpsychology, behavior and social networking* 2011 May; 14(5): 265-6

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**Editors-in-Chief statement regarding published clinical trials conducted without IRB approval by Joachim Boldt.**  
*Minerva anestesiologica* 2011 May; 77(5): 562-3

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**Ye, Chenglin; Giangregorio, Lora; Holbrook, Anne; Pullenayegum, Eleanor; Goldsmith, Charlie H; Thabane, Lehana**  
**Data withdrawal in randomized controlled trials: Defining the problem and proposing solutions: a commentary.**  
*Contemporary clinical trials* 2011 May; 32(3): 318-22

**Abstract:** It is not uncommon for a participant to withdraw from a randomized controlled trial (RCT). The withdrawal of a participant results in missing data and the potential for withdrawal bias. Data withdrawal, or a request from a
participant to withdraw all of their previously collected data from a study, is particularly problematic because it leaves little opportunity to characterize or statistically address those that have withdrawn to minimize withdrawal bias. The aim of this commentary is to (1) provide a synthesis of available information on the ethical and methodological issues related to data withdrawal in RCTs and (2) provide some suggestions on how to minimize the impact of data withdrawal during the execution or analysis phases of anRCT. We searched PubMed, EMBASE and JSTOR for published articles on data withdrawal. In addition, we used internet sources as an additional tool to identify content on data withdrawal from research ethics guidelines, legislation, research ethics boards, funding agencies, professional organizations and researchers. We did not find any definitive guidelines for dealing with data withdrawal. We propose recommendations for minimizing the occurrence of data withdrawal, including explicit and clear descriptions in consent forms of how data will be handled after participant withdrawal. We also suggest using imputation techniques to deal with the missing data during analysis. The current commentary can be used to minimize the impact of data withdrawal in RCTs.

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**Document 99**

Chambers, David W

**Confusions in the equipoise concept and the alternative of fully informed overlapping rational decisions.**

Medicine, health care, and philosophy 2011 May; 14(2): 133-42

**Abstract:** Despite its several variations, the central position of equipoise is that subjects in clinical experiments should not be randomized to conditions when others believe that better alternatives exist. This position has been challenged over issues of which group in the medical or research community is authorized to make that determination, and it has been argued that informed consent provides sufficient ethical protection for participants independent of equipoise. In this paper I frame ethical participation in clinical research as a two-party decision process involving offering and accepting participation under informed consent. Nine conditions are identified in which it is possible that potential participants and researchers or care professionals can rationally choose divergent actions based on identical understandings of the situation. Under such circumstances, researchers or care professionals cannot ethically substitute their understanding of equipoise in the situation for the patients' choices, or vice versa.

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**Document 100**

Lemke, Amy A; Smith, Maureen E; Wolf, Wendy A; Trinidad, Susan Brown; GRRIP Consortium

**Broad data sharing in genetic research: views of institutional review board professionals.**


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**Document 101**

Silva, Diego S; Goering, Paula N; Jacobson, Nora; Streiner, David L

**Off the beaten path: conducting ethical pragmatic trials with marginalized populations.**

IRB 2011 May-Jun; 33(3): 6-11

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**Document 102**

Levine, Robert J; Gordon, Judith B; Mazure, Carolyn M; Rubin, Philip E; Schaller, Barry R; Young, John L

**Response to open peer commentaries on "Social contexts influence ethical considerations of research".**

Beyond the IRB: local service versus global oversight.

Dealing with the long-term social implications of research.
The American journal of bioethics : AJOB 2011 May; 11(5): 5-9

Power and representation of the public's values in a social implications of research commission.
The American journal of bioethics : AJOB 2011 May; 11(5): 10-1

Targeting funding sources: a strategic mechanism of research regulation.
The American journal of bioethics : AJOB 2011 May; 11(5): 17-8

The need for topically focused efforts to deal with the long-term social implications of research.
The American journal of bioethics : AJOB 2011 May; 11(5): 19-20
Document 108
White, Gladys B
**Designing a disconnect?**

Document 109
de Melo-Martin, Inmaculada
**IRBs and the long-term social implications of research.**
The American journal of bioethics : AJOB 2011 May; 11(5): 22-3

Document 110
Gordon, Judith B; Levine, Robert J; Mazure, Carolyn M; Rubin, Philip E; Schaller, Barry R; Young, John L
**Social contexts influence ethical considerations of research.**
The American journal of bioethics : AJOB 2011 May; 11(5): 24-30

**Abstract:** This article argues that we could improve the design of research protocols by developing an awareness of and a responsiveness to the social contexts of all the actors in the research enterprise, including subjects, investigators, sponsors, and members of the community in which the research will be conducted. "Social context" refers to the settings in which the actors are situated, including, but not limited to, their social, economic, political, cultural, and technological features. The utility of thinking about social contexts is introduced and exemplified by the presentation of a hypothetical case in which one central issue is limitation of the probability of injury to subjects by selection of individuals who are not expected to live long enough for the known risks of the study to become manifest as harms. Benefits of such considerations may include enhanced subject satisfaction and cooperation, community acceptance, and improved data quality, among other desirable consequences.

Document 111
Morgan, Branwen
**Experts emphasize need for speed in launch of Australian trials.**
Nature medicine 2011 May; 17(5): 521

Document 112
**[Research subject to approval or clinical patient care?]. = Genehmigungspflichtige Forschung oder klinische Patientenversorgung?**
RöFo : Fortschritte auf dem Gebiete der Röntgenstrahlen und der Nuklearmedizin 2011 May; 183(5): 485
**Document 113**

Weijer, Charles; Grimshaw, Jeremy M; Taljaard, Monica; Binik, Ariella; Boruch, Robert; Brehaut, Jamie C; Donner, Allan; Eccles, Martin P; Gallo, Antonio; McRae, Andrew D; Saginur, Raphael; Zwarenstein, Merrick

**Ethical issues posed by cluster randomized trials in health research.**

Trials 2011 April 20; 12: 100

**Abstract:** The cluster randomized trial (CRT) is used increasingly in knowledge translation research, quality improvement research, community based intervention studies, public health research, and research in developing countries. However, cluster trials raise difficult ethical issues that challenge researchers, research ethics committees, regulators, and sponsors as they seek to fulfill responsibly their respective roles. Our project will provide a systematic analysis of the ethics of cluster trials. Here we have outlined a series of six areas of inquiry that must be addressed if the cluster trial is to be set on a firm ethical foundation: 1. Who is a research subject? 2. From whom, how, and when must informed consent be obtained? 3. Does clinical equipoise apply to CRTs? 4. How do we determine if the benefits outweigh the risks of CRTs? 5. How ought vulnerable groups be protected in CRTs? 6. Who are gatekeepers and what are their responsibilities? Subsequent papers in this series will address each of these areas, clarifying the ethical issues at stake and, where possible, arguing for a preferred solution. Our hope is that these papers will serve as the basis for the creation of international ethical guidelines for the design and conduct of cluster randomized trials.

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**Document 114**

Dyer, Clare

**Consultant is suspended for inventing data for drug trial.**

BMJ (Clinical research ed.) 2011 April 7; 342: d2261

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**Document 115**

Vellinga, Akke; Cormican, Martin; Hanahoe, Belinda; Bennett, Kathleen; Murphy, Andrew W

**Opt-out as an acceptable method of obtaining consent in medical research: a short report.**

BMC medical research methodology 2011 April 6; 11: 40

**Abstract:** A prospective cohort study was set up to investigate a possible association between antibiotic prescribing and antibiotic resistance of E. coli urinary tract infection in the community. Participation of patients with urinary tract infection was obtained through an opt-out methodology. This short paper reports on the acceptability of the opt-out recruitment approach.

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**Document 116**

Srinivasan, Sandhya

**HPV vaccine trials and sleeping watchdogs.**

Indian journal of medical ethics 2011 Apr-Jun; 8(2): 73-4

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**Document 117**

Bandewar, Sunita V.S.; John, T.A.

**SEARCH's HBNC trial: toward a broader debate on the ethics of social intervention research**

Indian Journal of Medical Ethics 2011 April-June; 8(2): 78-85
Document 118
Pandiya, Anvita
Quality of independent review board/ethics committee oversight in clinical trials in India.
Perspectives in clinical research 2011 Apr; 2(2): 45-7
Georgetown users check Georgetown Journal Finder for access to full text

Document 119
Grzybowski, Andrzej; Sade, Robert; Loff, Bebe
Ethical problems in invasive clinical research.
Ophthalmology 2011 Apr; 118(4): 787-8; author reply 788-9
Georgetown users check Georgetown Journal Finder for access to full text

Document 120
Edwards, Sarah J L
Response to open peer commentaries on "assessing the remedy: the case for contracts in clinical trials".
The American journal of bioethics : AJOB 2011 Apr; 11(4): W1-3
Georgetown users check Georgetown Journal Finder for access to full text

Document 121
Edwards, Sarah J L
Assessing the remedy: the case for contracts in clinical trials.
The American journal of bioethics : AJOB 2011 Apr; 11(4): 3-12
Abstract: Current orthodoxy in research ethics assumes that subjects of clinical trials reserve rights to withdraw at any time and without giving any reason. This view sees the right to withdraw as a simple extension of the right to refuse to participate all together. In this paper, however, I suggest that subjects should assume some responsibilities for the internal validity of the trial at consent and that these responsibilities should be captured by contract. This would allow the researcher to impose a penalty on the subject if he were to withdraw without good reason and on a whim. This proposal still leaves open the possibility of withdrawing without penalty when it is in the subject's best interests to do so. Giving researchers recourse to legal remedy may now be necessary to protect the science, as existing methods used to increase retention are inadequate for one reason or another.
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Document 122
De Ville, Kenneth
The case against contract: participant and investigator duty in clinical trials.
The American journal of bioethics : AJOB 2011 Apr; 11(4): 16-8
Georgetown users check Georgetown Journal Finder for access to full text
**Document 123**
Schonfeld, Toby; Anderson, James
**Dropdown by design: advance planning for research participant noncompliance.**
Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 124**
Rice, Stephen; Trafimow, David
**Known versus unknown threats to internal validity: a response to Edwards.**
The American journal of bioethics : AJOB 2011 Apr; 11(4): 20-1
Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 125**
Lynch, John A
"Through a glass darkly": researcher ethnocentrism and the demonization of research participants.
Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 126**
Buccafurni, Diana
**Can contracts enhance participant autonomy in clinical trials?**
Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 127**
Hanson, Stephen S
**The perspective of an IRB member.**
Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 128**
Dranseika, Vilius; Gefenas, Eugenijus; Cekanauskaite, Asta; Hug, Kristina; Mezinska, Signe; Peicius, Eimantas; Silis, Vents; Soosaar, Andres; Strosberg, Martin
**Twenty years of human research ethics committees in the Baltic States.**
Developing world bioethics 2011 Apr; 11(1): 48-54
**Abstract:** Two decades have passed since the first attempts were made to establish systematic ethical review of human research in the Baltic States. Legally and institutionally much has changed. In this paper we provide an historical and structural overview of ethical review of human research and identify some problems related to the role of ethical review in establishing quality research environment in these countries. Problems connected to (a) public availability of information, (b) management of conflicts of interest, (c) REC composition and motivation of REC members, and (d) differing levels of stringency of ethical review for different types of studies, are identified.
Recommendations are made to strengthen cooperation among the Baltic RECs.

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**Document 129**

Rees, Colin

**A simple guide to gaining ethical approval for perioperative nursing research.**


**Abstract:** Research ethics relate to three groups of perioperative nurses: those who undertake research within the clinical area, those clinically responsible for patients taking part in research studies or trials, and finally the students and qualified staff who critique research articles and want to ensure that the standard of ethical rigour is acceptable. This article contains guidelines based on essential research ethical principles for each of these three groups and outlines the application process for gaining ethical approval.

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**Document 130**

Beauchamp, T L

**Viewpoint: why our conceptions of research and practice may not serve the best interest of patients and subjects.**

Journal of internal medicine 2011 Apr; 269(4): 383-7

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**Document 131**

Verweij, M F

**Commentary: the distinction between research and practice--a response to T. Beauchamp.**

Journal of internal medicine 2011 Apr; 269(4): 388-91

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**Document 132**

Ravinetto, Raffaella; Buvé, Anne; Halidou, Tinto; Lutumba, Pascal; Talisuna, Ambrose; Juffrie, Mohammad; D'Alessandro, Umberto; Boelaert, Marleen

**Double ethical review of North-South collaborative clinical research: hidden paternalism or real partnership?**

Tropical medicine & international health : TM & IH 2011 Apr; 16(4): 527-30

**Abstract:** Despite their universal character, the ethical principles governing clinical research need to be translated into procedures and practices, which will vary among countries and regions because of differences in local cultural norms and in the available resources. Double ethical review, by which a research protocol is submitted for ethical clearance both in the country or countries where the research takes place and in the country of the sponsor or funding agency, will then help ensure that all relevant perspectives are taken into account. In addition, a geographically and culturally close ethics committee can do a much better informed and comprehensive assessment of the respective skills of the clinical sites and of the sponsor. But the practical implementation of double ethical review can bring significant difficulties and delays, especially in multi-site and multi-country researches. Currently, most ethics committees do not proactively seek communication with others evaluating the same research protocol in different socio-economical and cultural contexts, so in practice there is no mutual learning process. Proactive communication would help to build collaborative partnership among ethical bodies, promoting common practices and resolving conflicting opinions.

Georgetown users check Georgetown Journal Finder for access to full text
Document 133
Chopra, Vineet; Davis, Matthew
In search of equipoise.
JAMA : the journal of the American Medical Association 2011 Mar 23; 305(12): 1234-5
Georgetown users check Georgetown Journal Finder for access to full text

Document 134
Crammond, Bradley R; Parker, Anna V; Brooks, Megan; Skiba, Marina; McNeil, John J
Self-audit as part of a research governance framework for health research.
Abstract: Clinical research is an area of increasing activity for hospitals, universities and research institutions, which requires formal governance and oversight to manage risks. Monitoring research practice should be a part of research governance activities. However, formal audits have proved time consuming for researchers and auditors. To increase attention to good research practice and screen for poor practice, the Department of Epidemiology and Preventive Medicine at Monash University and the Alfred Research and Ethics Unit in Melbourne have developed a brief self-audit tool for researchers. We evaluated the self-audit using a questionnaire for researchers. The results were positive, with most respondents believing that it promoted good research practice.
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Document 135
Julious, Steven A; Pyke, Stephen; Hughes, Sara
Best practice for statisticians in industry sponsored trials.
BMJ (Clinical research ed.) 2011 March 15; 342: d1636
Georgetown users check Georgetown Journal Finder for access to full text

Document 136
Liu, Joseph L Y; Wyatt, Jeremy C
The case for randomized controlled trials to assess the impact of clinical information systems.
Abstract: There is a persistent view of a significant minority in the medical informatics community that the randomized controlled trial (RCT) has a limited role to play in evaluating clinical information systems. A common reason voiced by skeptics is that these systems are fundamentally different from drug interventions, so the RCT is irrelevant. There is an urgent need to promote the use of RCTs, given the shift to evidence-based policy and the need to demonstrate cost-effectiveness of these systems. The authors suggest returning to first principles and argue that what is required is clarity about how to match methods to evaluation questions. The authors address common concerns about RCTs, and the extent to which they are fallacious, and also discuss the challenges of conducting RCTs in informatics and alternative study designs when randomized trials are infeasible. While neither a perfect nor universal evaluation method, RCTs form an important part of an evaluator's toolkit.
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Document 137
Wiwanitkit, Viroj
The university and the responsible conduct of research.
Science and engineering ethics 2011 Mar; 17(1): 195
Document 138

Sekine, Toru; Shimada, Michiko

[Protection of human subjects in medical research: from the viewpoint of historical development of ethical regulations].


Abstract: Recent clinical research is conducted based on bioethical consideration of human subjects. The Ethical Guidelines for Clinical Studies (EGCS) form the standard for this 'subject protection'. In current clinical research, consideration of subject rights and life is held more important than the scientific and social value of the research. We describe herein the major revisions and history of ethical considerations leading up to implementation of the revised EGCS on April 1, 2009. The obligations of clinical researchers regarding ethical studies and training and enrollment in insurance for subject compensation have been added to these latest guidelines. The role of ethics review boards, which supervise whether clinical researchers are actively performing subject protection, is also becoming extremely important.

Document 139

Pandey, Arvind; Aggarwal, Abha; Seth, S D; Maulik, Mohua; Juneja, Atul

Strengthening ethics in clinical research.
The Indian journal of medical research 2011 Mar; 133(3): 339-40

Document 140

Shilling, V; Williamson, P R; Hickey, H; Sowden, E; Smyth, R L; Young, B

Processes in recruitment to randomised controlled trials of medicines for children (RECRUIT): a qualitative study.


Abstract: To investigate recruitment processes across a range of clinical trials and from the perspective of parents, young people and practitioners to identify strategies to improve recruitment and its conduct across the spectrum of trials of medicines for children.

Document 141

Letourneau, Genevieve

Plea to establish a registry of clinical trials on cognitive-behavioural therapies and cognitive remediation.

Canadian journal of psychiatry. Revue canadienne de psychiatrie 2011 Mar; 56(3): 189; author reply 189-90

Document 142

Murakami, Masami

[Ethical problems in utilization of specimens after laboratory examinations for clinical studies].


Abstract: Ethical Committee in Japanese Society of Laboratory Medicine published "Opinions of Japanese Society of Laboratory Medicine about utilization of specimens after laboratory examinations for laboratory work, education

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**Document 143**

Lavery, James V

*How can institutional review boards best interpret preclinical data?*


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**Document 144**

Kimmelman, Jonathan; London, Alex John

*Predicting harms and benefits in translational trials: ethics, evidence, and uncertainty.*


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**Document 145**

Furge, Laura Lowe

*Institutional review boards and educational research.*


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**Document 146**

Hansson, Mats G

*[Research obstacles mean increased risks for patients]. = Hinder för forskning innebär ökade risker för patienterna.*

Läkartidningen 2011 Mar 2-8; 108(9): 452-3

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**Document 147**

Kass, Nancy E; Pronovost, Peter J

*Quality, safety, and institutional review boards: navigating ethics and oversight in applied health systems research.*


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**Document 148**

Goldblatt, Hadass; Kamieli-Miller, Orit; Neumann, Melanie

**Sharing qualitative research findings with participants: study experiences of methodological and ethical dilemmas.**

Patient education and counseling 2011 Mar; 82(3): 389-95

**Abstract:** Sharing qualitative research findings with participants, namely member-check, is perceived as a procedure designed to enhance study credibility and participant involvement. It is rarely used, however, and its methodological usefulness and ethical problems have been questioned. This article explores benefits and risks in applying member-check when studying healthcare topics, questioning the way it should be performed.

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**Document 149**

Blake, Valerie; Joffe, Steve; Kodish, Eric

**Harmonization of ethics policies in pediatric research.**

The Journal of law, medicine & ethics : a journal of the American Society of Law, Medicine & Ethics 2011 Spring; 39(1): 70-8

Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 150**

Stepan, Karen A; Gonzalez, Amy P; Dorsey, Vivian S; Frye, Debra K; Pyle, Nita D; Smith, Regina F; Throckmorton, Terry A; Villejo, Louise A; Cantor, Scott B

**Recommendations for enhancing clinical trials education: a review of the literature.**


**Abstract:** This study aims to apply the evidence-based practice (EBP) process to determine the factors that influence patients' understanding of, participation in, and satisfaction with clinical trials, the informed consent process, and treatment decisions and to make recommendations for improving clinical trials education. Beginning with evidence retrieval, the authors identified key search terms and searched MEDLINE--Ovid, MEDLINE--PubMed, and the Cumulative Index to Nursing and Allied Health Literature to identify articles published between July 2001 and July 2006 that highlighted clinical trials education. The articles were reviewed for clinical trials patient education information, clinician methods of communicating clinical trial information to patients, and patient satisfaction with the clinical trials process, including the informed consent process. As a result, practice changes were recommended for the patient/family, staff/community, and institution. From the literature review, 81 articles were identified. Recurring themes included decision-making, patient education, staff education, and pediatrics. Most articles focused on methods and strategies aimed at improving education at the patient/family, staff/community, and institutional levels. The issues surrounding clinical trial education are complex due to multiple variables interfering with poor patient understanding of, participation in, and satisfaction with clinical trial treatment decisions. On the basis of our findings, we recommend that clinicians involved in educating patients, families, staff, and communities about clinical trials have an awareness of and understanding for very complex issues.

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**Document 151**

Allardyce, Randall A; Bagshaw, Philip F; Frampton, Christopher M; Frizelle, Francis A; Hewett, Peter J; Rieger, Nicholas A; Smith, J Shona; Solomon, Michael J; Stevenson, Andrew R L

**Ethical issues with the disclosure of surgical trial short-term data.**

ANZ journal of surgery 2011 Mar; 81(3): 125-31

**Abstract:** This paper describes the distinctions between major surgical and pharmaceutical trials and questions the application of a common ethical paradigm to guide their conduct and reporting.
Document 152
Abbott, Lura; Grady, Christine

**A systematic review of the empirical literature evaluating IRBs: what we know and what we still need to learn.**

**Abstract:** Institutional review boards (IRBs) are integral to the U.S. system of protection of human research participants. Evaluation of IRBs, although difficult, is essential. To date, no systematic review of IRB studies has been published. We conducted a systematic review of empirical studies of U.S. IRBs to determine what is known about the function of IRBs and to identify gaps in knowledge. A structured search in PubMed identified forty-three empirical studies evaluating U.S. IRBs. Studies were included if they reported an empirical investigation of the structure, process, outcomes, effectiveness, or variation of U.S. IRBs. The authors reviewed each study to extract information about study objectives, sample and methods, study results, and conclusions. Empirical evidence collected in forty-three published studies shows that for review of a wide range of types of research, U.S. IRBs differ in their application of the federal regulations, in the time they take to review studies, and in the decisions made. Existing studies show evidence of variation in multicenter review, inconsistent or ambiguous interpretation of the federal regulations, and inefficiencies in review. Despite recognition of a need to evaluate effectiveness of IRB review, no identified published study included an evaluation of IRB effectiveness. Multiple studies evaluating the structure, process, and outcome of IRB review in the United States have documented inconsistencies and inefficiencies. Efforts should be made to address these concerns. Additional research is needed to understand how IRBs accomplish their objectives, what issues they find important, what quality IRB review is, and how effective IRBs are at protecting human research participants.

Document 153
Geisser, Michael E; Alschuler, Kevin N; Hutchinson, Raymond

**A delphi study to establish important aspects of ethics review.**
Journal of empirical research on human research ethics : JERHRE 2011 Mar; 6(1): 21-4

**Abstract:** Little research has been done to examine the cost-effectiveness of REC review, or the components of review that make the greatest contributions to the protection of human subjects. We describe a process used to obtain consensus on the important categories and outcomes of REC review using the Delphi method and an array of stakeholders in a limited domain of research (biomedical). Study participants recruited from the University of Michigan Medical School's RECs, REC council, and principal investigators identified the following six categories as being the most important aspects of REC review: (1) A favorable risk/benefit ratio; (2) minimization of risk to subjects; (3) clarity of consent; (4) protection of vulnerable populations; (5) protection of privacy and confidentiality; and (6) review time. We believe that this kind of information can be used to assist in the development of a metric to assess the effectiveness and efficiency of REC review in the various research domains.

Document 154
Sauder, Sara; Stein, Rachel; Feinberg, Emily; Bauchner, Howard; Banks, Mary; Silverstein, Michael

**When the subject is more than just the subject: two case studies of family involvement in human subjects research.**

**Abstract:** Institutional review boards (IRBs) protect human research subjects by reviewing research to ensure compliance with federal regulations and institutional policies. One of the most important functions of IRBs is to ensure that investigators anticipate, plan for, and minimize risks to subjects. Under certain circumstances, however, participation in research may pose risks to nonsubject family members or other members of a subject's social network. In the context of a research protocol designed to test an intervention to prevent depression among a population of culturally diverse, urban mothers, we present two case studies of unanticipated problems, which
demonstrate how nonsubject family members can either impact, or be impacted by, an individual's participation in research. The case studies illustrate the incongruence between federal regulations addressing IRB approval of research—which focus specifically on risks to subjects—and regulations on reporting incidents that occur during the conduct of the research, which extend to risks involving "others" as well. The cases also illustrate how risks to "others" can be accentuated in certain cultures where codependent family structures may increase the role that family members play in an individual's decision to participate in research. The question is raised as to whether this incongruence can inadvertently result in investigators and IRBs under-appreciating the risks that participation in research can pose to nonsubjects.

Document 155
Malmqvist, Erik; Juth, Niklas; Lynöe, Niels; Helgesson, Gert

*Early stopping of clinical trials: charting the ethical terrain.*
Kennedy Institute of Ethics journal 2011 Mar; 21(1): 51-78

**Abstract:** The decision to terminate a clinical trial earlier than planned is often described as ethically problematic, but it is rarely systematically analyzed as an ethical issue in its own right. This paper provides an overview of the main ethical considerations at stake in such decisions and of the main tensions between these considerations. Arguments about informed consent and the impact of early stopping on research and society are explored. We devote particular attention to a familiar conflict that arises with special urgency when early data suggest that the experimental treatment is superior. Should the trial be stopped so that participants in the control group will not be allocated a seemingly inferior treatment, or should it continue in pursuit of evidence conclusive enough to improve the care of future patients? We scrutinize three ways to address this problem. Rather than dissolving the tension, they represent different trade-offs between the respective welfare interests of subjects and future patients.

Document 156
Malmqvist, Erik

*(Mis)understanding exploitation.*

Document 157
Cook, Ann Freeman; Hoas, Helena

*Protecting research subjects: IRBs in a changing research landscape.*
IRB 2011 Mar-Apr; 33(2): 14-9

Document 158
Macfarlane, Pamela A; Looney, Marilyn A

*Expediting the institutional review board process for exercise protocols.*
Research quarterly for exercise and sport 2011 Mar; 82(1): 129-34
Document 159
Xuemei, Liu; Youping, Li; Shangqi, Song; Senlin, Yin; Williams, Shawna
Ethical review reporting of Chinese trials records in WHO primary registries.
Journal of medical ethics 2011 Mar; 37(3): 144-8
Abstract: To investigate the report rate of ethical review in registered Chinese trials records.

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Document 160
Korn, Edward L; Freidlin, Boris
Inefficacy interim monitoring procedures in randomized clinical trials: the need to report.
The American journal of bioethics : AJOB 2011 Mar; 11(3): 2-10
Abstract: If definitive evidence concerning treatment effectiveness becomes available from an ongoing randomized clinical trial, then the trial could be stopped early, with the public release of results benefiting current and future patients. However, stopping an ongoing trial based on accruing outcome data requires methodological rigor to preserve validity of the trial conclusions. This has led to the use of formal interim monitoring procedures, which include inefficacy monitoring that will stop a trial early when the experimental treatment appears not to be working. For participants, inefficacy monitoring is especially important as it ensures that they are not being treated worse than if they had not enrolled on the trial. We discuss the importance of reporting with trial results the formal interim inefficacy monitoring guidelines that were utilized, and, if none were used, the reasons for their absence. A survey of two leading medical journals suggests that this is not current practice.

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Document 161
Ozdemir, Vural; Joly, Yann; Knoppers, Bartha M
ACCE, pharmacogenomics, and stopping clinical trials: time to extend the CONSORT statement?

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Document 162
Wittes, Janet
Discussion of paper by Korn and Freidlin.

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Document 163
Trafimow, David; Rice, Stephen
Korn and Freidlin's misunderstanding of the null hypothesis significance testing procedure.

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Document 164
Braillon, Alain
**The many moral responsibilities of independent data-monitoring committees.**

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Anderson, James R; Krailo, Mark
**The Children's Oncology Group routinely applies "lack of efficacy" interim monitoring to its randomized clinical trials.**

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Hoffart, Jürgen; Teichmann, Arndt; Wessler, Ignaz
**Biomedical research in Germany: the role of ethics committee and state medical association.**
Anesthesia and analgesia 2011 Mar; 112(3): 501-3

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Katz, Jeffrey N; Wright, John; Levy, Bruce A; Baron, John A; Losina, Elena
**Departures from community equipoise may lead to incorrect inference in randomized trials.**

**Abstract:** To assess the impact of selective enrollment on the results of randomized controlled trials (RCTs).

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Montedori, Alessandro; Bonacini, Maria Isabella; Casazza, Giovanni; Luchetta, Maria Laura; Duca, Piergiorgio; Cozzolino, Francesco; Abraha, Iosief
**Modified versus standard intention-to-treat reporting: are there differences in methodological quality, sponsorship, and findings in randomized trials? A cross-sectional study.**
Trials 2011 February 28; 12: 58

**Abstract:** Randomized controlled trials (RCTs) that use the modified intention-to-treat (mITT) approach are increasingly being published. Such trials have a preponderance of post-randomization exclusions, industry sponsorship, and favourable findings, and little is known whether in terms of these items mITT trials are different with respect to trials that report a standard intention-to-treat.

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Sengupta, Amit; Shenoi, Anjali; Sarojini, N B; Madhavi, Y
**Human papillomavirus vaccine trials in India.**
Lancet 2011 Feb 26; 377(9767): 719

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Document 170

Knellwolf, Anne-Laure; Bauzon, Stéphane; Alberighi, Ornella Della Casa; Lutsar, Irja; Bácsy, Emö; Alfarez, Deborah; Panei, Pietro

Framework conditions facilitating paediatric clinical research.

Italian journal of pediatrics 2011 February 23; 37: 12

Abstract: The use of unlicensed and "off-label" medicines in children is widespread. Between 50-80% of the medicines currently administered to children have neither been tested nor authorized for their use in the paediatric population which represents approximately 25% of the whole European population. On 26 January 2007, entered into force the European Regulation of Paediatric Medicines. It aims at the quality of research into medicines for children but without subjecting the paediatric population to unnecessary clinical trial. This article addresses ethical and legal issues arising from the regulation and makes recommendations for the framework conditions facilitating the development of clinical research with children.

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Document 171

Campbell, M K; Entwistle, V A; Cuthbertson, B H; Skea, Z C; Sutherland, A G; McDonald, A M; Norrie, J D; Carlson, R V; Bridgman, S;

KORAL study group

Developing a placebo-controlled trial in surgery: issues of design, acceptability and feasibility.

Trials 2011 February 21; 12: 50

Abstract: Surgical placebos are controversial. This in-depth study explored the design, acceptability, and feasibility issues relevant to designing a surgical placebo-controlled trial for the evaluation of the clinical and cost effectiveness of arthroscopic lavage for the management of people with osteoarthritis of the knee in the UK.

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Document 172

Goldenberg, Neil A; Spyropoulos, Alex C; Halperin, Jonathan L; Kessler, Craig M; Schulman, Sam; Turpie, Alexander G G; Skene, Allan M; Cutler, Neal R; Hiatt, William R;

Antithrombotic Trials Leadership and Steering Group

Improving academic leadership and oversight in large industry-sponsored clinical trials: the ARO-CRO model.

Blood 2011 Feb 17; 117(7): 2089-92

Abstract: Standards for clinical trial design, execution, and publication have increased in recent years. However, the current structure for interaction among the pharmaceutical sponsor funding a drug or device development program, the contract research organization (CRO) that typically assists in executing the trial, regulatory agencies, and academicians, provides inadequate leadership and oversight of the development process. Conventional academic steering committees are not provided with the independent infrastructure by which to verify statistical analyses and conclusions regarding safety and efficacy. We propose an alternative approach centered on partnerships between CROs and university-based academic research organizations (AROs). In this model, the ARO takes responsibility for processes that address journal requirements and regulatory expectations for independent academic oversight (including oversight of Steering Committee and Data and Safety Monitoring Board activities), whereas the CRO provides infrastructure for efficient trial execution, site monitoring, and data management. The ARO engages academic experts throughout the trial process and minimizes conflicts of interest in individual industry relationships via diversification of sponsors, agents, and therapeutic areas. Although numerous models can be entertained, the ARO-CRO model is uniquely structured to meet the demand for greater assurance of integrity in clinical trials and the needs of each stakeholder in the process.

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**Ethical issues in the conduct of clinical trials in obstructive sleep apnea.**


**Abstract:** Scientifically rigorous clinical trials are needed to test continuous positive airway pressure's (CPAP) effect on important clinical endpoints known to be associated with obstructive sleep apnea, such as myocardial infarction, cardiac arrhythmias, stroke, mortality, seizures, and cognitive function. In this "Special Article," we review the regulatory and ethical issues that surround the design and conduct of CPAP trials, including selection of the appropriate control condition, exclusion criteria, and follow-up duration.

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**[Informed consent in clinical trials and pharmacogenetic substudies]. = Consentimiento informado en ensayos clínicos y subestudios de Farmacogenética.**

Medicina clínica 2011 Feb 12; 136(3): 134-6

Georgetown users check [Georgetown Journal Finder](#) for access to full text.

**[Honest and justifiable research]. = Redelig og forsvarlig forskning.**

Tidsskrift for den Norske lægeforening : tidsskrift for praktisk medicin, ny række 2011 Feb 4; 131(3): 260

Georgetown users check [Georgetown Journal Finder](#) for access to full text.

**The ethics of clinical research.**

The Journal of hand surgery 2011 Feb; 36(2): 308-15

**Abstract:** The purpose of this article is to discuss the ethical concepts involved in the conception, design, execution, analysis, publication, and reporting of clinical research. Although it might seem burdensome to comply with these ethical necessities, they can assist in the organization of a well-run clinical trial, if considered at the onset of a study, while also protecting the valuable human subjects who volunteer for these trials.

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**Research ethics II: Mentoring, collaboration, peer review, and data management and ownership.**


**Abstract:** In this series of articles—Research Ethics I, Research Ethics II, and Research Ethics III—the authors provide a comprehensive review of the 9 core domains for the responsible conduct of research (RCR) as articulated by the Office of Research Integrity. In Research Ethics II, the authors review the RCR domains of mentoring, collaboration, peer review, and data management and ownership.
Document 178

Cacchione, Pamela Z

When is institutional review board approval necessary for quality improvement projects?
Clinical nursing research 2011 Feb; 20(1): 3-6

Document 179

Malafaia, Guilherme; Rodrigues, Aline Sueli de Lima; Talvani, André

Ethics in the publication of studies on human visceral leishmaniasis in Brazilian periodicals.
Revista de saúde pública 2011 Feb; 45(1): 166-72

Abstract: To analyze ethical aspects of Brazilian articles on human visceral leishmaniasis, published after Resolution CNS 196/1996, and to analyze the policy on Brazilian periodicals on research ethics.

Document 180

Chakladar, Abhijoy; Eckstein, Sue; White, Stuart M

Paper use in research ethics applications and study conduct.

Abstract: Application for Research Ethics Committee (REC) approval and the conduct of medical research is paper intensive. This retrospective study examined all applications to a single REC in the south of England over one year. It estimated the mass of paper used, comparing the proportional paper consumption of different trial types and during different stages of the research process, quantifying the consumption in terms of carbon dioxide emissions. In 2009, 68 trials were submitted to the REC. Total paper consumption for the REC process and study conduct was 176,150 sheets of A4 paper (879 kg), equivalent to an estimated 11.5 million sheets (88 tonnes, 2100 trees) a year for the U.K.; the REC process accounted for 26.4%. REC applications and the conduct of approved trials generate considerable environmental impact through paper consumption contributing to the NHS’s carbon footprint. Paper use might be reduced through the implementation of digital technologies and revised research methods, namely changing attitudes in both researchers and ethics committees.

Document 181

Cohn, John R

Alphabet soup: ABAI, ABMS, and MOC vs EBM, VBM, and IRB.
Annals of allergy, asthma & immunology : official publication of the American College of Allergy, Asthma, & Immunology 2011 Feb; 106(2): 79-80

Document 182

Ubel, Peter A; Silbergleit, Robert

Science and behavior.
Menikoff, Jerry

Overinterpreting equipoise.
The American journal of bioethics: AJOB 2011 Feb; 11(2): 13-4

Wasson, Katherine

Behavior equipoise: is it ready for prime time?
The American journal of bioethics: AJOB 2011 Feb; 11(2): 14-6

Crites, Joshua

Are more trials really the answer? Putting behavioral equipoise in check.
The American journal of bioethics: AJOB 2011 Feb; 11(2): 16-7

MacDonald, Chris

Clinical judgment and deep value commitments.

Abstract: There has been much philosophical interest regarding the 'hierarchy of evidence' used to determine which study designs are of most value for reporting on questions of effectiveness, prognosis, and so on. There has been much less philosophical interest in the choice of outcome measures with which the results of, say, an RCT or a cohort study are presented. In this paper, we examine the FDA's recently published guidelines for assessing the psychometric adequacy of patient-reported outcome measures. We focus on their recommendations for...
demonstrating content validity and also for how researchers should weigh up the sum of psychometric evidence when choosing these measures. We argue that questions regarding judgment and understanding meaning of these measures should play a more central role in determining their adequacy.

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**Document 189**

Stanev, Roger  
**Statistical decisions and the interim analyses of clinical trials.**  
Theoretical medicine and bioethics 2011 Feb; 32(1): 61-74  
**Abstract:** This paper analyzes statistical decisions during the interim analyses of clinical trials. After some general remarks about the ethical and scientific demands of clinical trials, I introduce the notion of a hard-case clinical trial, explain the basic idea behind it, and provide a real example involving the interim analyses of zidovudine in asymptomatic HIV-infected patients. The example leads me to propose a decision analytic framework for handling ethical conflicts that might arise during the monitoring of hard-case clinical trials. I use computer simulations to show how the framework can assist in reconciling certain ethical conflicts. The framework is partial, lacking the precision of a complete systematization of statistical monitoring procedures in practice.

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**Document 190**

Lorimer, Karen; Gray, Cindy M; Hunt, Kate; Wyke, Sally; Anderson, Annie; Benzeval, Michaela  
**Response to written feedback of clinical data within a longitudinal study: a qualitative study exploring the ethical implications.**  
BMC medical research methodology 2011 January 27; 11: 10  
**Abstract:** There is a growing ethical imperative to feedback research results to participants but there remains a striking lack of empirical research on how people respond to individualised feedback. We sought to explore longitudinal study participants’ response to receiving individual written feedback of weight-related and blood results, and to consider the balance of harms against benefits.

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**Document 191**

Toal, Martin J  
**Industry sponsored bias: NICE may be biased too.**  
BMJ (Clinical research ed.) 2011 January 25; 342: d474  
Georgetown users check [Georgetown Journal Finder](https://journal.finder.georgetown.edu) for access to full text.

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**Document 192**

Schilling, Robert F  
**Tripping on the HIPAA Hurdle.**  
Annals of internal medicine 2011 Jan 18; 154(2): 133-4  
Georgetown users check [Georgetown Journal Finder](https://journal.finder.georgetown.edu) for access to full text.

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**Document 193**

Samuel Reich, Eugenie
Cancer trial errors revealed.  
Nature 2011 Jan 13; 469(7329): 139-40

Investigator experiences with financial conflicts of interest in clinical trials.  
Trials 2011 January 12; 12: 9

Abstract: Financial conflicts of interest (fCOI) can introduce actions that bias clinical trial results and reduce their objectivity. We obtained information from investigators about adherence to practices that minimize the introduction of such bias in their clinical trials experience.

What oncologists believe they said and what patients believe they heard: an analysis of phase I trial discussions.  

Abstract: PURPOSE: Evaluation of the communication and informed consent process in phase I clinical trial interviews to provide authentic, practice-based content for inclusion in a communication skills training intervention for health care professionals.

Ethics of transparency in research reports.  
Indian journal of medical ethics 2011 Jan-Mar; 8(1): 31-6

Abstract: Transparency in research methods and results is now widely seen as an imperative if the healthcare and research enterprise is to be truly successful. A patient-centred focus in the conduct of clinical care includes its safety, effectiveness, efficiency, equity, and timeliness. Innovative ways are being developed to understand, disseminate, and rapidly apply the best evidence to care delivery. In this article, we demonstrate the use of simple and appropriate statistics in research reports that should help healthcare providers apply knowledge to practice by making it easier for them to understand clinical medicine.

Health systems research and the Gadchiroli debate: a plea for universal and equitable ethics.  
Indian journal of medical ethics 2011 Jan-Mar; 8(1): 47-8
Document 198

Kantharia, N D; Yadav, P; Deoghare, S
Jaykaran

**Reporting of the methodological quality and ethical aspects in clinical trials published in Indian journals: a survey.**
Journal of postgraduate medicine 2011 Jan-Mar; 57(1): 82-3

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Document 199

Smith, M

**2007 National Statement on Ethical Conduct in Human Research: not worth the paper it is written on?**
Internal medicine journal 2011 Jan; 41(1a): 73

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 200

Clancy, Anne

**An embodied response: ethics and the nurse researcher.**
Nursing ethics 2011 Jan; 18(1): 112-21

**Abstract:** The aim of this study is to reflect on situational ethics in qualitative research and on a researcher's embodied response to ethical dilemmas. Four narratives are presented. They are excerpts from field notes taken during an observational study on Norwegian public health nursing practice. The stories capture situational ethical challenges the author experienced during her research. The author's reflections on feelings of uncertainty, discomfort and responsibility, and Levinas' philosophy help to illuminate the ethical challenges faced. The study shows that the researcher always participates, to some degree, and is never merely a spectator making solely rational choices. Ethical challenges in field research cannot always be solved, yet must be acknowledged. Feelings of vulnerability are embodied responses that remind us of the primacy of ethics. More so, it is the primacy of ethics that gives rise to feelings of vulnerability and embodied responses.

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Document 201

Brecher, Bob; Gardener, Guy; Velepi, Marina; Walsh, Aileen; Belshaw, Christopher; Holland, Stephen

**Is it appropriate for research ethics committees to make judgements about the scientific quality of research proposals?**

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 202

Dute, Joseph

**ECHR 2011/5 case of Gillberg v. Sweden, 2 November 2010, no. 41723/06 (third section).**
European journal of health law 2011 Jan; 18(1): 88-91

Georgetown users check [Georgetown Journal Finder](#) for access to full text
Document 203

Tereskerz, Patti M; Guterbock, Thomas M; Kermer, Deborah A; Moreno, Jonathan D

An opinion and practice survey on the structure and management of data and safety monitoring boards.
Accountability in research 2011 Jan; 18(1): 1-30

Abstract: There is little to no empirical data available on how data and safety monitoring boards (DSMBs) are structured and how they operate. The purpose of this study was to provide data on this. To accomplish this goal, we administered a random survey on current structure and management practices and opinions as reported by principal investigators (PIs) and biostatisticians. We also surveyed Institutional Review Board (IRB) community members, as proxies for the public, as to their opinions on how DSMBs should be structured and managed. A final purpose was to compare opinions about what should be taking place to what is actually happening.

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Document 204

Jureidini, Jon N; McHenry, Leemon B

Conflicted medical journals and the failure of trust.
Accountability in research 2011 Jan; 18(1): 45-54

Abstract: Journals are failing in their obligation to ensure that research is fairly represented to their readers, and must act decisively to retract fraudulent publications. Recent case reports have exposed how marketing objectives usurped scientific testing and compromised the credibility of academic medicine. But scant attention has been given to the role that journals play in this process, especially when evidence of research fraud fails to elicit corrective measures. Our experience with The Journal of the American Academy of Child and Adolescent Psychiatry (JAACAP) illustrates the nature of the problem. The now-infamous Study 329 of paroxetine in adolescent depression was negative for efficacy on all eight protocol-specified outcomes and positive for harm, but JAACAP published a report of this study that concluded that "paroxetine is generally well tolerated and effective for major depression in adolescents." The journal's editors not only failed to exercise critical judgment in accepting the article, but when shown evidence that the article misrepresented the science, refused either to convey this information to the medical community or to retract the article.

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Document 205

Sandhu, Jagdeep; Khan, Nyla

Our first experience of an ethics committee: entering the Dragon's Den.
The British journal of general practice : the journal of the Royal College of General Practitioners 2011 Jan; 61(582): 70

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 206

Aartsma-Rus, Annemieke

The risks of therapeutic misconception and individual patient (n=1) "trials" in rare diseases such as Duchenne dystrophy.

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Document 207

Carroll, Tamar W; Gutmann, Myron P
The limits of autonomy: the Belmont Report and the history of childhood.
Journal of the history of medicine and allied sciences 2011 Jan; 66(1): 82-115

Abstract: This article examines the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research recommendations on children as research subjects in the context of the history of American childhood. The Commission's deliberations took place during the post-World War II period of rapid changes in understandings of childhood and adolescence, brought on in part by school children's highly visible roles as risk-taking protagonists in the polio vaccine trials and the civil rights movement; by the children's rights movement and court decisions granting children and adolescents greater autonomy in divorce cases and in delinquency and mental health hearings, among other rights; and finally by a renewed movement for child protection led by parents of disabled children and by polio survivors themselves. The National Commission's final recommendations emphasized the need for parents to approve, for children above age seven to assent to research, and for children in special care (either medical, psychiatric, or because they were orphans or had committed juvenile crimes) generally to be subjects of research only if there was some direct connection between the reasons for their special care and the objectives of the research. Ultimately, in these recommendations, the National Commission charted a middle ground between the children's rights movement, which advocated enhanced self-determination for children, and the disability rights movement, which urged greater protection for children.

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Document 208
Helgesson, Gert; Eriksson, Stefan
The moral primacy of the human being: a reply to Parker.

Abstract: In a previous paper in the Journal of Medical Ethics, the authors argued that the research ethical principle stating that the individual shall have priority over science, found in many guidelines, is utterly unclear and because of this should be explicated or otherwise deleted. In a recent commentary, Parker argued that this leaves us defending a position that would allow totalitarian regimes to pursue glory at the expense of its citizens. The present response addresses this and similar accusations.

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Document 209
VandenBosch, Terry M; Maio, Ronald F
Institutional not-for-cause compliance review programs.
IRB 2011 Jan-Feb; 33(1): 15-7

Georgetown users check Georgetown Journal Finder for access to full text

Document 210
Shiloff, J Deborah; Magwood, Bryan; Malisza, Krisztina L
MRI research proposals involving child subjects: concerns hindering research ethics boards from approving them and a checklist to help evaluate them.

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Document 211
Braillon, Alain
Sciensationalism.
Document 212

Knowles, Rachel L; Bull, Catherine; Wren, Christopher; Dezateux, Carol

Ethics, governance and consent in the UK: implications for research into the longer-term outcomes of congenital heart defects.

Archives of disease in childhood 2011 Jan; 96(1): 14-20

Abstract: To explore the effect of research ethics, governance and consent requirements and recent reforms on UK-wide follow-up of children with congenital heart defects (CHD).

Document 213

Singleton, P D

Do researchers know what they are doing?

Archives of disease in childhood 2011 Jan; 96(1): 3-4

Document 214

United States. Department of Health and Human Services; United States. Food and Drug Administration; Center for Biologics Evaluation and Research (U.S.); and Center for Drug Evaluation and Research (U.S.)

GUIDANCE FOR INDUSTRY: POSTMARKETING STUDIES AND CLINICAL TRIALS—IMPLEMENTATION OF SECTION 505(Q)(3) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT: DRUG SAFETY


http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm172001.pdf (link may be outdated)

Document 215

McPhaul, Michael J. and Toto, Robert D.

American Federation for Medical Research

CLINICAL RESEARCH: FROM PROPOSAL TO IMPLEMENTATION


Call number: R853.C55 C43 2011

Document 216

Amdur, Robert J. and Bankert, Elizabeth A.

INSTITUTIONAL REVIEW BOARD: MEMBER HANDBOOK


Call number: R852.5.A463 2011
"Members of the same club": challenges and decisions faced by US IRBs in identifying and managing conflicts of interest.

**Abstract:** Conflicts of interest (COIs) in research have received increasing attention, but many questions arise about how Institutional Review Boards (IRBs) view and approach these.

Mansour, Mansour

**Methodological and ethical challenges in investigating the safety of medication administration.**

**Abstract:** The aim of this article is to highlight some of the methodological and ethical challenges that the researcher faced when conducting a study of the safety of medication administration.

Brekelmans, Cecile T M; Kenter, Marcel J H; Bouter, Lex M; Koëter, Gerard H

**[Patient safety in clinical intervention research]. = Patiëntveiligheid bij klinisch interventieonderzoek.**

**Abstract:** In clinical intervention research, the monitoring of patient safety is essential. In December 2009, a symposium on the role of the different parties involved was organised. Research starts with a robust protocol with a section dealing with interim decision-making and procedures for reporting during the research. After the approval by an accredited Ethics Committee, the responsibility for the patient safety primarily lies with the investigators and sponsor (in the case of investigator-initiated research generally the Institutional Board of Directors). In addition, the appointment of a Data and Safety Monitoring Committee (DSMC) has become more frequent during recent years. This committee monitors the safety of patients by means of evaluation of interim results and advises the sponsor accordingly. The decision process concerning premature ending is a clinical decision, which should not exclusively be based on exceeding a statistical limit. The focus of the DSMC should be on safety issues; only in exceptional cases should a trial be discontinued because of clear efficacy, or the lack of it.

Marckmann, Georg; Strech, Daniel

**[Data transparency - an ethical imperative? Approaching the issues]. = Datentransparenz - ein ethischer Imperativ? Eine Problemskizze.**

**Abstract:** Several studies show that the findings of clinical trials are often not published in full, resulting in a biased presentation of results (publication bias). First, this paper discusses the ethical arguments in favour of complete transparency of biomedical research data. There are relevant deontological (like obligations towards study participants and research sponsors) and consequentialist (harm for patients and misallocation of scarce resources) ethical reasons for the full publication of all trial results, which cannot be overridden by counter arguments like freedom of research, data protection or the individual interests of researchers and manufacturers. The article therefore discusses (1) which strategies are appropriate to guarantee data transparency and (2) who bears responsibility for the implementation of these strategies. Finally, open questions and the need for further action will be discussed.
Document 221

Smith, C J

**Randomized controlled trials.**

Phlebology / Venous Forum of the Royal Society of Medicine 2011; 26(2): 84-5

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 222

Feldman, James

**Institutional review boards and protecting human research participants.**

JAMA : the journal of the American Medical Association 2010 Dec 15; 304(23): 2591-2; author reply 2592

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 223

Bristol, Nellie

**US reviews human trial participant protections.**

Lancet 2010 Dec 11; 376(9757): 1975-6

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 224

Nicholas, Joanne

**NCI's clinical trial system: efficiencies grow, debate goes on.**

Journal of the National Cancer Institute 2010 Dec 1; 102(23): 1750-1, 1755

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Document 225

Schmidt, H; Mehring, S; McMillan, J

**Interpreting the declaration of Helsinki (2008): "must", "should" and different kinds of obligation.**


**Abstract:** The Declaration of Helsinki is widely regarded as the preeminent code of research ethics. Revised six times since 1964, the versions differ in their substantive requirements, and also in the way that obligations are expressed, especially regarding the use of the prescriptors "should" and "must". The 2000 version contained roughly two-thirds "should" versus one-third "must". But this ratio was inversed in the final 2008 version—although in its penultimate draft practically all occurrences of "must" had been replaced with "should". We consider and analyze the significance of these variations for policy and practice. We argue that the Declaration can plausibly be viewed as 'soft law'. In interpreting it in legislative and jurisdictional contexts the terms "should" and "must" cannot be seen as synonymous. Even if the soft-law claim is rejected, and the Declaration is viewed as providing ethical guidance only, the question of how to interpret "should" and "must" remains. We explore three possible interpretations: categorical versus hypothetical requirements; perfect versus imperfect obligations; and aspiration versus obligation. We conclude that the most plausible way of understanding the distinction is in relation to the strength of the categorical obligations which the Declaration seeks to set out.

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Abstract: Clinical research plays a key role both in the development of innovative health products and in the optimisation of medical strategies, leading to evidence-based practice and healthcare cost containment. ECRIN is a distributed ESFRI-roadmap pan-European infrastructure designed to support multinational clinical research, making Europe a single area for clinical studies, taking advantage of its population size to access patients, and unlocking latent scientific providing services to multinational. Servicing of multinational trials started during the preparatory phase, and ECRIN has applied for ERIC status in 2011. In parallel, ECRIN has also proposed an FP7 integrating activity project to further develop, upgrade and expand the ECRIN infrastructure built up during the past FP6 and FP7 projects, facilitating an efficient organization of clinical research in Europe, with ECRIN developing generic tools and providing generic services for multinational studies, and supporting the construction of pan-European disease-oriented networks that will in turn act as ECRIN users. This organization will improve Europe's attractiveness for industry trials, boost its scientific competitiveness, and result in better healthcare for European citizens. The three medical areas supported in this project (rare diseases, medical devices, and nutrition) will serve as pilots for other biomedical research fields. By creating a single area for clinical research in Europe, this structure will contribute to the implementation of the Europe flagship initiative 2020 'Innovation Union', whose objectives include defragmentation of research and educational capacities, tackling the major societal challenges (starting with healthy aging), and removing barriers to bringing ideas to the market.

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Abstract: The financing of clinical studies by the pharmaceutical industry is a controversial topic both internationally and in here in Germany. The well-known unacceptable shortcomings require no further confirmation. It is, however, indisputable that the pharmaceutical industry and medical science are co-dependent. Neither the marketing of industrial products nor the research and education of clinical scientists could function without this cooperation. Therefore, all partners need suggestions concerning goal orientation and consensus. The aim of this discussion is to formulate just such suggestions. To structure this discussion, we have raised the following questions: Must we always be suspicious of the results of studies financed by the pharmaceutical industry? We have to keep in mind that in Germany all clinical trials leading to approval of a drug were supported by the industry. What, exactly, do we want to achieve with our explicit and often justified criticism of these studies? What should be done to achieve a higher validity of the published data if we avoid answering the decisive question of whether we accept the challenge of continuing to let research and teaching be financed by the pharmaceutical industry or reject this kind of cooperation and support altogether.

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Abstract: Federal regulations are the minimum requirements for conducting clinical studies. Some innovation would improve the situation of many involved in these studies, including: study subjects, those who monitor studies, and clinical investigators as well as Institutional Review Boards. Respecting patient and whistle-blower input; appreciating research staff contributions; and implementing a systems and partnership approach would foster quality
and advance clinical research.

Statistical power, the Belmont report, and the ethics of clinical trials.

Vollmer, Sara H; Howard, George

Abstract: Achieving a good clinical trial design increases the likelihood that a trial will take place as planned, including that data will be obtained from a sufficient number of participants, and the total number of participants will be the minimal required to gain the knowledge sought. A good trial design also increases the likelihood that the knowledge sought by the experiment will be forthcoming. Achieving such a design is more than good sense—it is ethically required in experiments when participants are at risk of harm. This paper argues that doing a power analysis effectively contributes to ensuring that a trial design is good. The ethical importance of good trial design has long been recognized for trials in which there is risk of serious harm to participants. However, whether the quality of a trial design, when the risk to participants is only minimal, is an ethical issue is rarely discussed. This paper argues that even in cases when the risk is minimal, the quality of the trial design is an ethical issue, and that this is reflected in the emphasis the Belmont Report places on the importance of the benefit of knowledge gained by society. The paper also argues that good trial design is required for true informed consent.

Responsible research: what is expected? Commentary on: "Statistical power, the Belmont Report, and the ethics of clinical trials".

Bird, Stephanie J

Abstract: "Responsible research" and "good science" are concepts with various meanings depending on one's perspective and assumptions. Fellow researchers, research participants, policy makers and the general public also have differing expectations of the benefits of research ranging from accurate and reliable data that extend the body of knowledge, to solutions to societal concerns. Unless these differing constituencies articulate their differing views they may fail to communicate and undermine the value of research to society.

Helicobacter pylori eradication therapy research: Ethical issues and description of results.

Graham, David Y

Abstract: As an infectious disease, the approach to anti-Helicobacter pylori therapy differs from other common gastrointestinal conditions because treatment success of more than 90% to 95% should be expected and the reasons for treatment failure can always be understood. Neither comparisons with another regimen nor randomization are required to identify a highly successful therapy. Treatment success should be judged first in relation to outcome (i.e. >= 95% or grade A). Inclusion of a known inferior regimen in a clinical trial is generally unethical. If the use of a known inferior drug is required by a regulatory agency, subjects must be given full and accurate information regarding expectations with each regimen; there can be no deceptions. Comparative trials should be restricted to highly successful treatments (i.e., comparisons of different doses, durations, compliance, cost, and so forth). Success should be judged as ordered categories such as <85%, 85%-89%, 90%-94%, or >= 95% and statistically equivalent regimens with the same grade success (i.e., 90%-94% [Grade B]) are inferior to those higher category (i.e., >= 95% [Grade A]) regimens. Only grade A or B regimens should be prescribed. Here we discuss anti-H pylori eradication studies from the perspective [corrected] of an infectious disease with the goal of providing recommendations regarding changes in approach and in reporting that should help resolve the ethical issues and make the results of
clinical trials more useful to clinicians.

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Document 232

Bird, S.J.

**Responsible research: what is expected?**

Science and Engineering Ethics 2010 December; 16(4): 693-696

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Document 233

Vollmer, S.H.; Howard, G.

**Statistical power, the Belmont Report, and the ethics of clinical trials**

Science and Engineering Ethics 2010 December; 16(4): 675-691

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Document 234

McConnell, Terrance

**The inalienable right to withdraw from research.**


**Abstract:** Most codes of research ethics and the practice of Institutional Review Boards (IRBs) allow human subjects to withdraw from research at any time. Consent forms invariably make a statement to this effect. So understood, a subject's right to withdraw from research is inalienable; she cannot, through her consent, surrender this right. Recently critics have argued that in selected circumstances the right to withdraw from research is alienable; subjects have the moral authority, through their consent, to obligate themselves not to withdraw. Two kinds of cases have been cited to support this. In one case, there will be great benefits lost if subjects are permitted to withdraw before the completion of the protocol. In the other case, there will be harm to third parties if subjects withdraw from the experiment. In this paper, I defend the inalienability of the right to withdraw from research. I argue, first, that securing the desired benefits and avoiding the feared harms can be achieved without allowing waiver. Second, I show that permitting waiver in these cases does not guarantee that the ends sought will be achieved. And third, I articulate positive reasons for conceiving subjects' right to withdraw from research as inalienable.

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Document 235

Lamas, Eugenia; Ferrer, Marcela; Molina, Alberto; Salinas, Rodrigo; Hevia, Adriana; Bota, Alexandre; Feinholz, Dafna; Fuchs, Michael; Schramm, Roland; Tealdi, Juan-Carlos; Zorrilla, Sergio

**A comparative analysis of biomedical research ethics regulation systems in Europe and Latin America with regard to the protection of human subjects.**

Journal of medical ethics 2010 Dec; 36(12): 750-3

**Abstract:** The European project European and Latin American Systems of Ethics Regulation of Biomedical Research Project (EULABOR) has carried out the first comparative analysis of ethics regulation systems for biomedical research in seven countries in Europe and Latin America, evaluating their roles in the protection of human subjects. We developed a conceptual and methodological framework defining 'ethics regulation system for biomedical research' as a set of actors, institutions, codes and laws involved in overseeing the ethics of biomedical research on humans. This framework allowed us to develop comprehensive national reports by conducting semi-structured interviews to key informants. These reports were summarised and analysed in a comparative analysis. The study showed that the regulatory framework for clinical research in these countries differ in scope. It showed that despite
the different political contexts, actors involved and motivations for creating the regulation, in most of the studied
countries it was the government who took the lead in setting up the system. The study also showed that Europe and
Latin America are similar regarding national bodies and research ethics committees, but the Brazilian system has
strong and noteworthy specificities.

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Pinxten, Wim; Nys, Herman; Dierickx, Kris
Access to investigational medicinal products for minors in Europe: ethical and regulatory issues in
negotiating children's access to investigational medicines.
Journal of medical ethics 2010 Dec; 36(12): 791-4
Abstract: Patients who search for a better treatment, an increased quality of life, or even a chance to preserve life
itself may claim to have an interest in accessing investigational medicinal products (IMP), particularly when no
validated treatment for their disease or condition exists. For many, awaiting the uncertain and time-consuming
process of converting an IMP into an approved drug may not appear a realistic option, as prognoses may be grim
and a dramatic outcome may seem hard to avert. Gaining access to an IMP, however, often proves to be a difficult
enterprise with a highly uncertain outcome. In addition, the process of seeking access to IMP is surrounded by
various ethical issues that will be explored in this article. This paper explores the ethical concerns in two potential
tracks of seeking access to IMP for minors: on an individual basis, or collectively, as a patient organisation. In this
discourse, several unique ethical and regulatory concerns related to the direct negotiation of access to IMP for minor
patients are identified, with a focus on product safety, the recruitment of research subjects, the unnoticed entry
of market mechanisms in the recruitment of research subjects, and the sidelining of third parties in the recruitment
process. The paper concludes with a concise reflection on the way forward. The quest for access to investigational
drugs is particularly relevant to paediatric practice, in which a significant share of the drugs prescribed has never
been tested in children or labelled for use in the paediatric population.

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Vergnes, Jean-Noel; Marchal-Sixou, Christine; Nabet, Cathy; Maret, Delphine; Hamel, Olivier
Ethics in systematic reviews.
Journal of medical ethics 2010 Dec; 36(12): 771-4
Abstract: Since its introduction by the Nuremberg Code and the Declaration of Helsinki, the place held by ethics in
biomedical research has been continuously increasing in importance. The past 30 years have also seen exponential
growth in the number of biomedical articles published. A systematic review of the literature is the scientific way of
synthesising a plethora of information, by exhaustively searching out and objectively analysing the studies dealing
with a given issue. However, the question of ethics in systematic reviews is rarely touched upon. This could lead to
some drawbacks, as systematic reviews may contain studies with ethical insufficiencies, may be a possible way to
publish unethical research and may also be prone to conflict of interest. Finally, informed consent given for an
original study is not necessarily still valid at the systematic review level. There is no doubt that routine ethical
assessment in systematic reviews would help to improve the ethical and methodological quality of studies in
general. However, ethical issues change so much with time and location, and are so broad in scope and in context
that it appears illusory to search for a universal, internationally accepted standard for ethical assessment in
systematic reviews. Some simple suggestions could nevertheless be drawn from the present reflection and are
discussed in the paper.

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Wolf, Leslie E
The research ethics committee is not the enemy: oversight of community-based participatory research.
Journal of empirical research on human research ethics : JERHRE 2010 Dec; 5(4): 77-86
Abstract: Researchers conducting community-based participatory research (CBPR) often complain about research ethics committee (REC) oversight of their research. RECs may contribute to researchers’ frustrations by seemingly focusing on form over substance and by failing to communicate effectively with researchers about their mission and their specific concerns. UCSF CBPR researchers presented their views of the UCSF REC's review of its tobacco use study in "It's Like Tuskegee in Reverse: A Case Study of Ethical Tensions in Institutional Review Board Review of Community-Based Participatory Research." This article builds on that case study by providing some perspectives from the REC side, identifying how the researchers and the REC came to be at odds, and seeking to bridge the gap between the CBPR and REC worlds. In particular, the article explores the different perspectives on who are human subjects under the federal regulations in CBPR research, who counts as the community, and the purpose of REC oversight. It offers concrete suggestions for improving the relationship between CBPR researchers and RECs.

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Document 239
Zeng, WeiQin; Resnik, David
Research integrity in China: problems and prospects.
Developing world bioethics 2010 Dec; 10(3): 164-71
Abstract: In little more than 30 years, China has recovered from the intellectual stagnation brought about by the Cultural Revolution to become a global leader in science and technology. Like other leading countries in science and technology, China has encountered some ethical problems related to the conduct of research. China's leaders have taken some steps to respond to these problems, such as developing ethics policies and establishing oversight committees. To keep moving forward, China needs to continue to take effective action to promote research integrity. Some of the challenges China faces include additional policy development, promoting education in responsible conduct of research, protecting whistle-blowers, and cultivating an ethical research environment.

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Document 240
Reyes-Garcia, Victoria
The relevance of traditional knowledge systems for ethnopharmacological research: theoretical and methodological contributions.
Journal of ethnobiology and ethnomedicine 2010 November 17; 6: 32
Abstract: Ethnopharmacology is at the intersection of the medical, natural, and social sciences. Despite its interdisciplinary nature, most ethnopharmacological research has been based on the combination of the chemical, biological, and pharmacological sciences. Far less attention has been given to the social sciences, including anthropology and the study of traditional knowledge systems.

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Document 241
Millum, Joseph; Menikoff, Jerry
Streamlining ethical review.
Annals of internal medicine 2010 Nov 16; 153(10): 655-7
Abstract: The review system for human subjects research in the United States has been widely criticized in recent years for requirements that delay research without improving human subject protections. Any major reformulation of regulations may take some time to implement. However, current regulations often allow for streamlined ethics review that does not jeopardize-and may improve-protections for research participants. The authors discuss underutilized options, including research that need not be classified as human subjects research, categories of studies that can be exempt from ethical review, studies that need only undergo expedited review by 1 institutional review board (IRB) member, and simplifying reviews of multicenter research by using the IRB of 1 institution. The authors speculate on multiple reasons for the underuse of these mechanisms and exhort IRBs and researchers to take advantage of these important opportunities to improve the review process.

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Salonia, Andrea

**Words of wisdom. Re: Biological, clinical, and ethical advances of placebo effects.**

*European uroloov* 2010 Nov; 58(5): 792-3

Dal-Ré, R; Luque-Montoro, I; Morejón-Bosch, E

*[Legibility of the patient information sheet after its review by the clinical research ethics committees]. = Legibilidad de la hoja de información para el paciente tras su revisión por los comités éticos de investigación clínica.*

*Revista clínica española* 2010 Nov; 210(10): 529-30

Letouzey, V; Deffieux, X

*[How to get an institutional review board (IRB) approval for clinical research]. = Comment écrire un « CEROG » ?*  

*Gynécologie, obstétrique & fertilité* 2010 Nov; 38(11): 716-7

Jansen, Tim C; Bakker, Jan; Kompanje, Erwin J O

**Inability to obtain deferred consent due to early death in emergency research: effect on validity of clinical trial results.**


**Abstract:** To illustrate the impact on the validity of trial results due to excluding patients from a randomized controlled trial for whom no deferred consent could be obtained after randomization because study procedures had already been finished.

Cope, Mark B; Allison, David B

**White hat bias: a threat to the integrity of scientific reporting.**


Bean, Sally; Henry, Blair; Kinsey, J Michelle; McMurray, Keitha; Parry, Catherine; Tassopoulos, Tiffany
Enhancing research ethics decision-making: an REB decision bank.
IRB 2010 Nov-Dec; 32(6): 9-12

Gallagher, Ann
The ethics of research ethics committees.
Nursing ethics 2010 Nov; 17(6): 683-4

Thorsen, Einar; Grønning, Marit; Troland, Kari
Diving and intrapulmonary shunting of venous gas microemboli.
Journal of clinical ultrasound : JCU 2010 Nov-Dec; 38(9): 497; author reply 498

Palmer, Roxanne
Clinical sabbatical aims to beef up trial-management skills.
Nature medicine 2010 Nov; 16(11): 1170

Gong, Michelle Ng; Winkel, Gary; Rhodes, Rosamond; Richardson, Lynne D; Silverstein, Jeffrey H
Surrogate consent for research involving adults with impaired decision making: survey of Institutional Review Board practices.
Critical care medicine 2010 Nov; 38(11): 2146-54

Maher, Lisa; White, Bethany; Hellard, Margaret; Madden, Annie; Prins, Maria; Kerr, Thomas; Page, Kimberly
Candidate hepatitis C vaccine trials and people who inject drugs: challenges and opportunities.
Vaccine 2010 Oct 21; 28(45): 7273-8

Abstract: People who inject drugs (PWID) are at high risk of HCV. Limited evidence of the effectiveness of prevention interventions and low uptake of treatment in this group highlight the need for increased investment in biomedical interventions, notably safe and efficacious vaccines. While several candidates are currently in development, field trials in PWID present challenges, including ethical issues associated with trial literacy, informed consent, and the potential for increased transmission of HCV.
consent and standards of care. Significant biological and social factors and differences between HIV and HCV suggest that HCV warrants targeted vaccine preparedness research to lay the groundwork for successful implementation of future trials.

Georgetown users check [Georgetown Journal Finder](#) for access to full text
Abstract: We performed a review of the constitution processes and functions of national commissions on health research ethics in Latin America and Europe countries, which are characterized by its relation with the legislation and governmental structures in health sector, but, especially, in almost totality of cases for being linked by the functioning of the Research Ethics Committees. On the basis of this review there are realized an initial balance sheet and perspectives of the conformation of a National Commission on Health Research Ethics in Peru.

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**Document 259**

Hurst, Samia

*What 'empirical turn in bioethics'?*

Bioethics 2010 Oct; 24(8): 439-44

**Abstract:** Uncertainty as to how we should articulate empirical data and normative reasoning seems to underlie most difficulties regarding the 'empirical turn' in bioethics. This article examines three different ways in which we could understand 'empirical turn'. Using real facts in normative reasoning is trivial and would not represent a 'turn'. Becoming an empirical discipline through a shift to the social and neurosciences would be a turn away from normative thinking, which we should not take. Conducting empirical research to inform normative reasoning is the usual meaning given to the term 'empirical turn'. In this sense, however, the turn is incomplete. Bioethics has imported methodological tools from empirical disciplines, but too often it has not imported the standards to which researchers in these disciplines are held. Integrating empirical and normative approaches also represents true added difficulties. Addressing these issues from the standpoint of debates on the fact-value distinction can cloud very real methodological concerns by displacing the debate to a level of abstraction where they need not be apparent. Ideally, empirical research in bioethics should meet standards for empirical and normative validity similar to those used in the source disciplines for these methods, and articulate these aspects clearly and appropriately. More modestly, criteria to ensure that none of these standards are completely left aside would improve the quality of empirical bioethics research and partly clear the air of critiques addressing its theoretical justification, when its rigour in the particularly difficult context of interdisciplinarity is what should be at stake.

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**Document 260**

Braga, Luis H P; Bagli, Darius J; Lorenzo, Armando J

*Placebo-controlled trials in pediatric urology: a cautionary view from an ethical perspective.*


**Abstract:** The ethical dispute regarding placebo-controlled trials is discussed in this review. Important issues, such as clinical equipoise, fiduciary obligation and middle ground theory, are examined in the context of pediatric urology clinical research. After reviewing the literature, the authors summarize specific indications for placebo-controlled trials in pediatric urology, and emphasize that physicians have ethical and moral obligations to patients, in the sense that one should carefully plan and conduct such trials in order to gain clinically important information without exposing children to undue risks.

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**Document 261**

Schlichting, Douglas E

*Destabilizing the 'equipoise' framework in clinical trials: prioritizing non-exploitation as an ethical framework in clinical research.*


**Abstract:** The framework of equipoise has been promulgated as an underlying requirement for conducting ethical clinical research. Equipoise is the term used for a state of indifference about which treatment intervention or innovation will provide the most benefit and the least harm to recipients. Drawing on healthcare, research, and ethics literature, this paper analyses the implications of equipoise from the perspective of several proponents and critics. Specifically the historical evolution of the concept based on Fried and Freedman's arguments is traced. A critique of
the concept, informed by contrasting perspectives, is offered. An alternative framework of non-exploitation as presented by Miller and Brody is argued to be superior in facilitating both the ultimate goals of research on human subjects and those of the healthcare professions'.

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### Document 262

**Moss, Sue**

**Design issues in cancer screening trials.**


**Abstract:** Randomised controlled trials avoid many of the potential biases associated with the evaluation of cancer screening. Nevertheless there are many issues concerning the design of such trials that require careful consideration and that will influence interpretation of the results. This article discusses issues related to recruitment and randomisation, which will affect the extent to which the population studied, is representative of the eventual target population of a screening programme. It addresses sample size considerations, the use of appropriate outcome measures and the timing of the intervention. Finally, issues related to ensuring appropriate analyses are discussed.

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### Document 263

**Farb, Andrew; Brown, Sheila A; Wolf, Deborah A; Zuckerman, Bram**

**Interventional cardiology live case presentations regulatory considerations.**


**Abstract:** Live case presentations are increasingly common at interventional cardiology conferences. Taking advantage of significant advances in communication technology, broadcasts of procedures can be viewed as an extension of traditional medical education targeted to large groups of practitioners. However, there are important ethical, commercial, and patient safety issues associated with live cases that deserve attention. Use of investigational devices in live case demonstrations is subject to review and approval by FDA's Center for Devices and Radiological Health (CDRH), and the outcomes of patients participating in live cases are considered in the overall clinical study results. This article discusses CDRH's regulatory view of live case presentations with a focus on patient safety, clinical trial integrity, and concerns regarding improper medical device promotion.

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### Document 264

**Chappuy, H; Baruchel, A; Leverger, G; Oudot, C; Brethon, B; Haouy, S; Auvrignon, A; Davous, D; Doz, F; Tréluyer, J M**

**Parental comprehension and satisfaction in informed consent in paediatric clinical trials: a prospective study on childhood leukaemia.**

Archives of disease in childhood 2010 Oct; 95(10): 800-4

**Abstract:** To evaluate the extent to which parents are satisfied with and understand the information they are given when their consent is sought for their child to participate in a phase III randomised clinical trial and the reasons for their decision.

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### Document 265

**Hall, Mark A; Friedman, Joëlle Y; King, Nancy M P; Weinfurt, Kevin P; Schulman, Kevin A; Sugarman, Jeremy**

**Commentary: Per capita payments in clinical trials: reasonable costs versus bounty hunting.**

Academic medicine : journal of the Association of American Medical Colleges 2010 Oct; 85(10): 1554-6

**Abstract:** Paying more for clinical research than the cost of doing the work may create a conflict of interest that
could lead to overzealous recruitment, putting participants and scientific integrity at risk. Thus, although various policies prohibit "finder's fees" simply for recruiting patients, paying the actual costs for research is permissible. Whereas industry-sponsored research routinely pays for the costs of each patient enrolled, the line between reasonable and excessive costs merits more attention. In academic medical centers (AMCs), institutional review boards and conflict of interest committees usually are not involved in reviewing research budgets to determine whether per capita payments are excessive. Also, the costs for clinical services in research are not standardized. Instead, budgets are negotiated both internally, among departments within research institutions, and externally, between researchers and sponsors. Sometimes, rates paid by sponsors exceed what researchers usually receive or are actually paid for particular services, generating a surplus. Nevertheless, the authors see only limited cause for concern because, at the AMCs with which the authors are familiar, any monetary surplus generally remains within the research enterprise to cover unanticipated budget shortfalls or to support research staff in the future during lean times. In addition, the surplus from research budgets is not shared directly with individual investigators. However, further investigation is needed to determine whether practices outside AMCs pose greater concerns.

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Document 266
Rhodes, Rosamond
Rethinking research ethics.
Abstract: Contemporary research ethics policies started with reflection on the atrocities perpetrated upon concentration camp inmates by Nazi doctors. Apparently, as a consequence of that experience, the policies that now guide human subject research focus on the protection of human subjects by making informed consent the centerpiece of regulatory attention. I take the choice of context for policy design, the initial prioritization of informed consent, and several associated conceptual missteps, to have set research ethics off in the wrong direction. The aim of this paper is to sort out these confusions and their implications and to offer instead a straightforward framework for considering the ethical conduct of human subject research. In the course of this discussion I clarify different senses of autonomy that have been confounded and present more intelligible justifications for informed consent. I also take issue with several of the now accepted dogmas that govern research ethics. These include: the primacy of informed consent, the protection of the vulnerable, the substitution of beneficence for research's social purpose, and the introduction of an untenable distinction between innovation and research.

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Document 267
Koski, Greg
"Rethinking research ethics," again: Casuistry, phronesis, and the continuing challenges of human research.

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Document 268
De Vreese, Leen; Weber, Erik; Van Bouwel, Jeroen
Explanatory pluralism in the medical sciences: theory and practice.
Theoretical medicine and bioethics 2010 Oct; 31(5): 371-90
Abstract: Explanatory pluralism is the view that the best form and level of explanation depends on the kind of question one seeks to answer by the explanation, and that in order to answer all questions in the best way possible, we need more than one form and level of explanation. In the first part of this article, we argue that explanatory pluralism holds for the medical sciences, at least in theory. However, in the second part of the article we show that medical research and practice is actually not fully and truly explanatory pluralist yet. Although the literature demonstrates a slowly growing interest in non-reductive explanations in medicine, the dominant approach in medicine is still methodologically reductionist. This implies that non-reductive explanations often do not get the attention they deserve. We argue that the field of medicine could benefit greatly by reconsidering its reductive
tendencies and becoming fully and truly explanatory pluralist. Nonetheless, trying to achieve the right balance in the
search for and application of reductive and non-reductive explanations will in any case be a difficult exercise.

Document 269
Kierzek, Gérald; Rac, Valeria; Pourriat, Jean-Louis
Is emergency research without initial consent justified? The consent substitute model.
Archives of internal medicine 2010 Sep 13; 170(16): 1508-9; author reply 1509

Document 270
Sugarman, Jeremy; Grace, William C
Ethics and the standards of prevention in HIV prevention trials.
AIDS (London, England) 2010 Sep 10; 24(14): 2298-9; author reply 2299-300

Document 271
Day, Michael
European drug agency calls for more ethical trials in developing countries.
BMJ (Clinical research ed.) 2010 September 10; 341: c4984

Document 272
Grady, Christine
Do IRBs protect human research participants?
JAMA : the journal of the American Medical Association 2010 Sep 8; 304(10): 1122-3

Document 273
Allison, David B; Cope, Mark B
Randomized controlled trials with statistically nonsignificant results.
JAMA : the journal of the American Medical Association 2010 Sep 1; 304(9): 965; author reply 965

Document 274
Mohindra, R K
A case of insufficient evidence equipoise: the NICE guidance on antibiotic prophylaxis for the prevention of infective endocarditis.
Journal of medical ethics 2010 Sep; 36(9): 567-70
Abstract: This paper argues that the National Institute for Health and Clinical Excellence should not offer guidance in
situations where there is insufficient evidence equipoise about the potential benefit of the treatment in question. This is broadly for two reasons. First, without knowing if the treatment is effective no cost-effectiveness judgement can be logically made. Second, the implementation of a population wide change in treatment where there is equipoise amounts to a de facto clinical trial that falls outside the Clinical Trials Regulations. As such there are strong ethical and possibly legal grounds for preventing such an outcome. Guidance based upon insufficient evidence equipoise also impacts upon the clinical discretion possessed by individual medical professionals.

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**Document 275**

Lima, Sandro Gonçalves de; Lima, Tatiana Albuquerque Gonçalves de; Macedo, Larissa Araripe de; Sá, Michel Pompeo Barros de Oliveira; Vidal, Marcela de Lima; Gomes, Alessandro Ferreira; Oliveira, Laura Correia; Santos, Ana Maria Aguiar

**Ethics in research with human beings: from knowledge to practice.**

Arquivos brasileiros de cardiologia 2010 Sep; 95(3): 289-94

**Abstract:** In Brazil, resolution 196/96 and its amendments regulate the preservation of rights, respect and dignity of human beings involved in research.

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**Document 276**

Quiroz, Estela

[Why to audit to research ethics committees?] = ¿Por qué auditar a los comités de ética en investigación?

Revista peruana de medicina experimental y salud pública 2010 Sep; 27(3): 443-8

**Abstract:** Ethics committees in biomedical research have the responsibility to ensure the protection of human participants in the studies. In order to improve the quality of their work they must undergo audit procedures commissioned by the sponsors and inspections done by the regulatory authorities. Through these procedures, improvement of their functions should be guaranteed, so they can optimize their tasks and accomplish in the best way the purpose for which they were created.

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**Document 277**

Berger, Vance W

**Minimization, by its nature, precludes allocation concealment, and invites selection bias.**

Contemporary clinical trials 2010 Sep; 31(5): 406

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**Document 278**

Petrini, Carlo; Lanza, Carlo

**When accident is culpable and negligence fortuitous: international repercussions of national legal contortions in clinical trials.**

Contemporary clinical trials 2010 Sep; 31(5): 405

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**Document 279**
The ethics of sham surgery on research subjects with cognitive impairments that affect decision-making capacity.

**Abstract:** Populations recruited to participate in sham surgery clinical trials sometimes include patients with cognitive impairments that affect decision-making capacity. In this commentary we examine arguments for and against including these patients in sham surgery clinical trials. We argue that patients with cognitive impairments that affect decision-making capacity should not be excluded from a sham surgery clinical trial if there are scientific reasons for including them in the study and basic ethical requirements for clinical research are met.

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Research Ethics Committee: mandatory necessity. Requirement needed.

**Abstract:** A review conducted in 2005 identified many of the communication difficulties experienced by patients and doctors when discussing phase 1 (P1) oncology trials. The current paper is an update of the area and focuses on studies that measure patient comprehension of information given during the P1 trial discussion and ways to enhance understanding. A literature search was performed for relevant articles published between January 2005 and July 1st 2009.

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Ethical issues in translational research.

**Abstract:** The translation of biomedical research knowledge to effective clinical treatment is essential to the public good and is a main focus of current health policy. However, recent health policy initiatives intended to foster the translation of basic science into clinical and public health advances must also consider the unique bioethical issues raised by the increased focus on translational research. Safety of study participants and balancing of risk due to treatment with the potential benefits of the research is tantamount. This article synthesizes theory from clinical ethics, operational design, and philosophy to provide a bioethical framework for the health policy of translational research.

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Ethical considerations for normal control subjects in MRI research.
Abstract: MRI is increasingly used as a research tool with the inclusion of "normal" control subjects, raising ethical issues when significant incidental abnormalities are found on research MRIs. We report two asymptomatic young men who had lesions discovered on MRIs performed for research in which they were acting as normal controls. We discuss the ethical considerations raised by these patients in imaging research, including appropriate subject selection, study design to include protocol mechanisms for incidental findings, informed consent and the need for expert clinical review of images.

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Document 284

Pitak-Amnop, Poramate; Hemprich, Alexander; Dhanuthai, Kittipong; Pausch, Niels Christian

Ethical conduct of human research: some controversies.


Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 285

Wells, Frank

The Stoke CNEP saga - did it need to take so long?

Journal of the Royal Society of Medicine 2010 Sep; 103(9): 352-6

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 286

Kaposy, Chris; Baylis, Françoise

Ethical, evidence-based guidelines for contraceptive use in research.


Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 287

Sirotin, Nicole; Wolf, Leslie E; Pollack, Lance M; Catania, Joseph A; Dolcini, M Margaret; Lo, Bernard

IRBs and ethically challenging protocols: views of IRB chairs about useful resources.


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Document 288

Ripley, Elizabeth; Macrina, Francis; Markowitz, Monika; Gennings, Chris

Why do we pay? A national survey of investigators and IRB chairpersons.

Journal of empirical research on human research ethics : JERHRE 2010 Sep; 5(3): 43-56

Abstract: The principle that payment to participants should not be undue or coercive is the consensus of international and national guidelines and ethical debates; however, what this means in practice is unclear. This study determined the attitudes and practices of IRB chairpersons and investigators regarding participant payment. One thousand six hundred investigators and 1900 IRB chairpersons received an invitation to participate in a web-based survey. Four hundred and fifty-five investigators (28.3%) and 395 IRB chairpersons (18.6%) responded. The survey
was designed to gather considerations that govern payment determination and practical application of these considerations in hypothetical case studies. The survey asked best answer, multiple choice, and open text questions. Short hypothetical case scenarios where presented, and participants were asked to rate factors in the study that might impact payment and then determine their recommended payment. A predictive model was developed for each case to determine factors which affected payment. Although compensation was the primary reason given to justify payment by both investigators and IRB chairpersons, the cases suggested that, in practice, payment is often guided by incentive, as shown by the impact of anticipated difficulty recruiting, inconvenience, and risk in determining payment. Payment models varied by type of study. Ranges for recommended payments by both groups for different types of procedures and studies are presented.
Bleyer, Bernhard

[Standardization of ethics committees in health care and nursing facilities: future perspectives for sustainable and effective counseling]. = Standardisierung von Ethikkomitees in Gesundheits- und Pflegeeinrichtungen: Zukunftsperspektiven für nachhaltige und effektive Beratung.

Pflege Zeitschrift 2010 Aug; 63(8): 486-9

Geller, Gail; Boyce, Alison; Ford, Daniel E; Sugarman, Jeremy

Beyond "compliance": the role of institutional culture in promoting research integrity.

Academic medicine : journal of the Association of American Medical Colleges 2010 Aug; 85(8): 1296-302

Abstract: To contribute data to conceptual explorations of the role of institutional culture in promoting research ethics and integrity.

Cheung, Winson Y; Pond, Gregory R; Heslegrave, Ronald J; Enright, Katherine; Potanina, Larissa; Siu, Lillian L

The contents and readability of informed consent forms for oncology clinical trials.


Abstract: OBJECTIVES: To compare the quality of informed consent forms (ICF) for different trial phases, funding sources, oncology subspecialties, disease settings, and intervention modalities. METHODS: ICF for prospectively conducted clinical trials were examined for their descriptions of benefits and risks, study alternatives, voluntary participation, and confidentiality. Readability was assessed with Flesch Reading Ease (FRE) score and Flesch-Kincaid Reading Grade Level. RESULTS: Among 262 evaluable trials, ICF contained an average of 3982 words, 379 sentences, and 10.5 pages. The mean FRE score and Reading Grade Level were 61.2 and 7.4, respectively. All ICF explicitly stated that the intervention was investigational. Only 2 (1%) promised direct personal benefits, 16 (6%) suggested the chance of cure or prolonged survival, and 89 (34%) indicated a potential for tumor response. Conversely, 239 (91%) mentioned the risk of serious harms, 217 (83%) admitted that some side effects could be unknown or unpredictable, and 126 (48%) reported hospitalization or death as a possibility. Alternatives to participation, right to withdraw from study, and data confidentiality were addressed in 242 (92%), 254 (97%), and 260 (99%) ICF, respectively. Hematology, industry-funded, metastatic, and systemic therapy trials were most likely to highlight major risks (P < 0.05). Readability was better in phase I trials and in studies, which were performed by medical oncologists, sponsored by governmental agencies, conducted in the metastatic setting, and involved systemic therapy (P < 0.05). CONCLUSIONS: ICF had acceptable readability and provided a realistic overview of the benefits and risks of clinical trials, but the potential for hospitalization or fatality was underreported.

Sofaer, Neema; Eyal, Nir

Translational research beyond approval: a two-stage ethics review.

Responses to open peer commentaries on "research exceptionalism".
The American journal of bioethics : AJOB 2010 Aug; 10(8): W4-6

Abstract: Commentators on the ethics of translational research find it morally problematic. Types of translational research are said to involve questionable benefits, special risks, additional barriers to informed consent, and severe conflicts of interest. Translational research conducted on the global poor is thought to exploit them and increase international disparities. Some commentators support especially stringent ethical review. However, such concerns are grounded only in pre-approval translational research (now called T1). Whether or not T1 has these features, translational research beyond approval (T2: phase IV, health services, and implementation research) is unlikely to and, when conducted on the global poor, may support development. Therefore, insofar as T1 is morally problematic, and no independent objections to T2 exist, the ethics of translational research is diverse: while some translational research is problematic, some is not. Funding and oversight should reflect this diversity, and T2 should be encouraged, particularly when conducted among the global poor.

Ethical analysis of translational research is more complex than distinguishing T1 from T2.

Bioethics and post-approval research in translational science.
Research exceptionalism.

Abstract: Research involving human subjects is much more stringently regulated than many other nonresearch activities that appear to be at least as risky. A number of prominent figures now argue that research is overregulated. We argue that the reasons typically offered to justify the present system of research regulation fail to show that research should be subject to more stringent regulation than other equally risky activities. However, there are three often overlooked reasons for thinking that research should be treated as a special case. First, research typically involves the imposition of risk on people who do not benefit from this risk imposition. Second, research depends on public trust. Third, the complexity of the moral decision making required favors ethics committees as a regulative solution for research.
Beyond research exceptionalism: a call for process redesign.
Bean, Sally

One size does not fit all: the ethical imperative to limit the concept of research exceptionalism.
McCullough, Melissa

Striking the right balance in research ethics and regulation.
Miller, Franklin G

Reversing "research exceptionalism".
Hansson, Sven Ove

Three worries about three arguments for research exceptionalism.
John, Stephen

Training needs assessment in research ethics evaluation among research ethics committee members in three African countries: Cameroon, Mali and Tanzania.
Ateudjieu, Jérôme; Williams, John; Hirtle, Marie; Baume, Cédric; Ikingura, Joyce; Niaré, Alassane; Sprumont, Dominique

Abstract: BACKGROUND: As actors with the key responsibility for the protection of human research participants,
Research Ethics Committees (RECs) need to be competent and well-resourced in order to fulfill their roles. Despite recent programs designed to strengthen RECs in Africa, much more needs to be accomplished before these committees can function optimally. OBJECTIVE: To assess training needs for biomedical research ethics evaluation among targeted countries. METHODS: Members of RECs operating in three targeted African countries were surveyed between August and November 2007. Before implementing the survey, ethical approvals were obtained from RECs in Switzerland, Cameroon, Mali and Tanzania. Data were collected using a semi-structured questionnaire in English and in French. Results: A total of 74 respondents participated in the study. The participation rate was 68%. Seventy one percent of respondents reported having received some training in research ethics evaluation. This training was given by national institutions (31%) and international institutions (69%). Researchers and REC members were ranked as the top target audiences to be trained. Of 32 topics, the top five training priorities were: basic ethical principles, coverage of applicable laws and regulations, how to conduct ethics review, evaluating informed consent processes and the role of the REC. CONCLUSION: Although the majority of REC members in the targeted African countries had received training in ethics, they expressed a need for additional training. The results of this survey have been used to design a training program in research ethics evaluation that meets this need.
Document 318

Ramiro Avilés, Miguel Angel

[Non-direct participants in drug clinical trials]. = Participantes indirectos en los ensayos clínicos con medicamentos.
Medicina clínica 2010 Jul 10; 135(5): 231-5

Document 319

Rehmann-Sutter, Christoph

Sino-European research ethics on the right path.
Nature 2010 Jul 1; 466(7302): 28

Document 320

Markman, Maurie

Serious ethical dilemma of single-agent pegylated liposomal Doxorubicin employed as a control arm in ovarian cancer chemotherapy trials.

Document 321

Wang, Sue-Jane

Multi-regional clinical trials–what are the challenges?

Document 322

Ibia, Ekopimo; Binkowitz, Bruce; Saillot, Jean-Louis; Talerico, Steven; Koerner, Chin; Ferreira, Irene; Agarwal, Anupam; Metz, Craig; Maman, Marianne

Ethical considerations in industry-sponsored multiregional clinical trials.

Abstract: During the last several decades, the scientific and ethics communities have addressed important ethical issues in medical research, resulting in the elaboration and adoption of concepts, guidelines, and codes. Ethical issues in the conduct of Multiregional Clinical Trials have attracted significant attention mainly in the last two decades. With the globalization of clinical research and the rapid expansion to countries with a limited tradition of biomedical research, sponsors must proactively address local ethical issues, the adequacy of oversight as well as the applicability and validity of data, and scientific conclusions drawn from diverse patient populations. This paper highlights some core ethical principles and milestones in medical research, and, from an industry perspective, it discusses ethical issues that the clinical trial team may face when conducting Multiregional Clinical Trials (MRCT, clinical trials conducted at sites located across multiple geographic regions of the world). This paper further
highlights the areas of consensus and controversies and proposes points to consider.

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Document 323

Pogorzelska, Monika; Stone, Patricia W; Cohn, Elizabeth Gross; Larson, Elaine

Changes in the institutional review board submission process for multicenter research over 6 years.


Abstract: Although collaborative research across sites is essential to increase the statistical power and generalizability of research findings, the need to undergo multiple institutional review board (IRB) reviews is a challenge. The purposes of this paper are to describe changes in the IRB submission process in 2 national multisite studies before and after the implementation of the Health Information Portability and Accountability Act (HIPAA) Privacy rule (2002 and 2008) and to discuss implications for policy and practice related to human subjects research. In the second study, there was a shorter mean approval time and reduced variability in the decision about the level of review, the mean number of pages per application doubled, and an increased proportion of IRBs required conflict of interest and data use agreements. Possible approaches to further enhance the efficiency and streamlining of the research review process are suggested.

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Document 324

Kim, Paul J

Human subject protection: overkill?

The Journal of foot and ankle surgery : official publication of the American College of Foot and Ankle Surgeons 2010 Jul-Aug; 49(4): 317-8

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Document 325

Nikarge, Sachin

The contours of clinical research in India.

Indian journal of medical ethics 2010 Jul-Sep; 7(3): 178-9

Georgetown users check Georgetown Journal Finder for access to full text
Dolgin, Elie
**Legalese creates consent 'conundrum' in clinical trials.**
Nature medicine 2010 Jul; 16(7): 727
Georgetown users check [Georgetown Journal Finder](#) for access to full text

McMillan, John
**Coercive offers and research participation: a comment on Wertheimer and Miller.**
*Abstract:* Concepts such as 'coercion' and 'inducement' are often used within bioethics without much reflection upon what they mean. This is particularly so in research ethics where they are assumed to imply that payment for research participation is unethical. Wertheimer and Miller advance our thinking about these concepts and research ethics in a significant way, specifically by questioning the possibility of genuine offers ever being coercive. This commentary argues that they are right to question this assumption, however, more needs to be said about the plausible coercive offer cases and to explain the normativity of these cases.
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Patrone, D
**Discrepancies between research advertisements and disclosure of study locations in trial registrations for USA-sponsored research in Russia.**
Journal of medical ethics 2010 Jul; 36(7): 431-4
*Abstract:* The full disclosure of all locations at which research is conducted is an important requirement of clinical trial registration. Yet, little is known about how well researchers and sponsors disclose this information in their registrations. The aim of this study is to examine the adequacy of study location disclosure on [http://ClinicalTrials.gov](http://ClinicalTrials.gov) for recent USA-sponsored research in the Russian Federation.
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Gefenas, E; Dranseika, V; Cekanauskaite, A; Hug, K; Mezinska, S; Peicius, E; Silis, V; Soosaar, A; Strosberg, M
**Non-equivalent stringency of ethical review in the Baltic States: a sign of a systematic problem in Europe?**
*Abstract:* We analyse the system of ethical review of human research in the Baltic States by introducing the principle of equivalent stringency of ethical review, that is, research projects imposing equal risks and inconveniences on research participants should be subjected to equally stringent review procedures. We examine
several examples of non-equivalence or asymmetry in the system of ethical review of human research: (1) the asymmetry between rather strict regulations of clinical drug trials and relatively weaker regulations of other types of clinical biomedical research and (2) gaps in ethical review in the area of non-biomedical human research where some sensitive research projects are not reviewed by research ethics committees at all. We conclude that non-equivalent stringency of ethical review is at least partly linked to the differences in scope and binding character of various international legal instruments that have been shaping the system of ethical review in the Baltic States. Therefore, the Baltic example could also serve as an object lesson to other European countries which might be experiencing similar problems.

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Document 330

Tsan, Min-Fu; Smith, Karen; Gao, Baochong

**Assessing the quality of human research protection programs: the experience at the Department of Veterans Affairs.**


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Document 331

Adams, Eike

**The joys and challenges of semi-structured interviewing.**

Community practitioner: the journal of the Community Practitioners' & Health Visitors' Association 2010 Jul; 83(7): 18-21

**Abstract:** Semi-structured interviewing is an important tool for gathering data in qualitative research. This paper explores some of the joys and challenges associated with research interviewing. It discusses some of the basic skills required to do interviewing well, some of the difficulties associated with interviewing on a practical and emotional level, and how to address them. Being a good interviewer in a research context means to be aware of the responsibility for the participants' wellbeing as well as one's own. Good listening skills and emotional control are among the most crucial skills to develop. This paper summarises some of the skills needed to remain or become a professional, empathetic and ethical interviewer in the context of community practice. If some basic guidelines are followed and combined with practice, the craft of interviewing can become an art.

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Document 332

Wright, Teresa

**The Stoke CNEP Saga - how it damaged all involved.**

Journal of the Royal Society of Medicine 2010 Jul; 103(7): 277-82

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Document 333

Willcox, Merlin L; Bodeker, Gerard

**The ethics of improving African traditional medical practice: a response.**


Georgetown users check [Georgetown Journal Finder](#) for access to full text
Consider fledgling researchers.

Singh, Surinder; Meakin, Richard; Iliffe, Steve

BMJ (Clinical research ed.) 2010 June 29; 340: c3448

Georgetown users check Georgetown Journal Finder for access to full text

[Ethics in clinical research].

Ogasawara, Katsuhiko

Nippon Hoshasen Gijutsu Gakkai zasshi 2010 Jun 20; 66(6): 668-72

Georgetown users check Georgetown Journal Finder for access to full text

Research ethics council faces dissolution.

Shuchman, Miriam

CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne 2010 Jun 15; 182(9): 890

Georgetown users check Georgetown Journal Finder for access to full text

[Difficulties and bureaucracy threat against clinical research] = Krångel och byråkrati hot mot klinisk forskning.

Yachnin, Jeffrey; Enblad, Gunilla

Läkartidningen 2010 Jun 9; 107(23): 1525-6

Georgetown users check Georgetown Journal Finder for access to full text

Ethical aspects of medical publications: clinical assays on biological agents.

Samara, Adil Muhib

Revista brasileira de reumatologia 2010 Jun; 50(3): 217-20

Georgetown users check Georgetown Journal Finder for access to full text

Survey of investigators' opinions on the acceptability of interactions with patients participating in clinical trials.

Dunlop, Boadie W; Vaughan, Christopher L


Abstract: There is growing concern about the ability of clinical trials to reliably detect differences between active drugs and placebo. To date, little attention has focused on how interactions between clinical trial investigators and patients may influence study outcomes. We sought to explore what types of interactions with patients investigators considered to be appropriate during placebo-controlled pharmacotherapy studies of major depressive disorder.
**Document 340**

Shah, Seema; Wendler, David  
**Interpretation of the subjects' condition requirement: a legal perspective.**  
**Abstract:** The U.S. Federal regulations allow institutional review boards (IRBs) to approve non-beneficial pediatric research when the risks are a minor increase over minimal, provided that the research is likely to develop generalizable knowledge about the subjects' disorder or condition. This "subjects' condition" requirement is quite controversial; commentators have argued for a variety of interpretations. Despite this considerable disagreement in the literature, there have not been any attempts to apply principles of legal interpretation to determine how the subjects' condition requirement should be understood.

**Document 341**

Sim, Julius  
**Addressing conflicts in research ethics: consent and risk of harm.**  
Physiotherapy research international : the journal for researchers and clinicians in physical therapy 2010 Jun; 15(2): 80-7  
**Abstract:** This paper explores some ethical conflicts that may arise in physiotherapy-related research, focusing particularly on the issues of informed consent and avoidance of harm. These central issues in research ethics are defined and related to fundamental moral principles such as respect for autonomy, respect for persons and non-maleficence, and their implications are examined through a set of hypothetical case studies, encompassing both quantitative and qualitative research approaches. It is argued that these ethical requirements may legitimately be traded off against each other, so that a prima facie need to gain informed consent or to avoid a risk of harm to participants may - within certain limits - be outweighed by other ethical requirements.

**Document 342**

DuBois, James M; Schilling, Debie A; Heitman, Elizabeth; Steneck, Nicholas H; Kon, Alexander A  
**Instruction in the responsible conduct of research: an inventory of programs and materials within CTSA s.**  
Clinical and translational science 2010 Jun; 3(3): 109-11  
**Abstract:** The National Institutes of Health (NIH) require instruction in the responsible conduct of research (RCR) as a component of any Clinical and Translational Science Award (CTSA). The Educational Materials Group of the NIH CTSA Consortium's Clinical Research Ethics Key Function Committee (CRE-KFC) conducted a survey of the 38 institutions that held CTSA funding as of January 2009 to determine how they satisfy RCR training requirements. An 8-item questionnaire was sent by email to directors of the Clinical Research Ethics, the Educational and Career Development, and the Regulatory Knowledge cores. We received 78 completed surveys from 38 CTSA s (100%). We found that there is no unified approach to RCR training across CTSA s, many programs lack a coherent plan for RCR instruction, and most CTSA s have not developed unique instructional materials tailored to the needs of clinical and translational scientists. We recommend collaboration among CTSA s and across CTSA key function committees to address these weaknesses. We also requested that institutions send electronic copies of original RCR training materials to share among CTSA s via the CTSpedia website. Twenty institutions submitted at least one educational product. The CTSpedia now contains more than 90 RCR resources.
Incidental findings found in "healthy" volunteers during imaging performed for research: current legal and ethical implications.

The British journal of radiology 2010 Jun; 83(990): 456-65

Abstract: Incidental findings found in "healthy" volunteers during research imaging are common and have important implications for study design and performance, particularly in the areas of informed consent, subjects' rights, clinical image analysis and disclosure. In this study, we aimed to determine current practice and regulations concerning information that should be given to research subjects when obtaining consent, reporting of research images, who should be informed about any incidental findings and the method of disclosure. We reviewed all UK, European and international humanitarian, legal and ethical agencies' guidance. We found that the guidance on what constitutes incidental pathology, how to recognise it and what to do about it is inconsistent between agencies, difficult to find and less complete in the UK than elsewhere. Where given, guidance states that volunteers should be informed during the consent process about how research images will be managed, whether a mechanism exists for identifying incidental findings, arrangements for their disclosure, the potential benefit or harm and therapeutic options. The effects of incidentally discovered pathology on the individual can be complex and far-reaching. Radiologist involvement in analysis of research images varies widely; many incidental findings might therefore go unrecognised. In conclusion, guidance on the management of research imaging is inconsistent, limited and does not address the interests of volunteers. Improved standards to guide management of research images and incidental findings are urgently required.

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Canis, M
[Reflexions on conflicts of interest]. = Réflexions à propos des conflits d'intérêt.

Georgetown users check Georgetown Journal Finder for access to full text

Gruat, Florence
["My wish is that each health establishment institutes an ethics monitor" (interview by Sylvie Warnet)] = "Mon souhait serait que chaque établissement de santé instaure une veille éthique".
Revue de l'infirmière 2010 Jun(161): 4-5

Georgetown users check Georgetown Journal Finder for access to full text

Bengtsson-Tops, A; Svensson, B
Mental health users' experiences of being interviewed by another user in a research project. A qualitative study.

Abstract: Although user involvement in research is an area of high priority there is a lack of knowledge about how users of the mental health system perceive participation in studies carried out by other users.

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Document 347
"(More) trials and tribulations": the effect of the EU directive on clinical trials in intensive care and emergency medicine, five years after its implementation.

Abstract: The European Clinical Trials Directive was issued in 2001 and aimed to simplify and harmonise the regulatory framework of clinical trials throughout Europe, thus stimulating European research. However, significant complexity and inconsistency remains due to disparate interpretation by EU member states. Critical care research has been particularly impacted due to variable and often restrictive consenting procedures for incapacitated subjects, with some countries requiring a court-appointed representative, while others recognise consent from family members and occasionally professional representatives. Furthermore, the absence of a waiver of consent threatened to put an end to emergency research in Europe and was met with varied responses. Approval procedures by ethics committees are equally inconsistent, particularly those relating to provision of a single opinion for multi-centre trials. Although evidence is somewhat mixed, this complexity as well as a general increase in administrative and financial burden following the Directive has been shown to cause a reduction in clinical trial activity in Europe, particularly academic trials. We aim to clarify some of these inconsistent procedures, particularly those relating to informed consent of incapacitated subjects, as well as discussing some general weaknesses and possible improvements of the Directive ahead of its planned revision in 2011.

Ohman, E Magnus; Roe, Matthew T; Armstrong, Paul W; Fox, Keith A; Prabhakaran, Dorairaj; White, Harvey D
Public sensationalism and clinical trials: how to address the challenges of science?

Sachs, Benjamin
Response to open peer commentaries on "The case for evidence-based rulemaking".

Sieber, Joan E
Stages of evidence-based ethical problem-solving in human research.

Guillemin, Marilys; Gillam, Lynn; Rosenthal, Doreen; Bolitho, Annie
Resources employed by health researchers to ensure ethical research practice.
Abstract: There is little empirical evidence about what resources health researchers use in order to make decisions about the ethical conduct of human research. Undertaking an empirical examination of how researchers understand research ethics and how they address ethical issues in research practice can lead to a richer understanding of how researchers approach research ethics. Our findings are based on interviews with 54 Australian health researchers. We conclude that, despite the considerable time devoted to ethics review, ethics committees and research guidelines were not seen as valuable resources for researchers undertaking research in the field. Although
researchers did not perceive ethics committees as a resource when faced with ethical issues in the field, they nevertheless perceived the process of ethics review as beneficial to them; this allowed them to clarify their research, make decisions about the ethical conduct of the research, as well as offering them a sense of protection when undertaking research. In the actual undertaking of research practice, it was their past professional experience and personal values that researchers considered most useful resources when encountering ethical problems.

Document 352
Floyd, Anna H L; Moyer, Anne

**Effects of participant preferences in unblinded randomized controlled trials.**
Journal of empirical research on human research ethics : JERHRE 2010 Jun ; 5(2): 81-93

**Abstract:** Little research has deliberately investigated the effects of participant preferences for treatment condition in unblinded randomized controlled trials. We designed a study with a non-patient sample comparing a randomized arm to a preference arm of the same trial to investigate: (1) whether having a choice to select one's preference affects feelings about participation, belief in treatment effectiveness, treatment contamination, intervention adherence and engagement, and trial attrition; and (2) the interaction of preferences and treatment assignment on these variables. Contamination and attrition were rare and excluded from analyses. There was no effect of choice. Participants mismatched to preference felt less positive about their experience, but this did not affect belief in treatment, adherence, or engagement. Stronger effects may occur for patient populations.

Document 353
Jang, Sekwon; Chae, Young Kwang; Haddad, Tufia; Majhail, Navneet S

**Conflict of interest in economic analyses of aromatase inhibitors in breast cancer: a systematic review.**
Breast cancer research and treatment 2010 Jun ; 121(2): 273-9

**Abstract:** To determine whether authors conducting economic analyses of aromatase inhibitors in breast cancer are less likely to reach unfavorable conclusions if the economic study is sponsored by the manufacturer of the drug. Articles reporting the economic analyses of aromatase inhibitors in breast cancer were selected from PubMed in May 2009. Information was collected on the types of analysis, the qualitative conclusion, the quantitative results, and the funding sources. Fisher's exact test was conducted to compare the frequency of unfavorable conclusions based on study sponsorship. Thirty-two eligible articles were identified. Twenty-six were funded by pharmaceutical companies, and 4 were funded by non-pharmaceutical companies. Two studies did not report a funding source. Twenty-one studies evaluated aromatase inhibitors in the adjuvant setting, while 11 studies examined their use in advanced breast cancer. Twenty-two studies evaluated one type aromatase inhibitor, while 10 compared multiple types of aromatase inhibitors. Only one of the 26 (4%) pharmaceutical company-sponsored studies reported unfavorable cost-effectiveness of an aromatase inhibitor, which was a competitor's product, whereas two of four (50%) non-pharmaceutical company-sponsored studies concluded aromatase inhibitors are not cost-effective in certain clinical scenarios (P < 0.05). Seven pharmaceutical company-sponsored studies conducted a comparison among several aromatase inhibitors; all 7 studies reported favorable conclusions for the sponsoring company's products. The majority of economic analyses of aromatase inhibitors in breast cancer are sponsored by pharmaceuticals. Economic evaluations of aromatase inhibitors in breast cancer that are funded by a pharmaceutical company are less likely to reach unfavorable conclusions about the sponsor's product.

Document 354
Griffiths, Rod

**The Stoke CNEP Saga - the Government enquiry in retrospect.**
Document 355

Sachs, Benjamin

**The case for evidence-based rulemaking in human subjects research.**


***Abstract***: Here I inquire into the status of the rules promulgated in the canonical pronouncements on human subjects research, such as the Declaration of Helsinki and the Belmont Report. The question is whether they are ethical rules or rules of policy. An ethical rule is supposed to accurately reflect the ethical fact (the fact that the action the rule prescribes is ethically obligatory), whereas rules of policy are implemented to achieve a goal. We should be skeptical, I argue, that the actions prescribed by the rules are ethically obligatory, and consequently we should focus our attention on how to craft the rules so as to promote the legitimate goals of human subjects research. Unfortunately, this cannot be done without evidence about the likely effects of various candidate policies-evidence we currently lack. Therefore, we should take the rules as mere starting points, subject to revision as the evidence comes in.

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Document 356

Kon, Alexander A.

**Ethical rules for human subjects research: a case where the "is" must inform the "ought".**


Georgetown users check [Georgetown Journal Finder](http://www.bioethics.net/journal/issues.php) for access to full text

Document 357

Resnik, David B.

**Public trust as a policy goal for research with human subjects.**


Georgetown users check [Georgetown Journal Finder](http://www.bioethics.net/journal/issues.php) for access to full text

Document 358

Evans, Emily L.

**In defense of valid design as a policy rule.**


Georgetown users check [Georgetown Journal Finder](http://www.bioethics.net/journal/issues.php) for access to full text

Document 359

Borgerson, Kirstin; Millum, Joseph

**A third way: ethics guidance as evidence-informed provisional rules.**
Document 360
Gerson, Jason; Goodman, Steven N.
An absence of evidence in "evidence-based rulemaking".
Georgetown users check Georgetown Journal Finder for access to full text

http://www.bioethics.net/journal/issues.php (link may be outdated)

Document 361
Hunter, David
Is there a case for a distinction between ethics and policy?
Georgetown users check Georgetown Journal Finder for access to full text

http://www.bioethics.net/journal/issues.php (link may be outdated)

Document 362
Bian, Zhao-Xiang; Wu, Tai-Xiang
Legislation for trial registration and data transparency.
Trials 2010 May 26; 11: 64
Abstract: Public confidence in clinical trials has been eroded by data suppression, misrepresentation and manipulation. Although various attempts have been made to achieve universal trial registration- e.g., Declaration of Helsinki, WHO clinical Trial Registry Platform (WHO ICTRP), the International Committee of Medical Journal Editors requirement- they have not succeeded, probably because they lack the enough power of enforcement. Legislation appears to be the most efficient and effective means to ensure that all researchers register their trials and disseminate their data accurately and in a timely manner. We propose that a global network be established. This could be accomplished in two steps. The first step is to legislate about trial registration and data transparency, such as USA's FDAAA Act 2007; and the second step to establish a global network to ensure uniform, international consistency in policy and enforcement of trial registration and data transparency.

Document 363
Jørgensen, Anders W; Gøtzsche, Peter C

[Insufficient access to research data not acceptable] = Manglende adgang til forskningsdata er uacceptabelt.
Ugeskrift for laeger 2010 May 24; 172(21): 1585

Georgetown users check Georgetown Journal Finder for access to full text

Document 364
Peppercorn, Jeffrey; Shapira, Iuliana; Collyar, Deborah; Deshields, Teresa; Lin, Nancy; Krop, Ian; Grunwald, Hans; Friedman, Paula; Partridge, Ann H; Schilsky, Richard L; Bertagnolli, Monica M

**Ethics of mandatory research biopsy for correlative end points within clinical trials in oncology.**


**Abstract:** Clinical investigators in oncology are increasingly interested in using molecular analysis of cancer tissue to understand the biologic bases of response or resistance to novel interventions and to develop prognostic and predictive biomarkers that will guide clinical decision making. Some scientific questions of this nature can only be addressed, or may best be addressed, through the conduct of a clinical trial in which research biopsies are obtained from all participants. However, trial designs with mandatory research biopsies have raised ethical concerns related to the risk of harm to participants, the adequacy of voluntary informed consent, and the potential for misunderstanding among research participants when access to an experimental intervention is linked to the requirement to undergo a research biopsy. In consideration of the ethical and scientific issues at stake in this debate, the Cancer and Leukemia Group B Ethics Committee proposes guidelines for clinical trials involving mandatory research biopsies. Any cancer clinical trial that requires research biopsies of participants must be well designed to address the scientific question, obtain the biopsy in a way that minimizes risk, and ensure that research participants are fully informed of the risks, rationale, and requirements of the study, as well as of treatment alternatives. Further guidelines and discussions of this issue are specified in this position paper. We feel that if these principles are respected, an informed adult with cancer can both understand and voluntarily consent to participation in a clinical trial involving mandatory research biopsy for scientific end points.
Document 369
London, Alex John; Kimmelman, Jonathan; Emborg, Marina Elena
Beyond access vs. protection in trials of innovative therapies.
Science 2010 May 14; 328(5980): 829-830
Georgetown users check Georgetown Journal Finder for access to full text
http://www.sciencemag.org/content/vol328/issue5980/ (link may be outdated)

Document 370
Martensen, Robert
Institutional review boards, professionalism, and the Internet.
Science translational medicine 2010 May 5; 2(30): 30cm15
Abstract: Even as the Internet generates pressures that erode professional authorities of all kinds, it also provides opportunities for researchers and their institutional review boards to bolster their status as trusted sources. To this end, we must work to improve clinical protocol design and approval procedures and maintain the integrity of the study participant recruitment process in clinical trials.
Georgetown users check Georgetown Journal Finder for access to full text

Document 371
Eggerth, Donald E.; Flynn, Michael A.
When the third world comes to the first: ethical considerations when working with Hispanic immigrants
Ethics and Behavior 2010 May-August; 20(3-4): 229-242
Georgetown users check Georgetown Journal Finder for access to full text

Document 372
Björck, Martin; Berg, Bengt; Hedin, Ulf; Wingren, Urban
[Ethics Review Boards discriminate against the most severely ill--Swedish researchers are prevented from participating in an international study]. = Etikprövningsnämnderna diskriminerar de svårast sjuka--svenska forskare stoppas från deltagande i internationell studie.
Läkartidningen 2010 May 26-Jun 1; 107(21): 1356-7
Georgetown users check Georgetown Journal Finder for access to full text

Document 373
Racine, Eric; Bell, Emily; Deslauriers, Constance
Canadian research ethics boards and multisite research: experiences from two minimal-risk studies.
IRB 2010 May-Jun; 32(3): 12-8
Georgetown users check Georgetown Journal Finder for access to full text

Document 374
Hansson, Mats G; Hakama, Matti
Ulysses contracts for the doctor and for the patient.
Contemporary clinical trials 2010 May; 31(3): 202-6

Abstract: Research subjects participating in randomised clinical trials have a right to drop out of a study without specifying any reason for this. However, leaving a trial may be contradictory to their own general interests in medical research since drop outs may lead to biased conclusions and loss of valuable medical information. We suggest in this paper that self-binding "Ulysses contracts" that are non-exploitative and based on autonomous decisions by research subjects as well as by investigating doctors should be implemented with stopping rules adjusted to the needs of different kinds of randomised clinical trials.

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Document 375
Gilgenkrantz, Simone
[Requiem for Henrietta] = Requiem pour Henrietta.
 Médecine sciences : M/S 2010 May ; 26(5): 529-33
Abstract: Fifty years after Henrietta Lacks died of aggressive glandular cervical cancer, the first cell line - HeLa cell line - is the workhorse of laboratories everywhere. It helped to produce drugs for numerous diseases, including poliomyelitis, Parkinson's, leukemias. But they are so outrageously robust that they contaminated hundred of other cell lines, as far away as Russia. For decades, biologists worked with contaminated cell lines and today, the problem is not yet solved. But the story of HeLa cells is also a moving reflection of racial and ethical issues in medicine in the late half-twentieth century in the USA.

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Document 376
Zee, Ying-Kiat; Chan, Sarah W; Harris, John; Jayson, Gordon C.
The ethical and scientific case for phase 2C clinical trials.
Lancet Oncology 2010 May; 11(5): 410-411

Georgetown users check Georgetown Journal Finder for access to full text

Document 377
Graffy, Jonathan; Bower, Peter; Ward, Elaine; Wallace, Paul; Delaney, Brendan; Kinmonth, Ann-Louise; Collier, David; Miller, Julia
Trials within trials? Researcher, funder and ethical perspectives on the practicality and acceptability of nesting trials of recruitment methods in existing primary care trials.
BMC medical research methodology 2010 April 30; 10: 38
Abstract: Trials frequently encounter difficulties in recruitment, but evidence on effective recruitment methods in primary care is sparse. A robust test of recruitment methods involves comparing alternative methods using a randomized trial, 'nested' in an ongoing 'host' trial. There are potential scientific, logistical and ethical obstacles to such studies.

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Document 378
Ledford, Heidi
Clinical drug tests adapted for speed.
Nature 2010 Apr 29; 464(7293): 1258

Georgetown users check Georgetown Journal Finder for access to full text
Document 379
Roehr, Bob
Institute urges overhaul of US cancer trials network.
BMJ: British Medical Journal 2010 April 24; 340(7752): 888
Georgetown users check Georgetown Journal Finder for access to full text

Document 380
Popelut, Antoine; Valet, Fabien; Fromentin, Olivier; Thomas, Aurélie; Bouchard, Philippe
Relationship between sponsorship and failure rate of dental implants: a systematic approach.
PloS one 2010 April 21; 5(4): e10274
Abstract: The number of dental implant treatments increases annually. Dental implants are manufactured by competing companies. Systematic reviews and meta-analysis have shown a clear association between pharmaceutical industry funding of clinical trials and pro-industry results. So far, the impact of industry sponsorship on the outcomes and conclusions of dental implant clinical trials has never been explored. The aim of the present study was to examine financial sponsorship of dental implant trials, and to evaluate whether research funding sources may affect the annual failure rate.
Georgetown users check Georgetown Journal Finder for access to full text

Document 381
Aldea, Ana; Tosca, Juan Francisco; Vera, Ernesto; Tristán, Carmen
Medicina clínica 2010 Apr 10; 134(10): 462-6
Georgetown users check Georgetown Journal Finder for access to full text

Document 382
Bleecker, Eugene R.; Nelson, Harold S.; Kraft, Monica; Corren, Jonathan; Meyers, Deborah A.; Yancey, Steven W.; Anderson, Wayne H.; Emmett, Amanda H.; Ortega, Hector A.
Meeting the obligation to balance bioethics and clinical trial design in asthma.
American Journal of Respiratory and Critical Care Medicine 2010 April 1; 181(7): 648-650
Georgetown users check Georgetown Journal Finder for access to full text

Document 383
Lund, Lars H; Ekman, Inger
Individual rights and autonomy in clinical research.
Georgetown users check Georgetown Journal Finder for access to full text

Document 384
Chapman, Vicki
How the human tissue authority's codes of practice are relevant to doctors.
Document 385

Klemperer, David

**Drug research: marketing before evidence, sales before safety.**
Deutsches Ärzteblatt international 2010 Apr; 107(16): 277-8

Abstract: In recent years, a number of studies have shown that clinical drug trials financed by pharmaceutical companies yield favorable results for company products more often than independent trials do. Moreover, pharmaceutical companies have been found to influence drug trials in various ways. This paper provides an overview of the findings of current, systematic studies on this topic.

Document 386

Schott, Gisela; Pachl, Henry; Limbach, Ulrich; Gundert-Remy, Ursula; Ludwig, Wolf-Dieter; Lieb, Klaus

**The financing of drug trials by pharmaceutical companies and its consequences. Part 1: a qualitative, systematic review of the literature on possible influences on the findings, protocols, and quality of drug trials.**
Deutsches Ärzteblatt international 2010 Apr; 107(16): 279-85

Abstract: In recent years, a number of studies have shown that clinical drug trials financed by pharmaceutical companies yield favorable results for company products more often than independent trials do. Moreover, pharmaceutical companies have been found to influence drug trials in various ways. This paper provides an overview of the findings of current, systematic studies on this topic.

Document 387

Schott, Gisela; Pachl, Henry; Limbach, Ulrich; Gundert-Remy, Ursula; Lieb, Klaus; Ludwig, Wolf-Dieter

**The financing of drug trials by pharmaceutical companies and its consequences: part 2: a qualitative, systematic review of the literature on possible influences on authorship, access to trial data, and trial registration and publication.**
Deutsches Ärzteblatt international 2010 Apr; 107(17): 295-301

Abstract: In recent years, a number of studies have shown that clinical drug trials financed by pharmaceutical companies yield favorable results for company products more often than independent trials do. Moreover, pharmaceutical companies have been found to influence drug trials in various ways. This overview of current, systematic studies on this topic is intended to identify and characterize the particular aspects of the performance of a drug trial that can be affected by financial support from a pharmaceutical company.

Document 388

Chanaud, Cheryl M

**Considerations for hospital approval of human participant research.**

Abstract: Hospitals often accept as sufficient the federal requirement that human participant research studies have Institutional Review Board (IRB) review and approval, but IRBs usually do not consider many practical matters that arise in the implementation and operation of an interventional clinical trial in the complex environment of the modern acute care hospital.
A pilot study evaluating an intervention designed to raise awareness of clinical trials among potential participants in the developing world.

Journal of medical ethics 2010 Apr; 36(4): 238-42

**Abstract:** BACKGROUND: This pilot study evaluated the speaking book 'What it means to be part of a clinical trial'. The book aims at empowering populations with information on their rights and responsibilities when enrolled in clinical research. Wide publication of the book—at significant cost—is anticipated. It is important that the book is evaluated within the communities for whom it is intended, and the necessary changes (if any) are made, before translation and large-scale publication takes place. OBJECTIVE: The objective of the study was to measure the efficacy and ease of use of the book. METHODS: Participants were recruited from a catering company. Participants were questioned on their knowledge of clinical trials and were then given the book. Instructions for use of the book were given to one group ('experimental' group). The other group ('control' group) was not given any instructions. A week later, the investigators returned, repeated the knowledge questions and asked 'ease of use' questions. RESULTS: A two-way repeated measure of covariants showed a statistically significant positive increase in knowledge of clinical trials among the intervention group (p=0.02). Results for the control group displayed trends that were not statistically significant. Percentage analysis of 'ease of use' questions proved that the book is easy to use, although some changes would be beneficial. CONCLUSION: This study revealed that the speaking book is easy to use. It significantly increased knowledge of clinical trials among the study sample if instructions on use of the book were provided.

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Ethics committees for biomedical research in some African emerging countries: which establishment for which independence? A comparison with the USA and Canada.


**Abstract:** CONTEXT: The conduct of medical research led by Northern countries in developing countries raises ethical questions. The assessment of research protocols has to be twofold, with a first reading in the country of origin and a second one in the country where the research takes place. This reading should benefit from an independent local ethical review of protocols. Consequently, ethics committees for medical research are evolving in Africa. OBJECTIVE: To investigate the process of establishing ethics committees and their independence. METHOD: Descriptive study of 25 African countries and two North American countries. Data were recorded by questionnaire and interviews. Two visits of ethics committee meetings were conducted on the ground: over a period of 3 months in Kigali (Rwanda) and 2 months in Washington DC (USA). RESULTS: 22 countries participated in this study, 20 from Africa and two from North America. The response rate was 80%. 75% of local African committees developed into national ethics committees. During the last 5 years, these national committees have grown on a structural level. The circumstances of creation and the general context of underdevelopment remain the major challenges in Africa. Their independence could not be ensured without continuous training and efficient funding mechanisms. Institutional ethics committees are well established in USA and in Canada, whereas ethics committees in North America are weakened by the institutional affiliation of their members. CONCLUSION: The process of establishing ethics committees could affect their functioning and compromise their independence in some African countries and in North America.

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Citius, altius, fortius—faster, stronger, higher.

Foot & ankle specialist 2010 Apr; 3(2): 63

Georgetown users check [Georgetown Journal Finder](http://www.georgetownjournalfinder.com) for access to full text.
What is an IRB, why do we need it, and what is a private IRB?

**Abstract:** Many foot and ankle specialists have interest in publishing research or technique articles to share their expertise with colleagues. It is now commonplace for medical journals to require all studies that involve patients or patient data to have institutional review board (IRB) approval. Working with an IRB can be a source of frustration or delay, but this does not necessarily need to be the case. The purpose of this review article is to clearly define what an IRB is and does, as well as why the IRB was created and continues to be necessary, and to review what IRB options exist, including the "private" IRB. This background knowledge can help the foot and ankle researcher have a better understanding of the process and perhaps improve efficiency.

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Screening and evaluation of study subjects in patient-oriented research.

**Abstract:** This article describes practical aspects of screening and evaluation of potential study subjects for patient-oriented research. Screening and evaluation comprise the crucial initial steps in the process of any patient-oriented research study. Appropriate infrastructure, operations, and documentation of the procedures needed to efficiently and effectively conduct screening and evaluation are described. A stepwise approach for screening and evaluating potential study subjects for determination of study eligibility is described. The design and conduct of screening and evaluation procedures should be protocol driven and compliant with regulatory requirements.

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Case-control studies: the importance of design and conduct.

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Midwifery basics: understanding research (6). Research ethics.

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A probiotics trial on trial: the problem of timely detection of adverse advents in therapeutic trials.

Georgetown users check [Georgetown Journal Finder](#) for access to full text
**Document 397**
Knottnerus, J André; Tugwell, Peter
*Expectation and (un)predictability.*
Journal of clinical epidemiology 2010 Apr ; 63(4): 345-6
Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 398**
Maloney, Dennis M.
*In Congress: Increasing access to certain clinical trials for research subjects receiving financial assistance*
Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 399**
Maloney, Dennis M.
*Options on IRB approval of research with conditions*
Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 400**
Maloney, Dennis M.
*Changes for Institutional Review Boards (IRBs)*
Human Research Report 2010 April; 25(4): 4
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**Document 401**
Maloney, Dennis M.
*Continuing reviews of research by Institutional Review Boards (IRBs)*
Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 402**
Simpson, Bob; Dissanayake, Vajira H.W.; Douglas-Jones, Rachel; Sariola, Salla
*Ethical review, remit and responsibility in biomedical research in South Asia.*
Indian Journal of Medical Ethics 2010 April-June; 7(2): 113-114
Georgetown users check [Georgetown Journal Finder](#) for access to full text

[http://www.issuesinmedicalethics.org/](http://www.issuesinmedicalethics.org/) (link may be outdated)
**Document 403**

Bassler, Dirk; Briel, Matthias; Montori, Victor M; Lane, Melanie; Glasziou, Paul; Zhou, Qi; Heels-Ansdell, Diane; Walter, Stephen D.; Guyatt, Gordon H.; Flynn, David N.; Elamin, Mohamed B.; Murad, Mohammad Hassan; Abu Elnour, Nisrin O.; Lampropoulos, Julianna F.; Sood, Amit; Mullan, Rebecca J.; Erwin, Patricia J.; Bankhead, Clare R.; Perera, Rafael; Ruiz Culebro, Carolina; You, John J.; Muller, Sohail M.; Kaur, Jagdeep; Nerenberg, Kara A.; Schünemann, Holger; Cook, Deborah J.; Lutz, Kristina; Ribic, Christine M.; Vale, Noah; Malaga, German; Akl, Elie A.; Ferreira-Gonzalez, Ignacio; Alonso-Coello, Pablo; Urrutia, Gerard; Kunz, Regina; Bucher, Heiner C.; Nordmann, Alain J.; Raatz, Heike; da Silva, Suzana Alves; Tuche, Fabio; Strahm, Brigitte; Djulbegovic, Benjamin; Adhikari, Neill K.J.; Mills, Edward J.; Gwadry-Sridhar, Femida; Kirpalani, Haresh; Soares, Heloisa P.; Karanicolas, Paul J.; Burns, Karen E.A.; Vandvik, Per Olav; Coto-Yglesias, Fernando; Chrispim, Pedro Paulo M.; Ramsay, Tim

**Stopping randomized trials early for benefit and estimation of treatment effects: systematic review and meta-regression analysis.**

JAMA: The Journal of the American Medical Association 2010 March 24; 303(12): 1180-1187

**Abstract:** CONTEXT: Theory and simulation suggest that randomized controlled trials (RCTs) stopped early for benefit (truncated RCTs) systematically overestimate treatment effects for the outcome that precipitated early stopping. OBJECTIVE: To compare the treatment effect from truncated RCTs with that from meta-analyses of RCTs addressing the same question but not stopped early (nontruncated RCTs) and to explore factors associated with overestimates of effect. DATA SOURCES: Search of MEDLINE, EMBASE, Current Contents, and full-text journal content databases to identify truncated RCTs up to January 2007; search of MEDLINE, Cochrane Database of Systematic Reviews, and Database of Abstracts of Reviews of Effects to identify truncated RCTs up to January 2008; search of MEDLINE, Cochrane Database of Systematic Reviews, and Database of Abstracts of Reviews of Effects to identify systematic reviews from which individual RCTs were extracted up to January 2008. STUDY SELECTION: Selected studies were RCTs reported as having stopped early for benefit and matching nontruncated RCTs from systematic reviews. Independent reviewers with medical content expertise, working blinded to trial results, judged the eligibility of the nontruncated RCTs based on their similarity to the truncated RCTs. DATA EXTRACTION: Reviewers with methodological expertise conducted data extraction independently. RESULTS: The analysis included 91 truncated RCTs asking 63 different questions and 424 matching nontruncated RCTs. The pooled ratio of relative risks in truncated RCTs vs matching nontruncated RCTs was 0.71 (95% confidence interval, 0.65-0.77). This difference was independent of the presence of a statistical stopping rule and the methodological quality of the studies as assessed by allocation concealment and blinding. Large differences in treatment effect size between truncated and nontruncated RCTs (ratio of relative risks <0.75) occurred with truncated RCTs having fewer than 500 events. In 39 of the 63 questions (62%), the pooled effects of the nontruncated RCTs failed to demonstrate significant benefit. CONCLUSIONS: Truncated RCTs were associated with greater effect sizes than RCTs not stopped early. This difference was independent of the presence of statistical stopping rules and was greatest in smaller studies.

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http://jama.ama-assn.org (link may be outdated)

**Document 404**

Torpy, Janet M.; Lynam, Cassio; Glass, Richard M.

**JAMA patient page. Randomized controlled trials.**

JAMA: The Journal of the American Medical Association 2010 March 24; 303(12): 1216

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http://jama.ama-assn.org (link may be outdated)

**Document 405**

Forster, Martin D; Saijo, Nagahiro; Seymour, Lesley; Calvert, Hilary

**Performing phase I clinical trials of anticancer agents: perspectives from within the European union and Japan.**

Clinical cancer research : an official journal of the American Association for Cancer Research 2010 Mar 15; 16(6): 1737-44

**Abstract:** Drug discovery and early clinical development is an international endeavor, conducted in partnership...
between commercial entities such as biotechnology and pharmaceutical companies and academic investigators. Although once considered quite disparate, early clinical trials requirements and conduct are largely harmonized between the European Union, Japan, and the United States, increasing the opportunities for productive commercial-academic collaborations.

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Document 406

Studdert, David M.; Vu, Tamara M.; Fox, Sarah S.; Anderson, Ian P.; Keeffe, Jill E.; Taylor, Hugh R.

**Ethics review of multisite studies: the difficult case of community-based indigenous health research.**

Medical Journal of Australia 2010 March 1; 192(5): 275-280

**Abstract:** Researchers have longstanding concerns about the logistical and administrative burdens posed by ethics review of multisite studies involving human participants. Centralised ethics review, in which approval by one committee has authority across multiple sites, is widely touted as a strategy for streamlining the process. The Harmonisation of Multi-centre Ethical Review (HoMER) project is currently developing such a system for Australia. It is unclear how centralised review will work for multisite Indigenous health research, where the views of local stakeholders are important and community consultation is mandatory. Our recent experience in conducting the National Indigenous Eye Health Survey (NIEHS) shows how elaborate the current ethics approval and community consultation processes can be, and points to several lessons and ideas to guide pending reforms.

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Document 407

Jekunen, A P; Pauwels, E K J; Kairemo, K J A

**Microdosing in early lead discovery.**

Bioanalysis 2010 Mar; 2(3): 421-8

**Abstract:** Microdosing provides a tool to enhance drug development by initiating human studies prior to Phase I studies. The purpose is to assist in the go versus no-go decision-making process and to eliminate early ineffective compounds from the drug pipeline. Selection of multiple potential leads can be performed at the clinical stage instead of in preclinical studies. The microdosing approach can be easily used for a molecularly targeted potential drug compound with a known mechanism of action. It provides useful data regarding accessibility and biodistribution that can be used in many estimations benefitting the development of the molecule. In addition, steady state and genetic investigations are becoming possible. Microdosing has a sparing effect on timelines and costs, however, the real importance is not yet known because, although it is known to be widely performed, only a few original reports have been published.

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Document 408

Bloomgarden, Zachary

**Troubling ethical questions from gestational diabetes trial.**


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Document 409

Salako, S.

**Research ethics committees and community values: Devlin, Dworkin, Hart and beyond**

Document 410

Kowalski, Charles J

Pragmatic problems with clinical equipoise.

Perspectives in biology and medicine 2010 Spring; 53(2): 161-73

Abstract: It is widely accepted that if one is to follow the ethical tenets of clinical equipoise, phase III controlled clinical trials must be designed pragmatically, to measure effectiveness rather than efficacy. This choice of a pragmatic rather than an explanatory approach to phase III clinical trial design has a number of consequences, some of which may be considered problematic. These include changes in what the trial is expected to accomplish, the way treatments are defined, the selection of subjects, the ways in which treatments are compared, and the assessment of the results. One also may end up challenging the real-world expectation that scientific results will be replicated before they are considered valid. This article discusses the connection between clinical equipoise and pragmatic trials, contrasts explanatory with pragmatic trials, points to the differences in the ways in which trial data are analyzed and interpreted, and discusses the power of replication, one of the defining hallmarks of the scientific method. Viewing clinical equipoise through a consequentialist lens reveals a number of problems, many of which are attributable to equipoise's insistence on a pragmatic approach to trial architecture.

Document 411

Stark, A R; Tyson, J E; Hibberd, P L

Variation among institutional review boards in evaluating the design of a multicenter randomized trial.


Abstract: OBJECTIVE: The objective of the study was to examine the variation among institutional review boards (IRBs) in evaluation of the study design of a multicenter trial. STUDY DESIGN: We assessed the first written response of local IRBs to each site investigator for a multicenter trial of vitamin A supplementation in extremely low birth weight (ELBW) infants performed by the National Institute of Child Health and Human Development Neonatal Research Network. Each author of this paper independently reviewed and categorized IRB concerns as major, minor or none, according to the predefined criteria. RESULT: Initially, 9 of 18 IRBs withheld approval because of at least one major concern. These concerns reflected difficulties in evaluating specific scientific issues for the design of the trial, including its justification, enrollment criteria, control and experimental therapies, co-interventions, toxicity assessment, outcome monitoring and informed consent. CONCLUSION: The difficulty in assessing appropriate trial design for the specific hypothesis under investigation resulted in considerable variability in the evaluation by local IRBs.

Document 412

Llanusa-Cestero, Renee


Accountability in research 2010 Mar ; 17(2): 96-113

Abstract: Declassification of documents has given rise to the allegation that the Central Intelligence Agency may have conducted unethical research targeting detainee subjects. That allegation is examined using document analysis and the development of research goals and roles as defined in the Common Rule. This article sets aside issues as to whether enhanced interrogation techniques described in the declassified documents rise to legal definitions of torture. Instead, it presents a post hoc ethics review raising questions addressed by Institutional Review Boards recommending the filing of a for-cause noncompliance complaint with the Office for Human Research Protection against the Central Intelligence Agency.
Anderson, James A; Kimmelman, Jonathan

**Extending clinical equipoise to phase 1 trials involving patients: unresolved problems.**
Kennedy Institute of Ethics journal 2010 Mar; 20(1): 75-98

**Abstract:** Notwithstanding requirements for scientific/social value and risk/benefit proportionality in major research ethics policies, there are no widely accepted standards for these judgments in Phase 1 trials. This paper examines whether the principle of clinical equipoise can be used as a standard for assessing the ratio of risk to direct-benefit presented by drugs administered in one category of Phase 1 study--first-in-human trials involving patients. On the basis of the supporting evidence for, and architecture of, Phase 1 studies, the articles offers two provisional conclusions: (1) the risks of drug administration in such trials cannot generally be justified on therapeutic grounds but by appeal to the social value of the research; and (2) a framework for adjudicating the ratio of risk/social-value must be developed.

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Samson, Kurt

**NerveCenter: Office of Inspector General warns NIH on lax COI oversight as many academic medical centers look inward.**
Annals of neurology 2010 Mar; 67(3): A7-A10

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Maloney, Dennis M.

**Using expedited review in continuing IRB review**
Human Research Report 2010 March; 25(3): 4

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Maloney, Dennis M.

**When changes occur after conditional IRB approval**

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Sieber, Joan E.

**Introduction: points to consider in community-engaged research.**

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Howard, Daniel L.; Boyd, Carlton L.; Nelson, Daniel K.; Godley, Paul
Getting from A to IRB: developing an institutional review board at a historically black university.

Abstract: Shaw University, the oldest historically black college or university in the southern USA, recently partnered with the University of North Carolina at Chapel Hill, a major research institution in North Carolina, to further develop Shaw's research infrastructure. One aim of the partnership involved establishing a human research ethics committee and an accompanying administrative structure and research ethics education program. This paper describes the process of developing an entire human research protection program de novo through collaboration with and mentoring by the members of the human research protection program at a nearby major research institution. This paper provides a detailed description of the aims, procedures, accomplishments, and challenges involved in such a project, which may serve as a useful model for other primarily teaching institutions wishing to develop research infrastructure and ethical capacity.

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* Article Document 419
Godlee, Fiona; Chalmers, Iain
Information about ongoing clinical trials for patients
BMJ: British Medical Journal 2010 February 27; 340(7744): 456-457

Georgetown users check Georgetown Journal Finder for access to full text

http://www.bmj.com (link may be outdated)

* Article Document 420
Miller, James Dabney
Registering clinical trial results: the next step.

Georgetown users check Georgetown Journal Finder for access to full text

http://jama.ama-assn.org (link may be outdated)

* Article Document 421
Katz, Michael S.; Smith, Mary L.
Central institutional review board-facilitated review metrics omit critical components.
Journal of Clinical Oncology 2010 February 20; 28(6): e105; author reply e106

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* File Document 422
Gerstein, Marc
Blood simple: Columbia University's ten-year cover-up of patient harm, conflicts of interest and administrative misconduct

* Article Document 423
More, Joseph
Risk money for trial volunteers
Document 424

DiGuiseppi, Carolyn; Coupland, Carol
The design and use of cluster randomised controlled trials in evaluating injury prevention interventions: part 1. Rationale, design and informed consent.

Document 425

Silva-Lima, Beatriz; Carlson, David; Jones, David R; Laurie, David; Stahl, Elke; Maria, Vasco; Janssens, Walter; Robinson, William T
The European and American use of exploratory approaches for first-in-human studies.
Clinical and translational science 2010 Feb; 3(1): 38-41
Abstract: Exploratory approaches for first-in-human clinical studies have evolved over the last few years and have stimulated the issuance of national regulatory guidances in some European countries as well as the United States. With the increasing implementation of these approaches and the recent preparation of a multiregional regulatory guidance (ICH M3 rev2), an exchange of experiences on the opportunities and challenges of exploratory clinical trials was desirable; thus, a workshop focusing on the use of this clinical approach was planned and conducted in Lisbon, Portugal, March 18-19, 2009 sponsored by the Portuguese Health Authority (INFARMED) and DIA. The structure of the workshop focused in three main areas. Regulatory representatives from Portugal, Belgium, Germany, the United Kingdom and the United States formally reviewed their experiences. This was followed by a discussion on issues from an ethics review perspective as well as an insight to the opportunities in the area of biologics. The industry perspective was presented by representatives from Merck, Pfizer, J&J, Novartis, Speedel, AstraZeneca, GSK, and Roche. Finally, through break out sessions, issues were identified to be addressed moving forward. It is the purpose of this paper to report on the outcome of this workshop.

Document 426

Lechopier, N
[Research and non-research. The values in the evaluation of epidemiological protocols] = Recherche et non-recherche. Les valeurs à l’oeuvre dans l’évaluation des protocoles épidaïmologiques.
Revue d'épidémiologie et de santé publique 2010 Feb; 58(1): 41-8
Abstract: BACKGROUND: Evaluation and ethical review of epidemiological research projects raises the problem of the limits between research and non-research. This ambiguous boundary reflects the status of this discipline at the crossroads between research and practical action. The question then is: in the field of health research, what gives data collection and analysis its quality of scientific activity? METHODS: A conceptual and empirical study has been conducted about the practices of epidemiological research evaluation, centred on the case of the French Consultative Committee for the data processing in health research (CCTIRS), which is a consultative board that permits the National commission for the personal data protection (CNIL) to take decision about health research protocols that process personal data. The study was realized from 2003 to 2006. RESULTS: It is shown that the evaluation of such research protocols processing personal data articulates intimately two kinds of criteria: methodology and relevance. By studying and characterizing the different kinds of protocols that are judged not to be "scientific research" (poor science, pseudo-science and non-science), it becomes possible to understand the motives that lead to distinguish between what is and what is not research in epidemiology. A special attention is given to two kinds of problematic cases: firstly, the case of conflict of interests into the protocols themselves (i.e.
seeding trials or surveys); secondly, the problem of epidemiological registers and other databases which are not hypothesis-oriented. This last case leads to relate the conceptual frame of the committee with historical circumstances (the way which this discipline was introduced in France) and also mere epistemological considerations (the question of induction and generalizability). CONCLUSION: The activity of this committee illustrates a differentiated conception of what is research in epidemiology, influenced by explanatory analytical research paradigms. Finally, the field of epidemiological research appears to be structured by some values that appear through the elaboration and the application of the ethical and regulatory texts.

Document 427

Maloney, Dennis M.

IRB approval with conditions must include verification step

Human Research Report 2010 February; 25(2): 4

Document 428

Ethical neuroscience.

Nature Neuroscience 2010 February; 13(2): 141

Document 429

Wagner, Todd H.; Murray, Christine; Goldberg, Jacquelyn; Adler, Jeanne M.; Abrams, Jeffrey

Costs and benefits of the national cancer institute central institutional review board.

Journal of Clinical Oncology 2010 February 1; 28(4): 662-666

Abstract: PURPOSE: In 2001, the National Cancer Institute (NCI) formed the Central Institutional Review Board (CIRB) to conduct a single human subjects review for its multisite phase III oncology trials. The goal of this study was to assess whether NCI's CIRB was associated with lower effort, time, and cost in processing adult phase III oncology trials. METHODS: We conducted an observational study and compared sites affiliated with the NCI CIRB to unaffiliated sites that used their local IRB for review. Oncology research staff and IRB staff were surveyed to understand effort and timing. Response rates were 60% and 42%, respectively. Analysis of these survey data yielded information on effort, timing, and costs. We combined these data with CIRB operational data to determine the net savings of the CIRB using a societal perspective. RESULTS: CIRB affiliation was associated with faster reviews (33.9 calendar days faster on average), and 6.1 fewer hours of research staff effort. CIRB affiliation was associated with a savings of $717 per initial review. The estimated cost of running the CIRB was $161,000 per month. The CIRB yielded a net cost of approximately $55,000 per month from a societal perspective. Whether the CIRB results in higher or lower quality reviews was not assessed because there is no standard definition of review quality. CONCLUSION: The CIRB was associated with decreases in investigator and IRB staff effort and faster protocol reviews, although savings would be higher if institutions used the CIRB as intended.

Document 430

Fregni, Felipe; Imamura, Marta; Chien, Hsin Fen; Lew, Henry L.; Boggio, Paulo; Kaptchuk, Ted J.; Riberto, Marcelo; Hsing, Wu Tu; Battistella, Linamara Rizzo; Furlan, Andrea

Challenges and recommendations for placebo controls in randomized trials in physical and rehabilitation medicine: a report of the international placebo symposium working group.

American Journal of Physical Medicine & Rehabilitation 2010 February; 89(2): 160-172

Abstract: Compared with other specialties, the field of physical and rehabilitation medicine has not received the
deserved recognition from clinicians and researchers in the scientific community. One of the reasons is the lack of sound evidence to support the traditional physical and rehabilitation medicine treatments. The best way to change this disadvantage is through a well conducted clinical research, such as standard placebo- or sham-controlled randomized clinical trials. Therefore, having placebo groups in clinical trials is essential to improve the level of evidence-based practice in physical and rehabilitation medicine that ultimately translates to better clinical care. To address the challenges for the use of placebo in physical and rehabilitation medicine and randomized clinical trials and to create useful recommendations, we convened a working group during the inaugural International Symposium in Placebo (February 2009, in Sao Paulo, Brazil) in which the following topics were discussed: (1) current status of randomized clinical trials in physical and rehabilitation medicine, (2) challenges for the use of placebo in physical and rehabilitation medicine, (3) bioethics, (4) use of placebo in acupuncture trials and for the treatment of low-back pain, (5) mechanisms of placebo, and (6) insights from other specialties. The current article represents the consensus report from the working group.

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Document 435
Cheng, Margaret Harris
Cambodia criticised over unethical drug trial.
Lancet 2010 January 16; 375(9710): 187-188
Georgetown users check Georgetown Journal Finder for access to full text

Document 436
Jones, Eleri; Kiddell, Kathleen; Saunders, John
Should healthy volunteers in clinical trials be paid according to risk? [debate]
BMJ: British Medical Journal 2010 January 16; 340(7738): 130-131
Georgetown users check Georgetown Journal Finder for access to full text

Document 437

Document 438
Maleson, Stephen
Biomedical research involving human subjects.
U.S. Army Medical Department journal 2010 Jan-Mar: 33-43
Georgetown users check Georgetown Journal Finder for access to full text

Document 439
Moja, Lorenzo
Clinical trials: trial registration cannot alone transform scientific conduct.
Georgetown users check Georgetown Journal Finder for access to full text

Document 440
Associazione Medica Mondiale
[The Helsinki Declaration]. = La Dichiarazione di Helsinki.
Assistenza infermieristica e ricerca : AIR 2010 Jan-Mar; 29(1): 41-4
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Clinical trials: trial registration cannot alone transform scientific conduct.

Research ethics committees: challenges in the submission and evaluation of scientific projects
Revista brasileira de enfermagem 2010 Jan-Feb; 63(1): 145-7
Abstract: This article aimed at reflecting and discussing about some difficulties in the submission and evaluation of scientific projects to the Research Ethics Committee, from an experience in post-graduation. Among these difficulties, there was a need for submission of a single project to several CEP as demand for part of the health facilities involved, which showed discrepancies with regard to the matter. Another issue, involving the reports, which are still based on biomedical models, which hinder the evaluation of research projects in nursing and other sciences. However, one of the great challenges of CEP is to ensure that researches with human beings are carried out within an ethics framework, without be an obstacle to their development.

The ethics review process in the Seventh Framework Programme of the European Commission
Revista de calidad asistencial : organo de la Sociedad Española de Calidad Asistencial 2010 Jan-Feb; 25(1): 48-51
Abstract: The Seventh Framework Programme of the European Commission (EC) is one of the most important instruments for public funding of research and technological development. Besides the scientific assessment of each proposal, the ethical issues raised in them are evaluated in accordance with the current European legislation and the ethical principles laid down in the international declarations supported by Member States. Such ethical review is organized by the "Governance and Ethics" Unit (Directorate-General for Research), although it is done by professionals from different sectors and backgrounds who register themselves voluntary in a database.

Are claims of advertisements in medical journals supported by RCTs?
The Netherlands journal of medicine 2010 Jan ; 68(1): 46-9
Abstract: BACKGROUND: Claims made in advertisements in medical journals might not always be supported by
high-quality evidence, and referenced studies may have been sponsored by the pharmaceutical industry itself. We studied to what extent randomised controlled trials (RCTs) support the claims in advertisements in leading medical journals. METHODS: Consecutive unique advertisements were selected from nine different medical journals, and evaluated by 250 medical students using a standardised score form. The quality of RCTs that were referenced in these advertisements was assessed with an instrument based on the Chalmers’ score. RESULTS: 158 RCTs from 94 advertisements were used in the study. In total 55% of the RCTs had a high-quality score, 44% intermediate, and <1% had a low-quality score. Almost 40% of the RCTs had a high-quality score and at the same time supported the claim for which they were cited, while only 17% were also not sponsored by a pharmaceutical company. CONCLUSION: RCTs used to support claims in medical advertisements are often not a high-quality and independent source of evidence. This distracts from the credibility of claims in advertisements, even in the high-ranked journals.

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Document 446
Maloney, Dennis M.
Financial conflicts of interest in research

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Document 447
Maloney, Dennis M.
IRB approval with conditions and when it cannot approve

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Document 448
Gilbert, Gregg H.; Qvist, Vibeke; Moore, Sheila D.; Rindal, D. Brad; Fellows, Jeffrey L.; Gordan, Valeria V.; Williams, O. Dale
Institutional review board and regulatory solutions in the dental PBRN.
Abstract: OBJECTIVES: Effectively addressing regulatory and human participant protection issues with Institutional Review Boards (IRBs, or ethics committees) and grants administration entities is an important component of conducting research in large collaborative networks. A dental practice-based research network called "DPBRN" (http://www.DPBRN.org) comprises dentists in two health maintenance organizations, several universities, seven US states, and three Scandinavian countries. Our objectives are to describe: a) the various human participants and regulatory requirements and solutions for each of DPBRN's five regions; b) their impact on study protocols and implementation; and c) lessons learned from this process. METHODS: Following numerous discussions with IRB and grants administrative personnel for each region, some practitioner-investigators are attached to their respective IRBs and contracting entities via sub-contracts between their organizations and the network's administrative site. Others are attached via Individual Investigator Agreements and contractually obligated via Memoranda of Agreement. RESULTS: IRBs approve general operations under one approval, but specific research projects via separate approvals. Various formal IRB and grants administrative agreements have been arranged to customize research to the network context. In some instances, this occurred after feedback from patients and practitioners that lengthy written consent forms impeded research and raised suspicion, instead of decreasing it. CONCLUSIONS: Instead of viewing IRBs and institutional administrators as potentially adversarial, customized solutions can be identified by engaging them in collegial discussions that identify common ground within regulatory bounds. Although time-intensive and complex, these solutions improve acceptability of practice-based research to patients, practitioners, and university researchers.

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Document 449
Savage, Teresa A.; Mukherjee, Debjani
The controversy surrounding central institutional review boards.
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Document 450
Bang, Abhay
Was the gadchiroli trial ethical? Response from the principal investigator.
Indian Journal of Medical Ethics 2010 January-March; 7(1): 12-14
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Document 451
Bandewar, Sunita
Assessing the social value of research involving "minimal risks": who is accountable?
Georgetown users check Georgetown Journal Finder for access to full text

Document 452
Bhan, Anant; Desikan, Prabha; Swarnalakshmi, S.; Kalantri, S.P.
Process, pitfalls and probity: sharing experiences on setting up and running ethics committees in India.
Indian Journal of Medical Ethics 2010 January-March; 7(1): 48-51
Georgetown users check Georgetown Journal Finder for access to full text

Document 453
Kvarstein, Gunnvald; Måwe, Leif; Indahl, Aage; Hol, Per Kristian; Tennøe, Bjørn; Digernes, Randi; Tønnessen, Tor Inge; Beivik, Harald; Stubhaug, Audun
Placebo control -- still the most ethical study design.
Pain 2010 January; 148(1): 174-175
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Document 454
United States. Food and Drug Administration [FDA]
Guidance for IRBs, clinical investigators, and sponsors. IRB continuing review after clinical investigation approval [draft guidance]

http://www.regulations.gov (link may be outdated)
Document 455

Bin al-Nawa, Khalid

*Dawabit mashru'iyyat al-tajarib al-tibbiyah wa atharuha 'ala al-mas'uliyah al-madaniyah* [Rules governing the permissibility of medical experiments and their impact on civil liability]


Document 456

Schrag, Zachary M.

*ETHICAL IMPERIALISM: INSTITUTIONAL REVIEW BOARDS AND THE SOCIAL SCIENCES, 1965-2009*


Call number: *H62.5 .U5 S37 2010*

Document 457

United States. Department of Health and Human Services; United States. Food and Drug Administration; Center for Biologics Evaluation and Research (U.S.); and Center for Drug Evaluation and Research (U.S.)

*GUIDANCE FOR INDUSTRY: M3(R2) NONCLINICAL SAFETY STUDIES FOR THE CONDUCT OF HUMAN CLINICAL TRIALS AND MARKETING AUTHORIZATION FOR PHARMACEUTICALS*


http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073246.pdf (link may be outdated)

Document 458

Abdel-aleem, Salah

*THE DESIGN AND MANAGEMENT OF MEDICAL DEVICE CLINICAL TRIALS: STRATEGIES AND CHALLENGES*


Document 459

Sacchini, D; Pennacchini, M

*Ethics committees.*

La Clinica terapeutica 2010; 161(3): 281-3

*Abstract:* Ethics committees (ECs) are a relevant body for dealing with ethical issues in healthcare. They born in order to resolve dilemmatic situations. Contemporary ECs are independent standing committees with multidisciplinary representation, including medicine, nursing, social work, law, pastoral care, healthcare administration, and other different expertises. The functions of ECs are various: estimating clinical trials; analyzing ethically relevant clinical cases; drafting hospital/organizational guidelines, and to carry out education activity. The composition and kind of skills requested in an EC could change according to national laws. About international ethical standards in clinical experimentation, the World Medical Association's Declaration of Helsinki is the reference according to which examining clinical trials by ECs.

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Document 460

Brody, Baruch A

**Ethical issues in surgical trials and in the diffusion of innovative therapies.**
Texas Heart Institute journal / from the Texas Heart Institute of St. Luke's Episcopal Hospital, Texas Children's Hospital 2010; 37(6): 685-6

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Document 461

Tashiro, Munehiro

[Conflict of interest in clinical research--trends in guidelines for research ethics in Japan and other countries].
Seishin shinkeigaku zasshi = Psychiatry et neurologia Japonica 2010; 112(11): 1130-5

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Document 462

Brichant, J F

[The Helsinki Declaration on Patient Safety in Anaesthesiology].
Acta anaesthesiologica Belgica 2010; 61(2): 49

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Document 463

Booth, Karen M

**A magic bullet for the "African" mother? Neo-Imperial reproductive futurism and the pharmaceutical "solution" to the HIV/AIDS Crisis.**
Social politics 2010; 17(3): 349-78

**Abstract:** On the basis of a close reading of popular and medical texts which address a debate over the ethics of clinical drug trials funded by the United States and designed mainly for sub-Saharan Africa, I argue that international public health discourse about infant HIV infection in that region reflects and legitimates a neo-imperialist, anti-reproductive justice ideology. Participants share a fetal-centered logic that US-funded biomedicine must shoulder the burden of rescuing sub-Saharan Africa from itself by using the bodies of HIV-positive pregnant women to transmit biomedicine's magic bullet-antiretroviral drugs-to the next generation. The survival of the fetus, disguised as the well-being of the HIV-positive woman and accomplished by the magic of biomedical research, becomes the survival of a region otherwise doomed by its present state of economic, political, and medical incapacity. This version of what queer theorist Lee Edelman (2004, No Future: Queer Theory and the Death Drive) calls "reproductive futurism" redounds to the benefit of the more explicitly women-hating and nationalist ideologies of still-powerful right-wing movements against reproductive and sexual rights.

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Document 464

Hegney, Desley; Chan, Tuck Wai

**Ethical challenges in the conduct of qualitative research.**
Nurse researcher 2010; 18(1): 4-7

Georgetown users check [Georgetown Journal Finder](#) for access to full text
Document 465
McGarry, Julie

**Exploring the effect of conducting sensitive research.**
Nurse researcher 2010; 18(1): 8-14

**Abstract:** The term 'sensitive research' has become recognised in health and social care research literature generally. It has been used to describe a wide range of topics, undertaken across a variety of disciplines and settings, using a range of methods. Drawing on evidence from other disciplines, this article examines the particular issues and effects that arise for nurses in carrying out sensitive research as the field continues to evolve.

Georgetown users check [Georgetown Journal Finder](http://jima.imana.org/index) for access to full text

Document 466
Houghton, Catherine E; Casey, Dympna; Shaw, David; Murphy, Kathy

**Ethical challenges in qualitative research: examples from practice.**
Nurse researcher 2010; 18(1): 15-25

**Abstract:** This article examines the many ethical challenges that are specific to qualitative research. These challenges concern the issues of informed consent procedures, the researcher-participant relationship, risk-benefit ratio, confidentiality and the dual role of the nurse-researcher. Each challenge will be examined and practical examples of how it was dealt with, using examples from a multiple case study, will be described.

Georgetown users check [Georgetown Journal Finder](http://jima.imana.org/index) for access to full text

Document 467
Fadel, Hossan E.

**Ethics of clinical research: an islamic perspective**

Georgetown users check [Georgetown Journal Finder](http://jima.imana.org/index) for access to full text

Document 468
Yap, Tsiao Yi; Kassimatis, Kathleen A.; Kodish, Eric D.

**Both sides of the coin: randomization from the perspectives of physician-investigators and patient-subjects**
Ethics & Behavior 2010; 20(5): 380-386

Georgetown users check [Georgetown Journal Finder](http://jima.imana.org/index) for access to full text

Document 469
Lelgemann, Monika; Wieseler, Beate; Gerd, Antes

**[False self-possession] = Falsche Gelassenheit.**
Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen 2010; 104(4): 281-3

Georgetown users check [Georgetown Journal Finder](http://jima.imana.org/index) for access to full text
**Document 470**
Lipscomb, Martin

**Participant overexposure and the role of researcher judgement.**
Nurse researcher 2010; 17(4): 49-59

**Abstract:** Ethical conduct discussion often focuses on decisions made before and during the research process. In contrast, this paper offers a reflective and personal post-factum critique of two distinct elements of ethical practice that emerged from a recent study of aspects of activity at a hospice in England. First, it is suggested that researcher judgement in protecting participants from 'overexposure' may have been insufficiently developed. Second, it is proposed that an unnecessarily individualist (biomedical) model of ethical good practice was uncritically accepted and that assumptions inherent in this approach should have been more thoroughly questioned. In conducting this study 'usual' measures were taken to protect from harm the individuals and organisation taking part. Before collecting data, which took the form of interview transcripts and notes made by the researcher in his role as staff nurse (participant observation), ethical approval was secured. Interviewees were known to the interviewer prior to interview.

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**Document 471**
Matutina, Robin E

**The concept analysis of therapeutic misconception.**
Nurse researcher 2010; 17(4): 83-90

**Abstract:** The concept of therapeutic misconception is explored following the Wilson method of concept analysis. The phenomenon, identified in the early 1980s, was first observed during interviews with psychiatric patients who had consented to research, but believed the study in which they were agreeing to participate was for their benefit. The concept has more recently been identified in oncology research subjects, primarily those participating in phase I trials. Using the Wilson method, the investigator identified four elements present in therapeutic misconception in which subjects: Confuse research with treatment. Believe they will receive physical benefit from study participation. Fail to list altruism and contribution to science as motives for participating.

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**Document 472**
Pemberton, John

**Unrecognised scurvy. Signs and requirements.**
BMJ (Clinical research ed.) 2010; 340: c590

Georgetown users check [Georgetown Journal Finder](http://jama.ama-assn.org/content/vol302/issue24/index.dtl) for access to full text

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**Document 473**
Lo, Bernard; Grady, Deborah

**Strengthening institutional review board review of highly innovative interventions in clinical trials.**

Georgetown users check [Georgetown Journal Finder](http://jama.ama-assn.org/content/vol302/issue24/index.dtl) for access to full text

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**Document 474**
Goldacre, Ben; Lawton, Vincent

**Is the conflict of interest unacceptable when drug companies conduct trials on their own drugs?**

*Note: The link may be outdated.*
Document 475

Feifel, David

The Use of Placebo-Controlled Clinical Trials for the Approval of Psychiatric Drugs: Part II-Ethical Considerations Related to the Individual Participant.
Psychiatry (Edgmont (Pa. : Township)) 2009 Dec; 6(12): 19-25

Abstract: This is Part 2 of a two-part series on the ethical issues surrounding the use of placebo arms in clinical trials for psychiatric drugs. Part 1 discussed the ethical argument from a statistical, population-based perspective. Part 2 explores the ethical issues of placebo-controlled studies as they relate to individual psychiatric patients who may participate in them. Many patients who are candidates for psychiatric clinical trials would receive poor treatment for their mental illness under standard treatment conditions. Industry-sponsored clinical trials often provide treatment resources otherwise not available to patients at a more intense level of care than the local standard. Moreover, study design features, such as those developed at University of California, San Diego (presented herein), can mitigate the risks of placebo arms. With this in mind, clinical trials represent an ethical option for many patients with chronic mental illness.

Document 476

McCluskey, Annie

When to seek ethical review for a study.
Australian occupational therapy journal 2009 Dec; 56(6): 371

Document 477

Kibble, Jonathan D

Ethical approval for research in physiology education.
Advances in physiology education 2009 Dec; 33(4): 268-9

Abstract: The goal of this article is to reflect on the contemporary ethical standards that should be applied to the publication of physiology education research. As teachers, we are all education researchers to some degree but our appreciation of when and how regulatory requirements apply to our work is variable. A significant number of articles in Advances in Physiology Education that might be classified as "research involving human participants" do not document ethical safeguards such as Institutional Review Board approval and informed consent, which are required according to journal policy. I elaborate my personal view that we should strive to maintain the present community standards for conducting and publishing education research. And, as always, I hope the road to hell is not paved with good intentions!

Document 478

Wu, Yelena; Deboeck, Pascal; Joseph, Megan; Hwang, Cindy; Perlis, Clifford S; Perlis, Roy H

Does study design explain the relationship between conflict of interest and positive outcome in clinical trials in psychiatry?
Document 479
Wilson, Barbara A
**Carrying out research into outcomes. Foreword.**
Neuropsychological rehabilitation 2009 Dec; 19(6): 785-9

Document 480
Malec, James F
**Ethical and evidence-based practice in brain injury rehabilitation.**
Neuropsychological rehabilitation 2009 Dec; 19(6): 790-806

**Abstract:** The ultimate goal of evidence-based medicine (EBM) is to develop a scientific basis for choosing interventions that will benefit individuals with defined characteristics under specified conditions. By referencing practice recommendations to the strength of the scientific evidence gleaned from systematic reviews, EBM avoids the influence of professional biases. The randomised controlled trial (RCT) has come to be considered the gold standard for EBM methodology. Strengths as well as risks and weaknesses of RCT-focused EBM are reviewed. EBM is also linked to the medical model in which the target of the intervention is a disorder within the individual patient. Some interventions in brain injury rehabilitation may be more appropriately studied within a social model of disability in which the target of intervention is the individual's environment or social system. While the pursuit of a scientific basis for practice is clearly an ethical mandate, defining ethical practice in the absence of strong evidence and in the presence of competing methodologies is elusive. Balancing these considerations, the ethical practice of brain injury rehabilitation requires an awareness not only of the scientific evidence for an intervention but also of current best practices recommended by professional traditions and consensus, the practice situation, and the individual's current and evolving situation, needs and preferences.

Document 481
European Commission
**Consultation on the assessment of how the 'Clinical Trials Directive' works**
Ethically Speaking 2009 December; 13: 57

Document 482
Maloney, Dennis M.
**Study reports savings with centralized protocol reviews**
Human Research Report 2009 December; 24(12): 6

Document 483
Maloney, Dennis M.
Major improvement needed in oversight of researchers
Human Research Report 2009 December; 24(12): 5
Georgetown users check Georgetown Journal Finder for access to full text

Document 484
Maloney, Dennis M.
IRB approval of certain research
Human Research Report 2009 December; 24(12): 4
Georgetown users check Georgetown Journal Finder for access to full text

Document 485
Ertell, Katherine
GAO undercover operation: IRB system vulnerabilities allowed bogus registration and HHS-approved assurance
Protecting Human Subjects 2009 Winter; (19): 8-9
Georgetown users check Georgetown Journal Finder for access to full text

http://humansubjects.energy.gov/doe-resources/newsletter/ (link may be outdated)

Document 486
Walton, Nancy
Facebook and human subjects research: investigators using social networks find challenges for ethics review boards
Protecting Human Subjects 2009 Winter; (19): 4-5
Georgetown users check Georgetown Journal Finder for access to full text

http://humansubjects.energy.gov/doe-resources/newsletter/ (link may be outdated)

Document 487
Ertell, Katherine
Succession planning for the HRPP and IRB: protect your organization from periods of confusion or paralysis by thinking in advance
Protecting Human Subjects 2009 Winter; (19): 1-3
Georgetown users check Georgetown Journal Finder for access to full text

http://humansubjects.energy.gov/doe-resources/newsletter/ (link may be outdated)

Document 488
Mamotte, Nicole; Wassenaar, Douglas
Ethics review in a developing country: a survey of South African social scientists' experiences.
Abstract: We report the findings of a preliminary study of social science researchers' experiences of ethics review from a developing country perspective. Social science researchers' experiences of ethics review were coded as
negative (42.6%), positive (21.3%), or mixed (36.2%). Ethics review was primarily experienced as negative for pragmatic reasons such as slow turnaround time, inadequate review and problems with the centralization of review. Our finding that South African researchers experience the same problems and frustrations with RECs as developed country researchers affirms that South Africa's problems with ethics review are not due to it being a less developed system, but to general review practices as they arise naturally in institutions. Developing countries thus have a unique opportunity to learn from the reported dissatisfactions and mistakes of developed countries, to avoid procedures that have hindered ethics review of much social science research in developed countries, and to fashion their own review procedures in ways that are more appropriate to key ethical issues arising in social science research and local conditions and resources.

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http://caliber.ucpress.net/toc/jer/4/4 (link may be outdated)

* Article Document 489

Nyika, Aceme; Kilama, Wenceslaus; Tangwa, Godfrey B.; Chilengi, Roma; Tindana, Paulina

Capacity building of ethics review committees across Africa based on the results of a comprehensive needs assessment survey.

Developing World Bioethics 2009 December; 9(3): 149-156

Abstract: A needs assessment survey of ethics review committees (ERCs) across Africa was conducted in order to establish their major needs and areas of weaknesses in terms of ethical review capacity. The response rate was 84% (31 of 37 targeted committees), and committees surveyed were located in 18 African countries. The majority of the responding committees (61%) have been in existence between 5 and 10 years; approximately 74% of the respondents were institutional committees, with the remainder being either national (6/31) or regional (2/31). In terms of the ethical review process, nine of the 31 committees that responded did not have standard operating procedures (SOPs), and seven of the 22 that did have SOPs had never revised them after their initial development (an average period of three years). Of the 31 committees, 10 operated without any ethical guidelines. Many of the committees (13/30) met once per month, and the number of proposals reviewed annually varied, ranging from five to over 100. All respondents relied on paper-based data management and archiving systems. Overall, the survey identified the major constraints on ERCs as lack of office equipment, outdated or lack of SOPs, lack of electronic data management systems, inadequate resources, lack of or insufficient expertise on the committees, and poor recognition of the importance of the role of the committees. Consequently, the authors are addressing the identified needs and weaknesses through the Bill and Melinda Gates Foundation-funded capacity building project. The impact of the intervention project will be assessed during and at the end of the four-year longitudinal project.

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http://www3.interscience.wiley.com/journal/117981440/home (link may be outdated)

* Article Document 490

Schatz, Gerald S.

Ethical lawyering in the protection of human subjects of biomedical and behavioral research


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* Article Document 491

Pérez Oliva, Milagros

[Partisan versions, facts and truth] = Las versiones de parte, los hechos y la verdad.

Gaceta sanitaria / S.E.S.P.A.S 2009 Nov-Dec; 23(6): 568

Georgetown users check Georgetown Journal Finder for access to full text
Assessing social risks prior to commencement of a clinical trial: due diligence or ethical inflation?

Burris, Scott; Davis, Corey

**Abstract:** Assessing social risks has proven difficult for IRBs. We undertook a novel effort to empirically investigate social risks before an HIV prevention trial among drug users in Thailand and China. The assessment investigated whether law, policies and enforcement strategies would place research subjects at significantly elevated risk of arrest, incarceration, physical harm, breach of confidentiality, or loss of access to health care relative to drug users not participating in the research. The study validated the investigator's concern that drug users were subject to serious social risks in the site localities, but also suggested that participation in research posed little or no marginal increase in risk and might even have a protective effect. Our experience shows that it is feasible to inform IRB deliberations with actual data on social risks, but also raises the question of whether and when such research is an appropriate use of scare research resources.

http://www.bioethics.net/journal/ (link may be outdated)

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Evaluating empirical assessments of social risk.

Schonfeld, Toby; Brown, Joseph S.

**The need to explicate the ethical evaluation tools to avoid ethical inflation.**

Bernabe, Rosemarie D.C.; van Thiel, Ghislaine J.M.W.; Raaijmakers, Jan A.M.; van Delden, Johannes J.M.

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http://www.bioethics.net/journal/ (link may be outdated)

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Deflating rhetoric about "ethical inflation".

Rennie, Stuart; Rosenfeld, Lawrence B.

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http://www.bioethics.net/journal/ (link may be outdated)

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The need for evidence-based research ethics.

Anderson, Emily E.; Sieber, Joan E.

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http://www.bioethics.net/journal/ (link may be outdated)
**Document 497**

Lynch, Holly Fernandez; Dawson, Liza

*Adding insult to injury: reluctance to engage in clinical research with at-risk groups further disenfranchises these populations.*


**Document 498**

Ozdemir, Vural

*What to do when the risk environment is rapidly shifting and heterogeneous? Anticipatory governance and real-time assessment of social risks in multiply marginalized populations can prevent IRB mission creep, ethical inflation or underestimation of risks.*

American Journal of Bioethics 2009 November; 9(11): 65-68

**Document 499**


*Harmonisation of ethics committees' practice in 10 European countries.*

Journal of Medical Ethics 2009 November; 35(11): 696-700

**Abstract:** BACKGROUND: The Directive 2001/20/EC was an important first step towards consistency in the requirements and processes for clinical trials across Europe. However, by applying the same rules to all types of drug trials and transposing the Directive's principles into pre-existing national legislations, the Directive somewhat failed to meet its facilitation and harmonization targets. In the field of ethics, the Directive 2001/20/EC conditioned the way of understanding and transposing the "single opinion" process in each country. This led to a situation in which two models of research ethics committees organisation systems exist, being the model in which the "single opinion" is considered to be the decision made by a single ethics committee more effective and simpler in terms of administrative and logistic workload. METHOD: A survey was conducted in 10 European countries. Members of the European Clinical Research Infrastructures Network working party number 1, with expertise in the field of ethics, responded. RESULTS: There is a major heterogeneity in the composition of ethics committees among the surveyed countries based on the number of members, proportion of experts versus lay members and expertise of the scientific members. A harmonized education of the ethics committees' membership based in common curricula is recommended by the majority of countries. CONCLUSIONS: Despite the efforts for harmonization of the European Clinical Trial Directive, from an ethical point of view, there remains a plurality of ethics committees' systems in Europe. It is important to comprehend the individual national systems to understand the problems they are facing.
Document 500

Ioannidis, John P.A.

**Adverse events in randomized trials: neglected, restricted, distorted, and silenced.**

Archives of Internal Medicine 2009 October 26; 169(19): 1737-1739

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http://archinte.ama-assn.org (link may be outdated)

Document 501

Pitrou, Isabelle; Boutron, Isabelle; Ahmad, Nizar; Ravaud, Philippe

**Reporting of safety results in published reports of randomized controlled trials.**

Archives of Internal Medicine 2009 October 26; 169(19): 1756-1761

**Abstract:** BACKGROUND: Reports of clinical trials usually emphasize efficacy results, especially when results are statistically significant. Poor safety reporting can lead to misinterpretation and inadequate conclusions about the interventions assessed. Our aim was to describe the reporting of harm-related results from randomized controlled trials (RCTs). METHODS: We searched the MEDLINE database for reports of RCTs published from January 1, 2006, through January 1, 2007, in 6 general medical journals with a high impact factor. Data were extracted by use of a standardized form to appraise the presentation of safety results in text and tables. RESULTS: Adverse events were mentioned in 88.7% of the 133 reports. No information on severe adverse events and withdrawal of patients owing to an adverse event was given in 27.1% and 47.4% of articles, respectively. Restrictions in the reporting of harm-related data were noted in 43 articles (32.3%) with a description of the most common adverse events only (n = 17), severe adverse events only (n = 16), statistically significant events only (n = 5), and a combination of restrictions (n = 5). The population considered for safety analysis was clearly reported in 65.6% of articles. CONCLUSION: Our review reveals important heterogeneity and variability in the reporting of harm-related results in publications of RCTs.

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http://archinte.ama-assn.org (link may be outdated)

Document 502

Smajdor, A.; Sydes, M.R.; Gelling, L.; Wilkinson, M.

**Applying for ethical approval for research in the United Kingdom**

BMJ: British Medical Journal 2009 October 24; 339(7727): 968-971

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http://www.bmj.com (link may be outdated)

Document 503

MacDonald, Tom

**Tom MacDonald replies to Marisa de Andrade [reply]**

BMJ: British Medical Journal 2009 October 24; 339(7727): 936

Georgetown users check [Georgetown Journal Finder](http://www.bmj.com) for access to full text

http://www.bmj.com (link may be outdated)

Document 504

Office for Human Research Protections [OHRP]
Guidance on IRB Continuing Review of Research

http://www.hhs.gov/ohrp/requests/200911guidance_rev.pdf (link may be outdated)

Document 505
Raymond, Agnès Saint; Sweeney, Fergus
Clinical trials in developing countries: risk or opportunity?

Document 506
Smith, Joanna; Cheater, Francine; Chatwin, John; Bekker, Hilary
Parent's involvement in decisions when their child is admitted to hospital with suspected shunt malfunction: study protocol.

Document 507
Doab, Anna; Topp, Libby; Day, Carolyn A; Dore, Gregory J; Maher, Lisa
Clinical trial literacy among injecting drug users in Sydney, Australia: A pilot study.
Contemporary clinical trials 2009 Sep; 30(5): 431-5

Document 508
Torralba, Karina D; Khan, Nasim A; Quismorio, Francisco P
Clinical trials and public trust: the geographical shift to the Asia-Pacific region.

Abstract: Multiple issues surrounding the publication of clinical trials and the conduct of clinical trials, especially those that are industry-sponsored, have raised doubts regarding the integrity of their results, and of the integrity of the medical profession. An appreciation of the historical and economic changes in the relationship between
physicians and industry is crucial to the understanding of these issues. Increasingly, as healthcare professionals and centers in the Asia-Pacific region become involved in corporate-funded multi-center drug trials, these ethical issues similarly come into play. It is imperative for medical leaders to take actions ensuring rights of subjects participating in these clinical trials, and to ensure the integrity of physicians and authors of clinical trials from this region of the world.

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**Document 509**
Garrafa, Volnei

Bioética and Debat 2009 September-December; 15(58): 15-18

Georgetown users check [Georgetown Journal Finder](http://www.ajph.org) for access to full text

**Document 510**
Lidz, Charles W.; Appelbaum, Paul S.; Joffe, Steven; Albert, Karen; Rosenbaum, Jill; Simon, Loma

*Competing commitments in clinical trials.*
IRB: Ethics and Human Research 2009 September-October; 31(5): 1-6

Georgetown users check [Georgetown Journal Finder](http://www.ajph.org) for access to full text

**Document 511**
Whicher, Danielle; Currie, Peter; Taylor, Holly A.

*Factors that influence institutional review board members' commitment to their role responsibilities.*

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**Document 512**
Bozeman, Barry; Slade, Catherine; Hirsch, Paul

*Understanding bureaucracy in health science ethics: toward a better institutional review board.*
American Journal of Public Health 2009 September; 99(9): 1549-1556

**Abstract:** Research involving human participants continues to grow dramatically, fueled by advances in medical technology, globalization of research, and financial and professional incentives. This creates increasing opportunities for ethical errors with devastating effects. The typical professional and policy response to calamities involving human participants in research is to layer on more ethical guidelines or strictures. We used a recent case-the Johns Hopkins University/Kennedy Kreiger Institute Lead Paint Study-to examine lessons learned since the Tuskegee Syphilis Study about the role of institutionalized science ethics in the protection of human participants in research. We address the role of the institutional review board as the focal point for policy attention.

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http://www.ajph.org (link may be outdated)

**Document 513**
Dongquan Chen, ; Chen, Wei-Bang; Soong, Mayhue; Soong, Seng-Jaw; Orthner, Helmuth F

*Turning Access into a web-enabled secure information system for clinical trials.*

**Abstract:** Organizations that have limited resources need to conduct clinical studies in a cost-effective, but secure way. Clinical data residing in various individual databases need to be easily accessed and secured. Although widely available, digital certification, encryption, and secure web server, have not been implemented as widely, partly due to a lack of understanding of needs and concerns over issues such as cost and difficulty in implementation.

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**Document 514**

Maloney, Dennis M.

**Special research review requirements**

Human Research Report 2009 August; 24(8): 5

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**Document 515**

Maloney, Dennis M.

**More aspects of direct accountability for IRBs**

Human Research Report 2009 August; 24(8): 5

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**Document 516**

Hutson, Stu

**Trauma trials kick off, putting patient consent rules in focus.**

Nature Medicine 2009 August; 15(8): 823

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**Document 517**

McGrath, Moriah McSharry; Fullilove, Robert E; Kaufman, Molly Rose; Wallace, Rodrick; Fullilove, Mindy Thompson

**The limits of collaboration: a qualitative study of community ethical review of environmental health research.**

American Journal of Public Health 2009 August; 99(8): 1510-1514

**Abstract:** OBJECTIVES: We assessed the effectiveness of various systems of community participation in ethical review of environmental health research. METHODS: We used situation analysis methods and a global workspace theoretical framework to conduct comparative case studies of 3 research organizations at 1 medical center. RESULTS: We found a general institutional commitment to community review as well as personal commitment from some participants in the process. However, difficulty in communicating across divides of knowledge and privilege created serious gaps in implementation, leaving research vulnerable to validity threats (such as misinterpretation of findings) and communities vulnerable to harm. The methods used in each collaboration solved some, but not all, of the problems that hindered communication. CONCLUSIONS: Researchers, community spokespersons, and institutional review boards constitute organizational groups with strong internal ties and highly developed cultures. Few cross-linkages and little knowledge of each other cause significant distortion of information and other forms of miscommunication between groups. Our data suggest that organizations designed to protect human volunteers are in the best position to take the lead in implementing community review.

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[http://www.ajph.org](http://www.ajph.org) (link may be outdated)
Cohen, Emma R.M.; O'Neill, Jennifer M.; Joffres, Michel; Upshur, Ross E.G.; Mills, Edward

**Reporting of informed consent, standard of care and post-trial obligations in global randomized intervention trials: a systematic survey of registered trials**
Developing World Bioethics 2009 August; 9(2): 74-80

**Abstract:** OBJECTIVE: Ethical guidelines are designed to ensure benefits, protection and respect of participants in clinical research. Clinical trials must now be registered on open-access databases and provide details on ethical considerations. This systematic survey aimed to determine the extent to which recently registered clinical trials report the use of standard of care and post-trial obligations in trial registries, and whether trial characteristics vary according to setting. METHODS: We selected global randomized trials registered on http://www.clinicaltrials.gov and http://www.controlled-trials.com. We searched for intervention trials of HIV/AIDS, malaria, and tuberculosis from 9 October 2004, the date of the most recent version of the Helsinki Declaration, to 10 April 2007. RESULTS: We collected data from 312 trials. Fifty-eight percent (58%, 95% CI = 53 to 64) of trial protocols report informed consent. Fifty-eight percent (58%, 95% CI = 53 to 64) of trials report active controls. Almost no trials (1%, 95% CI = 0.5 to 3) mention post-trial provisions. Most trials measure surrogate outcomes. Twenty percent (20%, 95% CI = 16 to 25) of trials measure patient-important outcomes, such as death; and the odds that these outcomes are in a low income country are five times greater than for a developed country (odds ratio (OR) 5.03, 95% CI = 2.70 to 9.35, p = < 0.001). Pharmaceutical companies are involved in 28% (CI = 23 to 33) of trials and measure surrogate outcomes more often than nonpharmaceutical companies (OR 2.45, 95% CI = 1.18 to 5.09, p = 0.31). CONCLUSION: We found a large discrepancy in the quality of reporting and approaches used in trials in developing settings compared to wealthier settings.

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Maloney, Dennis M.

**More examples of when IRBs don't have to conduct reviews**
Human Research Report 2009 July; 24(7): 5

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Maloney, Dennis M.

**Human subjects research without an approved IND**
Human Research Report 2009 July; 24(7): 4

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Maloney, Dennis M.

**National group says IRBs should be held responsible**
Human Research Report 2009 July; 24(7): 3

Georgetown users check [Georgetown Journal Finder](http://www3.interscience.wiley.com/journal/117981440/home) for access to full text

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Straight, Timothy M.
Clinical research regulation: challenges to the institutional review board system.
Clinics in Dermatology 2009 July-August; 27(4): 375-383

Georgetown users check Georgetown Journal Finder for access to full text

Weyers, Wolfgang
Medical experiments on humans and the development of guidelines governing them: the central role of dermatology.
Clinics in Dermatology 2009 July-August; 27(4): 384-394

Georgetown users check Georgetown Journal Finder for access to full text

de Sá, Maria de Fátima Freire; Moureira, Diogo Luna
El marco normativo para la protección de la integridad en la investigación en Brasil. [The regulatory framework for the protection of human integrity in Brazil]
Revista de Derecho y Genoma Humano = Law and the Human Genome Review 2009 July-December; (31): 79-106

Georgetown users check Georgetown Journal Finder for access to full text

King, Nancy M.P.
Benefits, harms, and motives in clinical research.
Hastings Center Report 2009 July-August; 39(4): 3

Georgetown users check Georgetown Journal Finder for access to full text

Miller, F.G.; Joffe, S.
Limits to research risks
Journal of Medical Ethics 2009 July; 35(7): 445-449

Abstract: Risk-benefit assessment is a routine requirement for research ethics committees that review and oversee biomedical research with human subjects. Nevertheless, it remains unclear how to weigh and balance risks to research participants against the social benefits that flow from generating biomedical knowledge. In this article, we address the question of whether there are any reasonable criteria for defining the limit of permissible risks to individuals who provide informed consent for research participation. We argue against any a priori limit to permissible research risks. However, attention to the uncertainty of potential social benefit that can be derived from any particular study warrants caution in exposing prospective research participants to a substantial likelihood of serious harm.

Georgetown users check Georgetown Journal Finder for access to full text

http://jme.bmj.com (link may be outdated)

Marshall, Jennifer; Hadskis, Michael R.
Canadian research ethics boards, MRI research risks, and MRI risk classification
Document 528
He, Jia; Jin, Zhichao; Yu, Danghui
**Statistical reporting in Chinese biomedical journals.**
Lancet 2009 June 20-26; 373(9681): 2091-2093
Georgetown users check [Georgetown Journal Finder](#) for access to full text

http://www.thelancet.com/journals/lancet/ (link may be outdated)

Document 529
Gelijns, Annetine C.; Ascheim, Deborah D.; Parides, Michael K.; Kent, K. Craig; Moskowitz, Alan J.
**Randomized trials in surgery.**
Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 530
Helfand, Brian T.; Mongiu, Anne K.; Roehrborn, Claus G.; Donnell, Robert F.; Bruskewitz, Reginald; Kaplan, Steven A.; Kusek, John W.; Coombs, Laura; McVary, Kevin T.;
**Variation in institutional review board responses to a standard protocol for a multicenter randomized, controlled surgical trial.**
Journal of Urology 2009 June; 181(6): 2674-2679
Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 531
Czarkowski, Marek; Rózanowski, Krzysztof
**Polish Research Ethics Committees in the European Union system of assessing medical experiments.**
Science and Engineering Ethics 2009 June; 15(2): 201-212
Georgetown users check [Georgetown Journal Finder](#) for access to full text

http://www.springerlink.com/content/120482/ (link may be outdated)

Document 532
Weisse, Allen B.
**I was a mole in an IRB**
Perspectives in Biology and Medicine 2009 Summer; 52(3): 435-441
Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 533
van der Graaf, Rieke; van Delden, Johannes J.M.
Response to Open Peer Commentaries on "What is The Best Standard for the Standard of Care in Clinical Research?"
American Journal of Bioethics 2009 June-July; 9(6-7): W7-W8
Georgetown users check Georgetown Journal Finder for access to full text

http://dx.doi.org/10.1080/15265160902918804 (link may be outdated)

* Document 534
Davies, H.; Wells, F.; Czarkowski, M.
Standards for research ethics committees: purpose, problems and the possibilities of other approaches
Journal of Medical Ethics 2009 June; 35(6): 382-383
Abstract: Criticism of ethical review of research continues and research ethics committees (RECs) need to demonstrate that they are "fit for purpose" by meeting acknowledged standards of process, debate and outcome. This paper reports a workshop in Warsaw in April 2008, organised by the European Forum for Good Clinical Practice, on the problems of setting standards for RECs in the European Union. Representatives from 27 countries were invited; 16 were represented. Problems identified were the limited and variable resources, difficulties of setting standards for ethical debate and its outcomes and that REC members, as volunteers, may resent the imposition of standards. Other ways to set standards were discussed, including analysis of current multicentre review, collecting REC member reports for review, learning from appeals and feedback from applicants, and use of other regional and national meetings. The place of a central, national board or ethics committee was debated as was the need for collaborating with partners in other fields.
Georgetown users check Georgetown Journal Finder for access to full text

http://jme.bmj.com (link may be outdated)

* Document 535
Schnitzbauer, Andreas; Lamby, Philipp E.; Mutzbauer, Ingrid; Zuelke, Carl; Schlitt, Hans J.; Geissler, Edward K.
Europe gets nul points for harmony in trials
BMJ: British Medical Journal 2009 May 30; 338(7706): 1302-1304
Georgetown users check Georgetown Journal Finder for access to full text

http://www.bmj.com (link may be outdated)

* Document 536
McGuinness, Sheelagh; Wilkinson, Ruth
Nurse research and the law in competent adults.
British Journal of Nursing 2009 May 14-27; 18(9): 559-560
Georgetown users check Georgetown Journal Finder for access to full text

* Document 537
Baquet, Claudia R; Mishra, Shiraz I; Weinberg, Armin D
A descriptive analysis of state legislation and policy addressing clinical trials participation.
Abstract: This report describes state policy and legislation related to clinical trials participation and Maryland's model to enhance clinical trial availability and participation.
Document 538

Jackson, G

**MIST-patching up the differences and the need for an independent overview.**
International journal of clinical practice 2009 May; 63(5): 677-8

Document 539

Dove, Alan

**Coast IRB hits treacherous waters.**
Nature Medicine 2009 May; 15(5): 470

Document 540

Rasmussen, Lisa M.

**Problems with minimal-risk research oversight: a threat to academic freedom?**
IRB: Ethics and Human Research 2009 May-June; 31(3): 11-16

Document 541

Tremblay, Michael

**Risks of doing as the romans do**
BMJ: British Medical Journal 2009 April 4; 338(7698): 806-807

Document 542

Garattini, Silvio; Chalmers, Iain

**Patients and the public deserve big changes in evaluation of drugs: ending the secrecy surrounding drug trials would benefit all parties**
BMJ: British Medical Journal 2009 April 4; 338(7698): 804-806

Document 543

Brahme, Radhika; Mehendale, Sanjay

**Profile and role of the members of ethics committees in hospitals and research organisations in Pune, india**
Document 544
Cadell, S; Ho, G; Jacques, L; Wilson, K; Davies, B; Steele, R
**Considerations for ethics in multisite research in paediatric palliative care.**
Palliative medicine 2009 Apr; 23(3): 274-5

Document 545
Maloney, Dennis M.
**Institutional review board (IRB) becomes embroiled in conflict of interest investigation**
Human Research Report 2009 April; 24(4): 9

Document 546
Maloney, Dennis m.
**University and outside consultants investigate allegations of noncompliance**
Human Research Report 2009 April; 24(4): 7

Document 547
Maloney, Dennis M.
**Federal agency is looking for input on data monitoring**
Human Research Report 2009 April; 24(4): 5

Document 548
Maloney, Dennis M.
**IRBs included in proposals to modify HIPAA privacy rule**
Human Research Report 2009 April; 24(4): 4

Document 549
Maloney, Dennis M.
**IRBs must estimate number of active protocols reviewed**
Human Research Report 2009 April; 24(4): 4
Maloney, Dennis M.

**Numerous recommendations on protecting human subjects**

Human Research Report 2009 April; 24(4): 3

Georgetown users check [Georgetown Journal Finder](#) for access to full text.

Maloney, Dennis M.

**More federal enforcement authority will affect institutional review boards (IRBs)**


Georgetown users check [Georgetown Journal Finder](#) for access to full text.

Puri, K.S.; Suresh, K.R.; Gogtay, N.J.; Thatte, U.M.

**Declaration of Helsinki, 2008: implications for stakeholders in research.**


Georgetown users check [Georgetown Journal Finder](#) for access to full text.

Permuth-Wey, Jennifer; Borenstein, Amy R.

**Financial remuneration for clinical and behavioral research participation: ethical and practical considerations.**


Georgetown users check [Georgetown Journal Finder](#) for access to full text.

Grotta, James; Barreto, Andrew

**Is it ethical to have a placebo arm in reperfusion trials in the 3- to 6-hour time window? Yes.**

Stroke 2009 April; 40(4): 1541-1542

Georgetown users check [Georgetown Journal Finder](#) for access to full text.

Donnan, Geoffrey A.; Davis, Stephen M.

**The ethics of thrombolytic trials beyond 3 (or 4.5) hours: randomized controlled trials are required to change clinical practice.**

Stroke 2009 April; 40(4): 1545

Georgetown users check [Georgetown Journal Finder](#) for access to full text.
**Document 556**
Köhmann, Martin; Schwab, Stefan
Is it ethical to have a placebo arm in reperfusion trials in the 3- to 6-hour time window? No: time frame or time gain?
Stroke 2009 April; 40(4): 1543-1544
Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 557**
Doppelfeld, E.
Responsibility and function of Research Ethics Committees = Aufgaben und Arbeitsweise Medizinischer Ethik-Kommissionen.
Bundesgesundheitsblatt, Gesundheitsforschung, Gesundheitsschutz 2009 April; 52(4): 387-393
Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 558**
Vogeli, Christine; Koski, Greg; Campbell, Eric G.
Policies and management of conflicts of interest within medical research institutional review boards: results of a national study.
Academic Medicine 2009 April; 84(4): 488-494
Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 559**
Schellings, Ron; Kessels, Alfons G.; ter Riet, Gerben; Sturmans, Ferd; Widdershoven, Guy A.; Knottnerus, J. André
Indications and requirements for the use of prerandomization.
Journal of Clinical Epidemiology 2009 April; 62(4): 393-399
Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 560**
Wolzt, Michael; Druml, Christiane; Leitner, Daniela; Singer, Ernst A.
Protocols in expedited review: tackling the workload of ethics committees.
Intensive Care Medicine 2009 April; 35(4): 613-615
Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 561**
Pehboeck, Daniel; Hohlneder, Matthias; Wenzel, Volker; Benzer, Amulf
Submission of clinical studies to ethics committees or clinical trials registers: the authors' point of view.
Intensive Care Medicine 2009 April; 35(4): 713-716
Georgetown users check [Georgetown Journal Finder](#) for access to full text
Document 562
Chassany, Olivier
Should European independent Ethics Committees be dismantled?
Intensive Care Medicine 2009 April; 35(4): 579-581
Georgetown users check Georgetown Journal Finder for access to full text

Document 563
United Kingdom. Academy of Medical Sciences
Global health diagnostics: research, development and regulation. Workshop report
London: Academy of Medical Sciences, 2009 April: 27 p.

http://www.acmedsci.ac.uk/p101puid149.html (link may be outdated)

Document 564
Camp, Jonathan W.; Barfield, Raymond C.; Rodriguez, Virginia; Young, Amanda J.; Finerman, Ruthbeth; Caniza, Miguela A.
Challenges faced by research ethics committees in El Salvador: results from a focus group study.
Developing World Bioethics 2009 April; 9(1): 11-17
Abstract: OBJECTIVE: To identify perceived barriers to capacity building for local research ethics oversight in El Salvador, and to set an agenda for international collaborative capacity building. METHODS: Focus groups were formed in El Salvador which included 17 local clinical investigators and members of newly formed research ethics committees. Information about the proposed research was presented to participants during an international bioethics colloquium sponsored and organized by the St. Jude Children's Research Hospital in collaboration with the National Ethics Committee of El Salvador and the University of El Salvador. Interviews with the focus group participants were qualitatively analyzed. RESULTS: Participants expressed the need to tailor the informed consent process and documentation to the local culture; for example, allowing family members to participate in decision-making, and employing shorter consent forms. Participants indicated that economic barriers often impede efforts in local capacity building. Participants valued international collaboration for mutual capacity building in research ethics oversight. CONCLUSIONS: Research ethics committees in El Salvador possess a basic knowledge of locally relevant ethical principles, though they need more training to optimize the application of bioethical principles and models to their particular contexts. Challenges increase the value of collaborative exchanges with ethics committee members in the United States. Further research on facilitating communication between host country and sponsor country ethics committees can maximize local research ethics expertise, and thus raise the standard of protecting human participants involved in international research.

Georgetown users check Georgetown Journal Finder for access to full text

Document 565
Gornall, Jonathan
Industry attack on academics – an apparently uncontentroversial study of potential industry influence on sponsored drug trials resulted in the authors facing accusations of misconduct
BMJ: British Medical Journal 2009 March 14; 338(7695): 626-628
Georgetown users check Georgetown Journal Finder for access to full text

http://www.bmj.com (link may be outdated)

Document 566
Sabisch, Katja
Standards der Forschung. Historische Entwicklung and ethische Grundlagen klinischer Studien, by Andreas Frewer and Ulf Schmidt (Hrsg) [book review]
Ethik in der Medizin 2009 March; 21(1): 80-82
Georgetown users check Georgetown Journal Finder for access to full text

Die erneut revidierte Deklaration von Helsinki, verabschiedet in Seoul 2008
Ethik in der Medizin 2009 March; 21(1): 45-67
Georgetown users check Georgetown Journal Finder for access to full text

One way to encourage more participation in clinical trials
Human Research Report 2009 March; 24(3): 9
Georgetown users check Georgetown Journal Finder for access to full text

University tells federal office how it will deal with subjects of halted studies
Human Research Report 2009 March; 24(3): 7
Georgetown users check Georgetown Journal Finder for access to full text

Costs affect recruitment and retention of subjects
Human Research Report 2009 March; 24(3): 5
Georgetown users check Georgetown Journal Finder for access to full text

Reporting adverse events to IRBs
Human Research Report 2009 March; 24(3): 4
Georgetown users check Georgetown Journal Finder for access to full text

Survey research and protection of human research subjects
Georgetown users check Georgetown Journal Finder for access to full text
**Document 573**

Fairman, Kathleen A.; Curtiss, Frederic R.

**What should be done about bias and misconduct in clinical trials?**

*Journal of Managed Care Pharmacy* 2009 March; 15(2): 154-160

**Abstract:** *BACKGROUND: To explore clinical ethics committees' deliberations and to identify areas for improvement.*

**DESIGN:** A pilot study including observations of committees deliberating a paper case, semistructured group interviews, and qualitative analysis of the data. **PARTICIPANTS:** Nine hospital ethics committees in Norway. **RESULTS AND INTERPRETATIONS:** Key elements of the deliberations included identifying the ethical problems; exploring moral values and principles; clarifying key concepts and relevant legal regulation; exploring medical facts, the patient's situation, the therapists' perspective, analogous clinical situations, professional uncertainties, the patient's and relatives' perspective, and clinical communication; identifying the involved parties and how to involve them; identifying possible courses of action, and possible conclusion and follow-up. The various elements were closely interwoven. The content and conclusions varied and seemed to be contingent on the committee members' interpretations, experience and knowledge. Important aspects of a clinical ethics deliberation were sometimes neglected. When the committees used a deliberation procedure and a blackboard, the deliberations tended to become more systematic and transparent. Many of the committees were insecure about how to include the involved parties and how to document the deliberations. **CONCLUSION:** Clinical ethics committees may provide an important arena for multidisciplinary discussions of complex clinical ethics challenges. However, this seems to require adequate composition, adoption of transparent deliberation procedures, and targeted training.

**Document 574**

Pedersen, Reidar; Akre, V.; Førde, R.

**What is happening during case deliberations in clinical ethics committees? A pilot study**

*Journal of Medical Ethics* 2009 March; 35(3): 147-152

**Abstract:** **BACKGROUND:** Clinical ethics consultation services have been established in many countries during recent decades. An important task is to discuss concrete clinical cases. However, empirical research observing what is happening during such deliberations is scarce. **OBJECTIVES:** To explore clinical ethics committees' deliberations and to identify areas for improvement. **DESIGN:** A pilot study including observations of committees deliberating a paper case, semistructured group interviews, and qualitative analysis of the data. **PARTICIPANTS:** Nine hospital ethics committees in Norway. **RESULTS AND INTERPRETATIONS:** Key elements of the deliberations included identifying the ethical problems; exploring moral values and principles; clarifying key concepts and relevant legal regulation; exploring medical facts, the patient's situation, the therapists' perspective, analogous clinical situations, professional uncertainties, the patient's and relatives' perspective, and clinical communication; identifying the involved parties and how to involve them; identifying possible courses of action, and possible conclusion and follow-up. The various elements were closely interwoven. The content and conclusions varied and seemed to be contingent on the committee members' interpretations, experience and knowledge. Important aspects of a clinical ethics deliberation were sometimes neglected. When the committees used a deliberation procedure and a blackboard, the deliberations tended to become more systematic and transparent. Many of the committees were insecure about how to include the involved parties and how to document the deliberations. **CONCLUSION:** Clinical ethics committees may provide an important arena for multidisciplinary discussions of complex clinical ethics challenges. However, this seems to require adequate composition, adoption of transparent deliberation procedures, and targeted training.

**Document 575**


**Subjects' views of obligations to ensure post-trial access to drugs, care and information: qualitative results from the Experiences of Participants in Clinical Trials (EPIC) study**

*Journal of Medical Ethics* 2009 March; 35(3): 183-188

**Abstract:** **OBJECTIVES:** To report the attitudes and opinions of subjects in US clinical trials about whether or not, and why, they should receive post-trial access (PTA) to the trial drug, care and information. **DESIGN:** Focus groups, short self-administered questionnaires. **SETTING:** Boston, Dallas, Detroit, Oklahoma City. **PARTICIPANTS:** Current and recent subjects in clinical trials, primarily for chronic diseases. **RESULTS:** 93 individuals participated in 10 focus groups. Many thought researchers, sponsors, health insurers and others share obligations to facilitate PTA to the trial drug, if it benefited the subject, or to a therapeutic equivalent. Some thought PTA obligations include providing transition care (referrals to non-trial physicians or other trials, limited follow-up, short-term drug supply) or care for long-term adverse events. Others held, in contrast, that there are no PTA obligations regarding drugs or care. However, there was agreement that former subjects should receive information (drug name, dosage received, market approval date, long-term adverse effects, trial results). Participants frequently appealed to health need, cost, relationships, reciprocity, free choice and sponsor self-interest to support their views. Many of their reasons overlapped with those commonly discussed by bioethicists. **CONCLUSION:** Many participants in US trials for chronic conditions thought there are obligations to facilitate PTA to the trial drug at a "fair" price; these views were
less demanding than those of non-US subjects in other studies. However, our participants' views about informational obligations were broader than those of other subjects and many bioethicists. Our results suggest that the PTA debate should expand beyond the trial drug and aggregate results.

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**Document 576**

van der Graaf, Rieke; van Delden, Johannes J.M.

**What is the best standard for the standard of care in clinical research?**

American Journal of Bioethics 2009 March; 9(3): 35-43

**Abstract:** During the past decennium, one of the main issues discussed in research ethics has been focused on the care that should be provided to the control group in a clinical trial. This discussion is also called the standard of care debate. Current international research ethics guidelines contain a wide variety of standards for the standard of care—including the provision of the highest attainable, the best available, the best current, a proven, and an established effective treatment. In this article, we systematically review the currently used standards and argue that none of the current standards is adequate to serve as a universal standard for the standard of care. Alex London has made a substantial proposal for a universal standard, but universally adopting his standard is problematic. In this article, we propose a revised version of London's standard.

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**Document 577**

Trommelmans, Leen; Dierickx, Kris

**Standard of care in clinical research with human tissue engineered products (HTEPs)**

American Journal of Bioethics 2009 March; 9(3): 44-45

---

**Document 578**

Mann, Howard

**Standard-of-care propositions should permit informative comparisons**

American Journal of Bioethics 2009 March; 9(3): 46-47

---

**Document 579**

Haire, Bridget

**Back to basics in clinical research ethics**

American Journal of Bioethics 2009 March; 9(3): 48-49
Some observations on "observational" research

Perspectives in Biology and Medicine 2009 Spring; 52(2): 252-263

Creating a controlled vocabulary for the ethics of human research: towards a biomedical ethics ontology.


Abstract: ONTOLOGIES DESCRIBE REALITY IN SPECIFIC domains in ways that can bridge various disciplines and languages. They allow easier access and integration of information that is collected by different groups. Ontologies are currently used in the biomedical sciences, geography, and law. A Biomedical Ethics Ontology (BMEO) would benefit members of ethics committees who deal with protocols and consent forms spanning numerous fields of inquiry. There already exists the Ontology for Biomedical Investigations (OBI); the proposed BMEO would interoperate with OBI, creating a powerful information tool. We define a domain ontology and begin to construct a BMEO, focused on the process of evaluating human research protocols. Finally, we show how our BMEO can have practical applications for ethics committees. This paper describes ongoing research and a strategy for its broader continuation and cooperation.

The biomedical ethics ontology proposal: excellent aims, questionable methods.


Abstract: KOEPSELL ET AL. (2009) DESCRIBE AN IDEAL biomedical ethics committee environment with efficiencies such as electronic and universal application forms and consent templates, automated decision-trees, and broad sharing of data. However, it is unclear that a biomedical ethics ontology (BMEO) is necessary or even helpful in establishing such environment. Two features of any applied ontology are particularly problematic in establishing a useful BMEO: (1) an ontology is a description of a domain of reality; and (2) the description is subject to ongoing revision as it is developed through open processes, e.g., the use of a wiki. A BMEO would need to address two main kinds of entities, regulatory definitions and ethical concepts, and is ill-suited to both. Regulatory definitions are fiats and ought to be adopted verbatim to ensure compliance, but in such cases we do not need the assistance of ontologists, and their modes of working (constant revision within open wiki-based communities) might even be counterproductive. Ethical concepts within pluralistic societies are social constructs, not a priori concepts or biological natural kinds, and the prospects of generating intuitive definitions that enjoy broad acceptance across cultures and institutional settings are slim. In making these arguments, I draw from the writings of leading applied ontologists and Koepsell et al.’s own proof of concept.


Abstract: EVALUATING THE EFFECTIVENESS OF A Research Ethics Committee or Institutional Review Board (IRB) continues to be a difficult task. There are limited data that examine the perceptions of members of IRBs about
their own performance or methods that would allow comparison among IRB panels at a single institution or between institutions. We piloted an anonymous survey instrument that examined members’ attitudes about the efficiency, procedures and outcomes of IRB meetings and developed a process for presentation and discussion of these results with panel members. This quality improvement process was initially completed with one panel, and then replicated with two other IRB panels at one institution. This allowed comparison of perceived IRB performance across panels at a single institution. Further research is required to determine the association between IRB members' perception of performance and other measures of IRB effectiveness and to examine the perceived performance of IRBs by other research stakeholders.

* Document 584
Taylor, Holly A.; Kass, Nancy E
Research Ethics Consultation at the Johns Hopkins Bloomberg School of Public Health.
IRB: Ethics and Human Research 2009 March-April; 31(2): 9-14

* Document 585
Tod, Angela Mary; Allmark, Peter; Alison, Althea
A practical guide to attaining research ethics approval in the U.K.

* Document 587
Bosch, Xavier; Titus, Sandra L.
Cultural challenges and international research integrity.
Lancet 2009 February 21; 373(9664): 610-612

* Document 588
American Dental Association [ADA]. Council on Ethics, Bylaws and Judicial Affairs [CEBJA]
Ethical considerations when using human subjects / patients in the examination process [resolution]
Document 589
Maloney, Dennis M.
University decides how to contact research subjects to tell them what really happened
Human Research Report 2009 February; 24(2): 7
Georgetown users check Georgetown Journal Finder for access to full text

Document 590
Maloney, Dennis M.
Research eligible for expedited IRB review
Human Research Report 2009 February; 24(2): 5
Georgetown users check Georgetown Journal Finder for access to full text

Document 591
Maloney, Dennis M.
Human subjects research versus quality improvement
Human Research Report 2009 February; 24(2): 5
Georgetown users check Georgetown Journal Finder for access to full text

Document 592
Maloney, Dennis M.
Reporting adverse events to the IRBs
Human Research Report 2009 February; 24(2): 3
Georgetown users check Georgetown Journal Finder for access to full text

Document 593
Maloney, Dennis M.
Final rules require registration of institutional review boards (IRBs)
Georgetown users check Georgetown Journal Finder for access to full text

Document 594
Rickles, Dean
Causality in complex interventions
Medicine, Health Care, and Philosophy 2009 February; 12(1): 77-90
Georgetown users check Georgetown Journal Finder for access to full text

http://www.ada.org/prof/prac/licensure/ethics_clinical_exam.pdf (link may be outdated)
Document 595
Kim, Scott; Ubel, Peter; De Vries, Raymond
Pruning the regulatory tree [commentary]
Nature 2009 January 29; 457(7229): 534-535
Georgetown users check Georgetown Journal Finder for access to full text

http://www.nature.com/nature/archive/ (link may be outdated)

Document 596
Lindelöf, Bernt; Lafolie, Pierre; Asp, Pernilla; Forssberg, Olof
Läkartidningen 2009 January 28-February 3; 106(5): 279-281
Georgetown users check Georgetown Journal Finder for access to full text

Document 597
Byerly, Wesley G.
Working with the institutional review board.
American Journal of Health-System Pharmacy 2009 January 15; 66(2): 176-184
Georgetown users check Georgetown Journal Finder for access to full text

Document 598
Byerly, Wesley G.
Working with the institutional review board
American Journal of Health-Systems Pharmacy 2009 January 15; 66: 176-184
Georgetown users check Georgetown Journal Finder for access to full text

Document 599
Kimmelman, Jonathan; Weijer, Charles; Meslin, Eric M.
Helsinki discord: FDA, ethics, and international drug trials.
Lancet 2009 January 3-9; 373(9657): 13-14
Georgetown users check Georgetown Journal Finder for access to full text

http://www.thelancet.com/journals/lancet/issue/current?tab=past (link may be outdated)

Document 600
Maloney, Dennis M.
University says it will contact former research subjects to give real reasons why study stopped
Document 601

Maloney, Dennis M.  
**Subjects' gender differences in clinical trials affect IRBs**  

Document 602

Maloney, Dennis M.  
**Research subjects cannot withdraw their data later**  

Document 603

Maloney, Dennis M.  
**What can be done when a subject is no longer participating in a study**  

Document 604

Blaskó, György; Kardos, Gabriella  
**Clinical research in Hungary. Infrastructure, organisation, legislation and framework. The situation in 2008.**  
Thérapie 2009 January-February; 64(1): 33-45

Document 605

Semaan, Salaam; Santibanez, Scott; Garfein, Richard S.; Heckathorn, Douglas D.; Des Jarlais, Don C.  
**Ethical and regulatory considerations in HIV prevention studies employing respondent-driven sampling.**  

Document 606

Wolf, Leslie E.  
**IRB policies regarding finder's fees and role conflicts in recruiting research participants.**  
Document 607
Sampson, Heather; Cox, Susan; Saginur, Raphael; Owen, Michael
Examining and understanding the need for Canadian Research Ethics Board (REB) member standardized education: governance views from the field
Georgetown users check Georgetown Journal Finder for access to full text

Document 608
Avard, Denise; Stanton-Jean, Michele; Woodgate, Roberta L.; Pullman, Daryl; Saginur, Raphael
Research ethics boards and challenges for public participation
Georgetown users check Georgetown Journal Finder for access to full text

Document 609
Saginur, Raphael; Deschamps, Pierre; Owen, Michael; Sampson, Heather
Ethics review of multi-centre trials: where do we stand?
Georgetown users check Georgetown Journal Finder for access to full text

Document 610
Owen, Michael; Emerson, Claudia; Kolopack, Pam; Preto, Nina; Sampson, Heather; Townsend, Anne; Willison, Donald; Woodgate, Roberta L.
Informing governance through evidence-based research on REBs: challenges and opportunities
Georgetown users check Georgetown Journal Finder for access to full text

Document 611
Cox, Susan; Townsend, Anne; Preto, Nina; Woodgate, Roberta L.; Kolopack, Pam
Ethical challenges and evolving practices in research on ethics in health research
Georgetown users check Georgetown Journal Finder for access to full text

Document 612
McDonald, Michael
From code to policy statement: creating Canadian policy for ethical research involving humans
Georgetown users check Georgetown Journal Finder for access to full text
Document 613
McDonald, Michael
Introduction
Georgetown users check Georgetown Journal Finder for access to full text

Document 614
Helmy, Adel; Timofeev, Ivan; Santarius, Tom; Hutchinson, Peter
What constitutes Clinical Equipoise?
British journal of neurosurgery 2009; 23(5): 564-5
Abstract: In order to incorporate patients ethically into randomised clinical trials, two related but distinct concepts are used: 'Clinical Equipoise' and the 'Uncertainty Principle'. We argue that true 'Clinical Equipoise', a consensus of opinion regarding valid treatment options, is a more valid way of recruiting to neurosurgical randomised clinical trials than the 'Uncertainty Principle', which reflects an individual clinician's uncertainty. This subtle distinction has implications for both recruitment and interpretation of the results of randomised clinical trials.
Georgetown users check Georgetown Journal Finder for access to full text

Document 615
Bueno, Mariana; Brevidelli, Maria Meimei; Cocarelli, Thaís; Santos, Gianni Mara Silva dos; Ferraz, Maria Auxiliadora; Mion Jr, Décio
Reasons for resubmission of research projects to the research ethics committee of a university hospital in São Paulo, Brazil.
Clinics (São Paulo, Brazil) 2009; 64(9): 831-6
Abstract: It is important to know the reasons for resubmitting research projects to the Research Ethics Committee in order to help researchers to prepare their research projects, informed consent forms and needed research documentation.
Georgetown users check Georgetown Journal Finder for access to full text

Document 616
Shinnar, Shlomo
Institutional review boards and ethical issues in randomized clinical trials.
Frontiers of Neurology and Neuroscience 2009; 25: 136-140
Georgetown users check Georgetown Journal Finder for access to full text

Document 617
Moule, Pam; Goodman, Margaret
Researching ethically
In their: Nursing Research: An Introduction. Los Angeles: SAGE, 2009: 53-72
Call number: RT81.5 .M68 2009

Document 618
Moule, Pam; Goodman, Margaret
Research ethics and governance
Document 619
Tremellen, Kelton; Belford, David
**Ethical issues in clinical research**
Call number: *RM301.27 .C578 2009*

Document 620
Beran, Roy G.
**Ethics of clinical research in drug trials**
Call number: *RM301.27 .C578 2009*

Document 621
Hood, Maureen N.; Kaar, Jason F.; Ho, Vincent R.
**Review boards**
Call number: *RM301.27 .C578 2009*

Document 622
Peppercorn, Jeffrey; Roberts, Thomas G.; Hammond, Tim G.
**History of clinical trial development and the pharmaceutical industry**
Call number: *RM301.27 .C578 2009*

Document 623
McCormick, Jennifer B.; Boyce, Angie M.; Cho, Mildred K.
**Biomedical scientists’ perceptions of ethical and social implications: is there a role for research ethics consultation?**
PloS One 2009; 4(3): e4659
Georgetown users check *Georgetown Journal Finder* for access to full text

Document 624
De Rossi, Costanza; Brunello, Antonella; Jirillo, Giuseppe; Jirillo, Antonio
**When an interim analysis of randomized trial changes the practice in oncology: The lesson of adjuvant trastuzumab and the HERA trial.**
Immunopharmacology and Immunotoxicology 2009; 31(1): 1-4
Georgetown users check *Georgetown Journal Finder* for access to full text

Document 625
Macneill, Paul Ulhas
Regulating experimentation in research and medical practice
Call number: R724 .C616 2009

*  Document 626
Luna, Florencia; Macklin, Ruth
Research involving human beings
Call number: R724 .C616 2009

*  Document 627
Raftery, James; Kerr, Christine; Hawker, Sheila; Powell, John
Paying clinicians to join clinical trials: a review of guidelines and interview study of trialists.
Trials 2009; 10: 15
Georgetown users check Georgetown Journal Finder for access to full text

Document 628
Griffiths, Frances
Considering the ethics of your research
In her: Research Methods for Health Care Practice. Los Angeles; London: SAGE, 2009: 42-54
Call number: RA440.85 .G75 2009

Document 629
Dellinger, R. Phillip; Vincent, Jean-Louis; Marshall, John; Reinhart, Konrad
Important issues in the design and reporting of clinical trials in severe sepsis and acute lung injury.
Journal of Critical Care 2008 December; 23(4): 493-499
Georgetown users check Georgetown Journal Finder for access to full text

*  Document 630
Wilson, Sue; Draper, Heather; Ives, Jonathan
Ethical issues regarding recruitment to research studies within the primary care consultation.
Family Practice 2008 December; 25(6): 456-461
Georgetown users check Georgetown Journal Finder for access to full text

Document 631
Maloney, Dennis M.
More support for initial and continuing education for Institutional Review Boards (IRBs)
Human Research Report 2008 December; 23(12): 9
Georgetown users check Georgetown Journal Finder for access to full text
Inappropriate expedited review causes suspension of Institutional Review Board's (IRB's) authority

Required education for IRB members and others

Examples of expedited review studies for IRBs

IRBs are prime audience for finalized guidance

The convergence of research and clinical practice: institutional review board review of humanitarian use device application

Abstract: We surveyed IRB chairs in the United States to ascertain whether their IRBs have clarity regarding their FDA-mandated role in reviewing humanitarian use device (HUD) applications, which are neither research devices nor fully tested treatments. Of 2,588 Chairs, 469 (18%) completed the survey, almost half of whom (44%) reported review of a HUD application within the previous five years. Findings suggest that many IRB Chairs are confused about what HUDs are, how to review HUD applications, and why IRBs should review them. We recommend that the FDA clarify their policies so that Chairs can provide the guidance necessary for IRBs to more effectively and consistently review HUD applications, and thereby better protect HUD-treated patients.
Survey of U.S. boards that review mental health-related research

Abstract: We obtained data on Institutional Review Boards (IRBs) that review mental health–related applications (MHRAs) in a national survey of institutions with federally assured human research protection programs. Approximately 57% of IRBs review MHRAs, and among these a small percentage may not have mental health experts on their committees (5%). Moreover, mental health experts on IRB committees at high research volume institutions are carrying substantially greater workloads than their lower volume counterparts. In terms of committee demographics, more women (36%) are serving as IRB Chairs on committees that review MHRAs than expected from their representation on medical or university faculties; ethnic minority faculty have lower representation among Chairs than might be expected from their overall faculty representation. Our findings suggest the need for additional studies to (a) examine if the number of mental health experts on IRBs should be increased particularly among IRBs reviewing a high volume of MHRAs, (b) determine if the breadth of expertise among IRB mental health experts corresponds to the range of substantive and methodological approaches represented by the mental health protocols under review, and (c) examine if recruiting IRB scientific expertise from outside an institution, a more common practice among smaller research entities, impacts review quality.

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* Document 638

Bartlett, Edward E.

International analysis of institutional review boards registered with the U.S. Office of Human Research Protections

Abstract: Institutional review boards form the backbone of the human subject protection system. Yet little is known about the characteristics of these committees. This study compiles and analyzes the data on 1,326 IRBs in 113 countries registered with the Office for Human Research Protections. The study analyzes data on the following IRB characteristics: institutional affiliation, number of full-time administrative positions, approximate total number of protocols, and number of currently active protocols supported by DHHS or regulated by the Food and Drug Administration. The analysis found that the most common IRB profile is to be affiliated with a clinical organization (41.9% of IRBs) and to have one full-time staff member (40.0%). Regarding protocol volume, the most common IRB profile was to have 26–99 currently active protocols (42.0% of IRBs), to have 1–25 DHHS protocols (46.6%), and 1–25 FDA-regulated protocols (45.6%). Further analyses reveal considerable differences among countries. This study can provide a baseline for future IRB evaluations.

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* Document 639

McDonald, Michael; Townsend, Anne; Cox, Susan M.; Damiano Paterson, Natasha; Lafrenière, Darquise

Trust in health research relationships: accounts of human subjects

Abstract: Trust is fundamental in health research, yet there is little empirical evidence that explores the meaning of trust from the perspective of human subjects. The analysis presented here focuses on how human subjects talked about trust in the in-depth interviews. It emerged from the accounts that trust could not be assumed in the research setting, rather it was portrayed as a dynamic concept, built and easily broken, characterized by reciprocity and negotiation. Human subjects were ambivalent about who, when, what, and how much to trust in the research endeavor. This paper adds a fresh perspective to the literature on trust, and so offers a currently neglected, and little understood dimension to the discourse around health research ethics.

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* Document 640

Klitzman, Robert

Views of the process and content of ethical reviews of HIV vaccine trials among members of US institutional
review boards and South African research ethics committees.
Developing World Bioethics 2008 December; 8(3): 207-218

Abstract: Given the ethical controversies concerning HIV vaccine trials (HVTs), we aimed to understand through an exploratory study how members of institutional review boards (IRBs) in the United States (US) and research ethics committees (RECs) in South Africa (SA) view issues concerning the process and content of reviews of these studies. We mailed packets of 20 questionnaires to 12 US IRB chairs and administrators and seven REC chairs to distribute to their members. We received 113 questionnaires (76 from the US and 37 from SA). In both countries, members tended to be white males with advanced academic degrees. Compared to the US, SA members called for 'major changes' in HVT protocols more frequently (p = 0.004), and were less likely to think that HVT participants understood risks and benefits (p = 0.033) or informed consent forms (p = 0.000). In both countries, members were divided on several critical issues (e.g. the minimum standard for treatment for HVT participants who became infected during the HVT), but agreed that they needed more training. Of the SA respondents, 40% reported that they were 'self-taught' in ethics. This study, the first we know of to offer quantitative data comparing US vs. non-US IRBs/RECs, thus suggests key similarities and differences (e.g. compared to SA respondents, US respondents appeared to overestimate participants' understanding of informed consent), along with needs for education. These initial exploratory data in this area have important implications for IRBs, RECs, policy-makers and scholars concerning future practice, training, policy, and investigations in research ethics, and prevention and treatment of HIV and other diseases in the developing world and elsewhere.

* Document 641

Reynolds, J.; Crichton, N.; Fisher, Wendy; Sacks, S.
Determining the need for ethical review: a three-stage Delphi study.
Journal of Medical Ethics 2008 December; 34(12): 889-894

Abstract: AIMS: The aims of the study were to explore expert opinion on the distinction between "research" and "audit", and to determine the need for review by a National Health Service (NHS) Research Ethics Committee (REC). BACKGROUND: Under current guidelines only "research" projects within the NHS require REC approval. Concerns have been expressed over difficulties in distinguishing between research and other types of project, and no existing guidelines appear to have been validated. The implications of this confusion include unnecessary REC applications, and crucially, the potential for ethically unsound projects to escape review. METHODS: A three-stage Delphi method was chosen to explore expert opinion and develop consensus. Stage 1 comprised ten semi-structured interviews gathering opinion on distinguishing between types of project and how to determine need for ethical review. Stages 2 and 3 were questionnaires, asking 24 "experts" to rate levels of ethical concern and types of project for a series of questions. Anonymised responses from stage 2 were fed back in stage 3. The final responses were analysed for consensus. RESULTS: Of 46 questions, consensus was achieved for 14 (30.4%) for level of ethical concern and for 15 (32.6%) for type of project. CONCLUSIONS: Several ideas proved discriminatory for classifying the type of project and assessing level of ethical concern, and they can be used to develop an algorithm to determine need for ethical review. There was little relationship between assessment of the level of ethical concern and classification of the project. There was inconsistency in defining and classifying studies as something other than "research" or "audit".

* Document 642

Rivera, Suzanne M.
Clinical research from proposal to implementation: what every clinical investigator should know about the institutional review board.
Journal of Investigative Medicine 2008 December; 56(8): 975-984

* Georgetown users check Georgetown Journal Finder for access to full text

http://jme.bmj.com/content/vol34/issue12/ (link may be outdated)
Document 643
Gross, Cary P.
Racial disparities in clinical trial enrolment [comment]
Lancet 2008 November 15-21; 372(9651): 1713-1714
Georgetown users check Georgetown Journal Finder for access to full text
http://www.thelancet.com/journals/lancet (link may be outdated)

Document 644
Beskow, Laura M.; Dame, Lauren; Costello, E. Jane
Certificates of confidentiality and compelled disclosure of data
Science 2008 November 14; 322(5904): 1054-1055
Georgetown users check Georgetown Journal Finder for access to full text
http://www.sciencemag.org (link may be outdated)

Document 645
Levens, Eric D.; DeCherney, Alan H.
Human oocyte research: the ethics of donation and donor protection
JAMA: The Journal of the American Medical Association 2008 November 12; 300(18): 2174-2176
Georgetown users check Georgetown Journal Finder for access to full text
http://jama.ama-assn.org (link may be outdated)

Document 646
Anya, Ike; Raine, Rosalind
Strengthening clinical and research ethics in Nigeria -- an agenda for change
Lancet 2008 November 1-7; 372(9649): 1594-1597
Georgetown users check Georgetown Journal Finder for access to full text
http://www.thelancet.com/home (link may be outdated)

Document 647
Quality assurance of ethical issues and regulatory aspects relating to good clinical practices in the HELENA Cross-Sectional Study.
Georgetown users check Georgetown Journal Finder for access to full text
Suter, Peter M.; Takala, Jukka

*Science, medicine and industry: are we getting out of the black hole in sepsis research?*


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Sweeney, Daniel A.; Danner, Robert L.; Eichacker, Peter Q.; Natanson, Charles

*Once is not enough: clinical trials in sepsis.*


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---

Finfer, Simon; Ranieri, V. Marco; Thompson, B. Taylor; Barie, Philip S.; Dhainaut, Jean-François; Douglas, Ivor S.; Gårdlund, Bengt; Marshall, John C.; Rhodes, Andrew


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Documents: 651 - 975 of 2150

* Article  Document 651
Portaluppi, Francesco; Touitou, Yvan; Smolensky, Michael H.
Ethical and methodological standards for laboratory and medical biological rhythm research. 
Chronobiology International 2008 November; 25(6): 999-1016
Georgetown users check Georgetown Journal Finder for access to full text

* Article  Document 652
Chamberlain, Barbara
The Office of Human Research Protections. 
Clinical Nurse Specialist 2008 November-December; 22(6): 268
Georgetown users check Georgetown Journal Finder for access to full text

* Article  Document 653
Siedlecki, Sandra L.
Making a difference through research. 
AORN Journal 2008 November; 88(5): 716-729
Georgetown users check Georgetown Journal Finder for access to full text

* Article  Document 654
Martinelli, Paul T.; Czelusta, Adam; Peterson, S. Ray
Self-experimenters in medicine: heroes or fools? Part II Anesthesia, surgery, therapeutics, vaccinations, and vitamin C. 
Clinics in Dermatology 2008 November-December; 26(6): 657-660; discussion 660-661
Georgetown users check Georgetown Journal Finder for access to full text

* Article  Document 655
Barchard, Kimberly A.; Williams, John
Practical advice for conducting ethical online experiments and questionnaires for United States psychologists. 
Behavior Research Methods 2008 November; 40(4): 1111-1128
Georgetown users check Georgetown Journal Finder for access to full text
Spike, Jeffrey
Extend the reach of institutional review boards first, then strengthen their depth.
American Journal of Bioethics 2008 November; 8(11): 11-12
Georgetown users check Georgetown Journal Finder for access to full text
http://bioethics.net (link may be outdated)

Schluger, Neil W.
Improving protection for human research subjects: better oversight, not just more oversight.
Georgetown users check Georgetown Journal Finder for access to full text
http://bioethics.net (link may be outdated)

Hunter, David L. H.
The ESRC research ethics framework and research ethics review at UK universities: rebuilding the Tower of Babel REC by REC.
Journal of Medical Ethics 2008 November; 34(11): 815-820
Abstract: The history of the National Health Service research ethics system in the UK and some of the key drivers for its change into the present system are described. It is suggested that the key drivers were the unnecessary delay of research, the complexity of the array of processes and contradictions between research ethics committee (REC) decisions. It is then argued that the primary drivers for this change are and will be replicated by the systems of research ethics review being put in place at UK universities in response to the Economic and Social Research Council research ethics framework. It is argued that this is particularly problematic for multi-centre review and for researchers who switch institutions. Finally, some potential solutions to this problem and their feasibility are discussed.
Georgetown users check Georgetown Journal Finder for access to full text
http://www.jmedethics.com (link may be outdated)

Dreger, Alice
The vulnerable researcher and the IRB
Georgetown users check Georgetown Journal Finder for access to full text
http://www.thehastingscenter.org/BioethicsForum (link may be outdated)

Dowling, Thomas C.
Disclosure and ethical conduct of clinical research
**Document 661**
Perlman, David

**Public health practice vs research: implications for preparedness and disaster research review by State Health Department IRBs.**
Disaster Medicine and Public Health Preparedness 2008 October; 2(3): 185-191

Georgetown users check [Georgetown Journal Finder](#) for access to full text.

**Document 662**
Saunders, John

**Chair, Committee for Ethical Issues in Medicine, Royal College of Physicians.**
Clinical Medicine 2008 October; 8(5): 508-511

Georgetown users check [Georgetown Journal Finder](#) for access to full text.

**Document 663**
Hanauer, Stephen B.

**The ethics of phase I trials of biologic agents.**
Nature Clinical Practice. Gastroenterology and Hepatology 2008; October; 5(10): 533

Georgetown users check [Georgetown Journal Finder](#) for access to full text.

**Document 664**
Cash, Richard

**Reviewing trials of traditional medicines and other challenges faced by ethics committees**
Indian Journal of Medical Ethics 2008 October-December; 5(4): 185-187

Georgetown users check [Georgetown Journal Finder](#) for access to full text

[http://www.ijme.in](http://www.ijme.in) (link may be outdated)

**Document 665**
Lis, Janet M.; Murray, Melinda G.

**The ins and outs of independent IRBs.**
Journal of Health and Life Sciences Law 2008 October; 2(1): 73, 75-122

Georgetown users check [Georgetown Journal Finder](#) for access to full text.

**Document 666**
Haramati, Linda B.

**Ethical trials to determine the risks and benefits of radiation exposure from coronary CT angiography.**
Journal of the American College of Radiology 2008 October; 5(10): 1073-1076
Document 667
Orvis, Alissa K.; Dellavalle, Robert P.
Institutional review board approval for surveys: why it is necessary.

Document 668
Maloney, Dennis M.
A senior administrator and the chairman of one Institutional Review Board (IRB) must be replaced [case study]
Human Research Report 2008 October; 23(10): 7

Document 669
Maloney, Dennis M.
Institutional Review Board (IRB) violated numerous regulations
Human Research Report 2008 October; 23(10): 6

Document 670
Maloney, Dennis M.
National group supports mandatory training for IRBs
Human Research Report 2008 October; 23(10): 5

Document 671
Maloney, Dennis M.
IRB members and special VA review committees
Human Research Report 2008 October; 23(10): 4

Document 672
Maloney, Dennis M.
When IRBs must review even without any research
Does the European clinical trials directive really improve clinical trial approval time?


Effects of disclosing financial interests on participation in medical research: a randomized vignette trial.

American Heart Journal 2008 October; 156(4): 689-697

The institutional review board and you

Respiratory Care 2008 October; 53(10): 1324

The historical, ethical, and legal background of human-subjects research

Respiratory Care 2008 October; 53(10): 1325-1329

The purpose, composition, and function of an institutional review board: balancing priorities

Respiratory Care 2008 October; 53(10): 1330-1336

Protecting vulnerable subjects in clinical research: children, pregnant women, prisoners, and employees

Respiratory Care 2008 October; 53(10): 1342-1349
Neff, Margaret J.
Institutional review board consideration of chart reviews, case reports, and observational studies
Respiratory Care 2008 October; 53(10): 1350-1353

Schwenzer, Karen J.
Practical tips for working effectively with your institutional review board
Respiratory Care 2008 October; 53(10): 1354-1361

de Melo-Martin, Inmaculada
Response to open peer commentaries on "A duty to participate in research: does social context matter?".
American Journal of Bioethics 2008 October; 8(10): W3-W4

* Rhodes, Rosamond
In defense of the duty to participate in biomedical research.
American Journal of Bioethics 2008 October; 8(10): 37-38

* Ho, Anita
Correcting social ills through mandatory research participation.

Fry, Craig L.
Research participation and internal normativity: understanding why people participate.
American Journal of Bioethics 2008 October; 8(10): 43-44

Impact of recent legislative bills regarding clinical research on Italian ethics committee activity
Journal of Medical Ethics 2008 October; 34(10): 747-750

Abstract: AIMS AND BACKGROUND: The present work assessed the impact of two decrees on ethics committees in Italy, aimed at bringing the national laws on the conduct of clinical trials into line with the rest of the EC, and regulating and facilitating not-for-profit research. MATERIAL AND METHODS: Prospectively collected data from an Italian multicentre study were examined with respect to the ethics review process. Administrative and time elements of the review process were audited. Main outcome measures were time between the application submission and the ethics committee definitive opinion, type and number of application submission forms, number of ethics committees that refused fee exemption, and time between the ethics committee approval and the administrative authorisation. RESULTS: A total of 134 local research ethics committees (LRECs) were approached. Application submission procedures and application forms varied greatly; paper submission was mandatory. The median time from submission to approval was 72 days. Only two LRECs refused the fee exemption. The median time from LREC approval to administrative agreement was 50 days and only 9.6% of local authorities came to a verbal agreement with the sponsor. CONCLUSIONS: Italian LRECs are still not sufficiently efficient in complying with the Directive 2001/20/EC requirement (60 days). Better coordination of LRECs work is needed although the optimal level of coordination between them is still unknown. In the meantime, national guidelines are needed concerning the application of Directive 2001/20/EC. The behaviour of Italian LRECs towards not-for-profit research was excellent although only the fee exemption was requested.

http://www.jmedethics.com (link may be outdated)
Lenzer, Jeanne

Truly independent research?
BMJ: British Medical Journal 2008 September 13; 337(7670): 602-606

Georgetown users check Georgetown Journal Finder for access to full text

http://www.bmj.com (link may be outdated)

Wildes, Kevin Wm.

The rebirth of a city: birth and achievement of the ethics review board

Georgetown users check Georgetown Journal Finder for access to full text

Clayman, Ralph V.; Agich, George J.

The ethical challenge posed by surgical innovation [discussion]
Medical Ethics Newsletter [Lahey Clinic] 2008 Fall; 15(3): 6-7

Georgetown users check Georgetown Journal Finder for access to full text

http://www.lahey.org/Ethics (link may be outdated)

Goodman, Allison J.

Abigail Alliance v. Von Eschenbach: restricting access to potentially lifesaving drugs since 2007

Georgetown users check Georgetown Journal Finder for access to full text

Bennett, Belinda; Karpin, Isabel

Regulatory options for gender equity in health research

Georgetown users check Georgetown Journal Finder for access to full text

Rogers, Wendy; Ballantyne, Angela

When is sex-specific research appropriate?
International Journal of Feminist Approaches to Bioethics 2008 Fall; 1(2): 36-57

Georgetown users check Georgetown Journal Finder for access to full text
Diniz, Debora
Research ethics in social sciences: the Severina's Story documentary
Georgetown users check Georgetown Journal Finder for access to full text

Short, Donald; Martineau, Fasken; Sampson, Heather; Heus, Katharine
Improving clinical research in Canada: Reb-LS with a cause
Heath Law in Canada 2008 September; 29(1): 1-4
Georgetown users check Georgetown Journal Finder for access to full text

Maloney, Dennis M.
OHRP investigation: numerous glaring deficiencies in overall human subject protections
Human Research Report 2008 September; 23(9): 7
Georgetown users check Georgetown Journal Finder for access to full text

Maloney, Dennis M.
IRBs and location of research sites
Human Research Report 2008 September; 23(9): 3
Georgetown users check Georgetown Journal Finder for access to full text

Schwartz, Barry;
Safety in human research: past problems and current challenges from a Canadian perspective.
HEC(Healthcare Ethics Committee)Forum 2008 September; 20(3): 277-290
Georgetown users check Georgetown Journal Finder for access to full text

Stefánsson, Einar; Atladóttir, Olóf Yrr; Gudbjornsson, Bjom; Guðbjörnsson, Bjöm
Are ethics rules too strict in retrospective clinical studies?
Acta Ophthalmologica 2008 September; 86(6): 588-590
Georgetown users check Georgetown Journal Finder for access to full text

Sims, Jennifer M.
An introduction to institutional review boards.
Dimensions of Critical Care Nursing 2008 September-October; 27(5): 223-225

Georgetown users check Georgetown Journal Finder for access to full text

Document 701
Chang, Jason J.; Xu, Jianqing; Fan, Daimin
Contemporary Clinical Trials 2008 September; 29(5): 654-662

Georgetown users check Georgetown Journal Finder for access to full text

Document 702
Singer, Eleanor; Couper, Mick P.
Do incentives exert undue influence on survey participation? Experimental evidence
Abstract: Monetary incentives are increasingly used to help motivate survey participation. Research Ethics Committees have begun to ask whether, and under what conditions, the use of monetary incentives to induce participation might be coercive. The article reports research from an online vignette-based study bearing on this question, concluding that at present the evidence suggests that larger incentives do not induce research participants to accept higher risks than they would be unwilling to accept with smaller ones.

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Document 703
DuBois, James M.; Volpe, Rebecca L.; Rangel, Erica K.
Hidden empirical research ethics: a review of three health journals from 2005 through 2006
Abstract: We hypothesized that a significant amount of empirical data pertinent to research ethics is currently inaccessible to research ethics committee or Institutional Review Board (IRB) members for at least three reasons: it is published in non-ethics journals; articles are not adequately indexed using ethics-related keywords; and articles do not discuss the ethical significance of their data. We reviewed all articles from three health journals from January 2005 to December 2006, and identified 26 articles that contained data pertinent to research ethics. Only 7 articles contained keywords clearly related to research ethics; 15 of the articles contained no discussion of the ethical significance of their findings. Overall the articles we found constituted 2.2% of the research articles published in the three journals during the two-year period. If the same average number of articles were extrapolated to the top 100 of the approximately 5,000 journals indexed in MEDLINE, then at least 433 hidden ethics articles would be published each year. We conclude that better indexing of articles is needed, that IRB members and researchers need training to identify relevant data in the literature, and that IRB composition should include members from diverse disciplines familiar with ethics-relevant empirical data in their respective disciplines.

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Document 704
DuBois, James M.
Hidden data for research ethicists: an introduction to the concept and a series of papers
Abstract: This special section of the Journal of Empirical Research on Human Research Ethics (JERHRE) is based upon the assumption that much of the best empirical data relevant to research ethics is hidden from the view of Research Ethics Committee (REC) members and others who are interested in research ethics. There are at least
three different senses in which ethics-relevant empirical research may be hidden: (1) it may be published in a journal that ethics committee members would not regularly read, (2) it may not use key words that would guide one to its ethics-relevant content, or (3) it may be sequestered in part of a research article that is about something else. This special section of JERHRE reviews all of these types of "hidden ethics" articles on the following issues: What is the relative frequency of hidden ethics articles in journals that focus on vulnerable populations? What does the non-ethics literature in clinical research and experimental economic decision theory teach us about ways of improving subjects' comprehension of risk information? How satisfied are parents and children with their experience with pediatric psychotropic medication trials? And, how can retention rates be improved in longitudinal studies of difficult regimens such as drug rehabilitation? There is a major amount of ethics-relevant literature that is hidden. Without better ways of communicating the existence of this literature through use of key words, or recasting of the information to highlight its relevance to research ethics in journals that ethics committee members read, the benefits of evidence-based ethical problem solving will be lost.

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* □ Document 705
Mann, Howard; Reyes, Maria
**Identifying the human research subject in cluster randomized controlled trials**
IRB: Ethics and Human Research 2008 September-October; 30(5): 14-18

Georgetown users check Georgetown Journal Finder for access to full text

* □ Document 706
Allison, Robert D.; Abbott, Lura J.; Wichman, Alison
**Nonscientist IRB members at the NIH**
IRB: Ethics and Human Research 2008 September-October; 30(5): 8-13

Georgetown users check Georgetown Journal Finder for access to full text

* □ Document 707
Rushton, H. Gil
**Institutional review board approval-more red tape or a step in the right direction?**
Journal of Urology 2008 September; 180(3): 804-805

Georgetown users check Georgetown Journal Finder for access to full text

* □ Document 708
Blümle, A.; Antes, G.; Schumacher, M.; Just, H.; von Elm, E.
**Clinical research projects at a German medical faculty: follow-up from ethical approval to publication and citation by others**

**Abstract:** Background: Only data of published study results are available to the scientific community for further use such as informing future research and synthesis of available evidence. If study results are reported selectively, reporting bias and distortion of summarised estimates of effect or harm of treatments can occur. The publication and citation of results of clinical research conducted in Germany was studied. Methods: The protocols of clinical research projects submitted to the research ethics committee of the University of Freiburg (Germany) in 2000 were analysed. Published full articles in several databases were searched and investigators contacted. Data on study and publication characteristics were extracted from protocols and corresponding publications. Results: 299 study protocols were included. The most frequent study design was randomised controlled trial (141; 47%), followed by uncontrolled studies (61; 20%), laboratory studies (30; 10%) and non-randomised studies (29; 10%). 182 (61%) were multicentre studies including 97 (53%) international collaborations. 152 of 299 (51%) had commercial (co-)funding
and 46 (15%) non-commercial funding. 109 of the 225 completed protocols corresponded to at least one full publication (total 210 articles); the publication rate was 48%. 168 of 210 identified publications (80%) were cited in articles indexed in the ISI Web of Science. The median was 11 citations per publication (range 0–1151).

Conclusions: Results of German clinical research projects conducted are largely underreported. Barriers to successful publication need to be identified and appropriate measures taken. Close monitoring of projects until publication and adequate support provided to investigators may help remedy the prevailing underreporting of research.

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http://www.jmedethics.com (link may be outdated)

*  Document 709
Wilkinson, Mark
Ethical review of undergraduate student research in the NHS: evolution of the system could benefit us all

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http://www.jmedethics.com (link may be outdated)

*  Document 710
Resnick, D.B.
Increasing the amount of payment to research subjects

Abstract: This article discusses some ethical issues that can arise when researchers decide to increase the amount of payment offered to research subjects to boost enrollment. Would increasing the amount of payment be unfair to subjects who have already consented to participate in the study? This article considers how five different models of payment—the free market model, the wage payment model, the reimbursement model, the appreciation model, and the fair benefits model—would approach this issue. The article also considers several practical problems related to changing the amount of payment, including determining whether there is enough money in the budget to offer additional payments to subjects who have already enrolled, ascertaining how difficult it will be to re-contact subjects, and developing a plan of action for responding to subjects who find out they are receiving less money and demand an explanation.

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http://www.jmedethics.com (link may be outdated)

*  Document 711
Benham, Bryan
Moral accountability and debriefing
Kennedy Institute of Ethics Journal 2008 September; 18(3): 253-273

Abstract: What is the ethical significance of debriefing in deceptive research? The standard view of debriefing is that it serves to disclose the deception to the participant and is a means of evaluating and mitigating potential harms that may have resulted from involvement in the research. However, as the article by Miller, Gluck, and Wendler in this issue of the Kennedy Institute of Ethics Journal points out, there has been little systematic attention to the ethics of debriefing, particularly with regard to the role of debriefing in addressing the prima facie moral wrong of deception itself. They argue that in addition to mitigating the harms of deception, debriefing should include an apology to participants for being deceived. In the current paper, I argue that an apology is not morally obligatory in most research contexts. Debriefing should be considered an opportunity to further define the researcher-participant relationship without the need to be remorseful about the research practice.
Debriefing and accountability in deceptive research

Miller, Franklin G.; Gluck, John P., Jr.; Wendler, David

Debriefing is a standard ethical requirement for human research involving the use of deception. Little systematic attention, however, has been devoted to explaining the ethical significance of debriefing and the specific ethical functions that it serves. In this article, we develop an account of debriefing as a tool of moral accountability for the prima facie wrong of deception. Specifically, we contend that debriefing should include a responsibility to promote transparency by explaining the deception and its rationale, to provide an apology to subjects for infringing the principle of respect for persons, and to offer subjects an opportunity to withdraw their data. We also present recommendations concerning the discussion of deception in scientific articles reporting the results of research using deception.

Comparing drug effectiveness at health plans: the ethics of cluster randomized trials

Sabin, James E.; Mazor, Kathleen; Meterko, Vanessa; Goff, Sarah L.; Platt, Richard

"Cluster randomized trials," in which groups of patients are randomly assigned to different therapeutic interventions, provide a powerful way of evaluating drugs. CRTs have not been widely used, in good part because of concerns about whether patients must give informed consent to participate in them. A better understanding of how CRTs fit into clinical practice resolves the concerns.

Learning from clinical experience

Baily, Mary Ann

Research ethics committees: the role of ethics in a regulatory authority

McGuinness, S.

This paper is an examination of how research ethics committees have evolved from being advisory committees to more formal regulatory authorities. It is argued that the role of ethics committees should be broader than simple ethical review. Inconsistency in outcome should not be taken to signal failure. Procedural fairness is of the utmost importance. Nor should ethics committees be seen to diminish the ethical responsibilities of researchers themselves.
Valdez-Martínez, Edith; Lifshitz-Guinzberg, Alberto; Medesigo-Micete, José; Bedolla, Miguel

Institutional ethics committees in Mexico: the ambiguous boundary between health care ethics and research ethics = Los comités de ética clínica en México: la ambigua frontera entre la ética asistencial y la ética en investigación clínica.


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Catholic Medical Association National Catholic Bioethics Center [NCBC]

A Catholic guide to ethical clinical research
Linacre Quarterly 2008 August; 75(3): 181-224

Georgetown users check Georgetown Journal Finder for access to full text


Adults with intellectual disabilities in research: scientific gatekeepers' perceptions of risks and protections [abstract]
Journal of Intellectual Disability Research 2008 August; 52(8-9): 697

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http://www.blackwell-science.com/jir (link may be outdated)

Elliott, D.

Research ethics boards: attitudes towards people with intellectual disabilities [abstract]
Journal of Intellectual Disability Research 2008 August; 52(8-9):697

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http://www.blackwell-science.com/jir (link may be outdated)

Driscoll, Andrea; Currey, Judy; Worrall-Carter, Linda; Stewart, Simon

Ethical dilemmas of a large national multi-centre study in Australia: time for some consistency.
Journal of Clinical Nursing 2008 August; 17(16): 2212-2220

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Maloney, Dennis M.

Local institutional review boards (IRBs) might or might not work with centralized IRBs (CIRBs)
Human Research Report 2008 August; 23(8): 9
* Document 722
Maloney, Dennis M.
Major proposal on the protection of human research participants
Human Research Report 2008 August; 23(8): 1-3

* Document 723
Shamoo, A.E.; Katzel, L.I.
How should adverse events be reported in US clinical trials?: ethical considerations.
Clinical Pharmacology and Therapeutics 2008 August; 84(2): 275-278

* Document 724
Zahedi, Farzaneh; Larijani, Bagher
National bioethical legislation and guidelines for biomedical research in the Islamic Republic of Iran.

* Document 725
Williams, John R.
The Declaration of Helsinki and public health.

* Document 726
Dixon-Woods, Mary; Angell, Emma; Tarrant, Carolyn; Thomas, Anne
What do research ethics committees say about applications to do cancer trials?
Lancet Oncology 2008 August; 9(8): 700-701

* Document 727
Pidgeon, Nick; Simmons, Peter; Sarre, Sophie; Henwood, Karen; Smith, Noel
The ethics of socio-cultural risk research
**Document 728**

Sheehan, M.

*Should research ethics committees meet in public?*

Journal of Medical Ethics 2008 August; 34(8): 631-635

Abstract: Currently, research ethics committees (RECs) in the UK meet behind closed doors—their workings and most of the content of their decisions are unavailable to the general public. There is a significant tension between this current practice and a broader societal presumption of openness. As a form of public institution, the REC system exists to oversee research from the perspective of society generally. An important part of this tension turns on the kind of justification that might be offered for the REC system. In this paper I adapt Daniels and Sabin's accountability for reasonableness model for just resource allocation to the research ethics context to provide some structural legitimacy and to enable progress on the question of openness. After considering the consequences of adopting this model for open REC meetings, I then examine some reasons that might be offered against open meetings. These arguments do not overwhelm the core intuitions behind the presumption of openness but they do, I suggest, give us reason to retreat from fully public meetings. I conclude that there should be important adjustments to the system towards public accountability and that there are grounds for stopping short of fully public meetings.

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http://www.jmedethics.com (link may be outdated)

---

**Document 729**

McNamee, David; James, Astrid; Kleinert, Sabine

*Protocol review at The Lancet*

Lancet 2008 July 19-25; 372(9634): 189-190

*Georgetown users check [Georgetown Journal Finder](http://www.thelancet.com/journals/lancet) for access to full text*

http://www.thelancet.com/journals/lancet (link may be outdated)

---

**Document 730**

Halpern, Scott D.; Doyle, Ramona; Kawut, Steven M.

*The ethics of randomized clinical trials in pulmonary arterial hypertension*


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**Document 731**

Next stop, don't block the doors: opening up access to clinical trials results

PLoS medicine 2008 July 15; 5(7): e160

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---

**Document 732**

Pandey, A.; Aggarwal, Ar.; Seth, Sd.; Maulik, M.; Bano, R.; Juneja, A.

*Clinical trials registry -- India: redefining the conduct of clinical trials.*

Indian Journal of Cancer 2008 July-September; 45(3): 79-82

*Georgetown users check [Georgetown Journal Finder](http://www.jmedethics.com) for access to full text*
**Borenstein, Jason**

**The expanding purview: institutional review boards and the review of human subjects research**

Accountability in Research 2008 July-September; 15(3): 188-204

**Abstract:** The implications of the institutional review board (IRB) system’s growing purview are examined. Among the issues discussed are whether IRBs are censoring research and whether the IRB review process fundamentally alters the research that is being conducted. The intersection between IRB review and free speech is also explored. In general, it is argued that the review system for human subjects research (HSR) should be modified in order to limit the scope of IRB review.

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**Amin, Sanjiv B.; McDermott, Michael P.; Shamoo, Adil E.**

**Clinical trials of drugs used off-label in neonates: ethical issues and alternative study designs**


**Abstract:** The use of drugs for indications unapproved by the Food and Drug Administration (FDA), often called "off label use," is widespread in children, including neonates. The widespread off-label use of drugs in neonates presents ethical and safety challenges. Since the passage of the Best Pharmaceuticals for Children Act (BPCA) in 2002, both the FDA and National Institutes of Health (NIH) have taken initiatives to facilitate and encourage research to achieve the necessary labeling for drugs routinely used in infants and children. Federal regulations provide broad rules and guidance for the protection of human subjects in research. However, there are ethical issues that a physician may face when designing clinical trials of drugs in neonates that are routinely used off-label and widely believed to be beneficial. We attempt to describe these ethical challenges and provide recommendations, including alternative study designs, to resolve them in an ethical framework that takes into account the Belmont Report, the statement of the World Medical Association (WMA), and federal regulations.

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**Buckley, Brendan M.**

**Clinical trials of orphan medicines**

Lancet 2008 June 14-20; 371(9629): 2051-2055

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[http://www.thelancet.com/journals/lancet](http://www.thelancet.com/journals/lancet) (link may be outdated)

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**Loblay, Robert H.**

**Human research ethics—a work in progress.**

Medical Journal of Australia 2008 June 2; 188(11): 628-629

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**Ballantyne, Angela J.; Rogers, Wendy A.**

**Fair inclusion of men and women in Australian clinical research: views from ethics committee chairs.**

Medical Journal of Australia 2008 June 2; 188(11): 653-656

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Document 744
Ndebele, Paul; Mfutso-Bengo, Joseph; Mduluza, Takafira
Compensating clinical trial participants from limited resource settings in internationally sponsored clinical trials: a proposal.
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http://www.mmj.medcol.mw/ (link may be outdated)

Document 745
Mfutso-Bengo, Joseph; Masiye, Francis; Muula, Adamson
Ethical challenges in conducting research in humanitarian crisis situations.
Georgetown users check Georgetown Journal Finder for access to full text

http://www.mmj.medcol.mw/ (link may be outdated)

Document 746
Maloney, Dennis M.
Future recommendations for IRBs on survey studies
Human Research Report 2008 June; 23(6): 5
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Document 747
Maloney, Dennis M.
Report: FDA should inspect more IRBs
Human Research Report 2008 June; 23(6): 5
Georgetown users check Georgetown Journal Finder for access to full text

Document 748
DuBois, James M.; Dueker, Jeffrey M.; Anderson, Emily E.; Campbell, Jean
The development and assessment of an NIH-funded research ethics training program
Academic Medicine 2008 June; 83(6): 596-603
Georgetown users check Georgetown Journal Finder for access to full text

http://www.academicmedicine.org/ (link may be outdated)

Document 749
Burns, Lawrence
What is the scope for the interpretation of dignity in research involving human subjects?
Medicine, Health Care and Philosophy 2008 June; 11(2): 191-208
Abstract: Drawing on Lennart Nordenfelt's distinction between the four distinct senses of dignity, I elucidate the meaning of dignity in the context of research involving human subjects. I acknowledge that different interpretations of the personal senses of dignity may be acceptable in human subject research, but that inherent dignity (Menschenwürde) is not open to interpretation in the same way. In order to map out the grounds for interpreting dignity, I examine the unique application of the principle of respect for dignity in Canada's research ethics guidelines. These guidelines are unique because they consider dignity to be a foundational concept and the protection of the dignity of research subjects is regarded as a measure that prevents "the impoverishment of humanity as a whole". While the conception of humanity invoked here is incomplete, Canada's research ethics guidelines nevertheless represent a more European approach to biomedical policy. Finally, in order to correct a pervasive blind spot in contemporary policy on research involving human subjects, I sketch a functional model for attributing inherent dignity that avoids the untenable connotations of speciesism.

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Document 750
Fisher, Jill A.
Practicing research ethics: private-sector physicians and pharmaceutical clinical trials
Social Science and Medicine 2008 June; 66(12): 2495-2505

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Document 751
Moscou, Susan
The conceptualization and operationalization of race and ethnicity by health services researchers.
Nursing Inquiry 2008 June; 15(2): 94-105

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Document 752
Simon Carney, A.; Watson, David I.
Human ethics and research governance: implications for surgical research.

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http://www3.interscience.wiley.com/journal/120118388/grouphome/home.html (link may be outdated)

Document 753
Boutain, Doris
The next crossroad: indigenous epistemologies for qualitative research and acceptance beyond IRB compliance.
Journal of Nursing Education 2008 June; 47(6): 243-244

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Document 754
Hallowell, Nina; Cooke, Sarah; Crawford, Gill; Parker, Michael; Lucassen, Anneke
Ethics and research governance: the views of researchers, health-care professionals and other stakeholders
Abstract: The objective of this study is to describe researchers', health-care providers' and other stakeholders' views of ethical review and research governance procedures. The study design involved qualitative semi-structured interviews. Participants included 60 individuals who either undertook research in the subspecialty of cancer genetics (n = 40) or were involved in biomedical research in other capacities (n = 20), e.g. research governance and oversight, patient support groups or research funding. While all interviewees observed that oversight is necessary to protect research participants, ethical review and research governance (ERG) arrangements were described negatively throughout these interviews. Interviewees identified a number of problems with ERG, including: over-bureaucratization, over-standardization of information requirements for different types of research, a lack of standardization in the types of information required by different committees for the same research and a lack of consistency in different committees' responses. A number of solutions were proposed including streamlining application procedures and harmonizing committees' responses and information requirements. Recent reports suggest that ethical review procedures and research governance arrangements threaten the possibility of undertaking clinical research in the UK, hence the introduction of the Integrated Research Application System (IRAS) is long overdue. However, while IRAS may solve some of the problems identified by interviewees, it remains to be seen to what extent it will impact upon the very negative perceptions of ethics and research governance procedures reported here.

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**Document 755**

McCartney, Margaret

**Leaping to conclusions**

BMJ: British Medical Journal 2008 May 31; 336(7655): 1213-1214

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**Document 756**

Dickens, Bernard M.


Annals of Internal Medicine 2008 May 20; 148(10): 796

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**Document 757**

Shalowitz, David I.; Miller, Franklin G.

**Communicating the results of clinical research to participants: attitudes, practices, and future directions.**


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**Document 758**

Maloney, Dennis M.

**Case study: university administrators told that they undermined the authority of their IRB**

Human Research Report 2008 May; 23(5): 7
Document 759
Maloney, Dennis M.
**Faculty views on burdens caused by IRB compliance**
Human Research Report 2008 May; 23(5): 5

Document 760
Ailinger, Rita L; Black, Patricia L; Lima-Garcia, Natalie
**Use of electronic monitoring in clinical nursing research.**
Clinical Nursing Research 2008 May; 17(2): 89-97

Document 761
Abdur Rab, Mohammad; Afzal, Mohammad; Abou-Zeid, Alaa; Silverman, Henry
**Ethical practices for health research in the Eastern Mediterranean region of the World Health Organization: a retrospective data analysis.**

Document 762
Erler, Cheryl J.; Thompson, Cheryl Bagley
**Part II: ethics, human rights, and clinical research.**
Air Medical Journal 2008 May-June; 27(3): 110-113

Document 763
Wendler, David; Grady, Christine
**What should research participants understand to understand they are participants in research?**
Bioethics 2008 May: 22(4): 203-208

**Abstract:** To give valid informed consent to participate in clinical research, potential participants should understand the risks, potential benefits, procedures, and alternatives. Potential participants also should understand that they are being invited to participate in research. Yet it is unclear what potential participants need to understand to satisfy this particular requirement. As a result, it is unclear what additional information investigators should disclose about the research; and it is also unclear when failures of understanding in this respect undermine the validity of potential participants' informed consent. An analysis of individuals' interests suggests that potential participants need to understand three additional facts to understand that they are being invited to participate in research: 1) research contribution: those who enroll in the study will be contributing to a project designed to gather generalizable knowledge to benefit others in the future; 2) research relationship: the investigators will rely on participants' efforts to gather the
generalizable knowledge to benefit others; and 3) research impact: the extent to which participating in the study will alter what participants do and what happens to them.

* Document 764
Barth, Immanuel; Krafft, Hartmut; Weber, Gabriele; Keller-Stanislawski, Brigitte; Cichutek, Klaus
Good clinical practice in the European Union
Human Gene Therapy 2008 May; 19(5): 441-442

* Document 765
Fromell, Gregg J.
Good clinical practice standards: what they are and some tools to support them
Human Gene Therapy 2008 May; 19(5): 431-440

* Document 766
Macklin, Ruth
How independent are IRBs?

* Document 767
Norton, Karleen; Wilson, Donna M.
Continuing ethics review practices by Canadian research ethics boards
IRB: Ethics and Human Research 2008 May-June; 30(3): 10-14

* Document 768
Arshad, A.; Arkwright, P.D.
Status of healthcare studies submitted to UK research ethics committees for approval in 2004-5
Journal of Medical Ethics 2008 May; 34(5): 393-395

Abstract: BACKGROUND: In view of the increasing complexity of research ethics committee (REC) applications and thus the time and expense involved in completing the forms, continual monitoring of outcome of clinical research studies for which ethics applications have been submitted is essential in determining whether resources are being effectively used, or alternatively whether significant numbers of research proposals are abandoned because of lack of funding or manpower. Previously published surveys for which data are available examined outcome of studies receiving REC approval 10 or more years ago. METHODS: A prospective questionnaire-based survey sent out in July 2006 to all 506 principal investigators who submitted research ethics applications to nine Greater Manchester RECs between April 2004 and March 2005. Data on the outcome of REC applications, and the status of the research study were collected and analysed. RESULTS: 288 of the 506 (57%) questionnaires were returned. 97% of REC applications were approved, and 87% of studies were in progress or had been completed 1-2 years after approval had been granted. Researchers employed by universities (51%), healthcare (43%) and the pharmaceutical industry...
(6%) had similar rates of success in initiating research studies. CONCLUSIONS: This survey suggests that most research studies submitted to RECs in Manchester, UK are approved and initiated.

http://www.jmedethics.com (link may be outdated)

Document 769
Gilbert, Susan
Financial ties in clinical trials: do volunteers care?

http://www.bioethicsforum.org (link may be outdated)

Document 770
Borer, Jeffrey S.; Gordon, David J.; Geller, Nancy L.
When should data and safety monitoring committees share interim results in cardiovascular trials?

http://jama.ama-assn.org (link may be outdated)

Document 771
von Elm, Erik; Röllin, Alexandra; Blümle, Anette; Huwiler, Karin; Witschi, Mark; Egger, Matthias
Publication and non-publication of clinical trials: longitudinal study of applications submitted to a research ethics committee.
Swiss Medical Weekly 2008 April 5; 138(13-14): 197-203

Document 772
Whitney, Simon N.; Alcser, Kirsten; Schneider, Carl; McCullough, Laurence B.; McGuire, Amy L.; Volk, Robert J.
Principal investigator views of the IRB system.
International Journal of Medical Sciences 2008 April 2; 5(2): 68-72

Document 773
Oyibo, W.A.; Krugher, M.; Fagbenro-Beyioku, A.F.
The roles, challenges and institutionalization of institutional review boards.
Pai, Sanjay A.


Indian Journal of Medicine 2008 April-June; 5(2): 89

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Maloney, Dennis M.

IRBs not getting COI data that the need for reviews

Human Research Report 2008 April; 23(4): 6

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Maloney, Dennis M.

Health care practice versus human subjects research

Human Research Report 2008 April; 23(4): 3

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---

Maloney, Dennis M.

Updated tutorial meets requirement for initial education on protecting subjects


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---

Lubowitz, James H.; Poehling, Gary G.; Burkhart, Stephen S.

Rules of the game: institutional review boards.

Arthroscopy 2008 April; 24(4): 373-374

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---

Raftery, J.; Bryant, J.; Powell, J.; Kerr, C.; Hawker, S.

Payment to healthcare professionals for patient recruitment to trials: systematic review and qualitative study.

Health Technology Assessment 2008 April; 12(10): 1-128, iii

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Document 780
Robertson, Christopher
Making pragmatism practicable for the institutional review board
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http://bioethics.net (link may be outdated)

Document 781
Benham, Bryan
What's in a name?
Georgetown users check Georgetown Journal Finder for access to full text
http://bioethics.net (link may be outdated)

Document 782
Kon, Alexander A.
Real pragmatism, kids, and the Clinical and Translational Science Award (CTSA)
American Journal of Bioethics 2008 April; 8(4): 45-47
Georgetown users check Georgetown Journal Finder for access to full text
http://bioethics.net (link may be outdated)

Document 783
Goldberg, Daniel
Pragmatism and virtue ethics in clinical research
Georgetown users check Georgetown Journal Finder for access to full text
http://bioethics.net (link may be outdated)

Document 784
Viens, A.M.
Towards a reasons-based pragmatic ethical framework
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http://bioethics.net (link may be outdated)

Document 785
Spriggs, Merle
Is pragmatism just an apology for unrestrained science?
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http://bioethics.net (link may be outdated)

* Document 786
Nelson, Robert M.
Institutional review boards lack the moral legitimacy to reinterpret subpart D
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http://bioethics.net (link may be outdated)

* Document 787
Lawrence, Ryan E.; Curlin, Farr A.
Misplaced flexibility: revise policies but cling to principles
American Journal of Bioethics 2008 April; 8(4): 36-37
Georgetown users check Georgetown Journal Finder for access to full text
http://bioethics.net (link may be outdated)

* Document 788
Trachtman, Howard
Minority report
Georgetown users check Georgetown Journal Finder for access to full text
http://bioethics.net (link may be outdated)

* Document 789
Hester, D. Micah; Brown, Joseph; Schonfeld, Toby
Pragmatism, principles, and protection
American Journal of Bioethics 2008 April; 8(4): 32-34
Georgetown users check Georgetown Journal Finder for access to full text
http://bioethics.net (link may be outdated)

* Document 790
Brendel, David H.; Miller, Franklin G.
A plea for pragmatism in clinical research ethics
American Journal of Bioethics 2008 April; 8(4): 24-31
Abstract: Pragmatism is a distinctive approach to clinical research ethics that can guide bioethicists and members of institutional review boards (IRBs) as they struggle to balance the competing values of promoting medical research and protecting human subjects participating in it. After defining our understanding of pragmatism in the setting of clinical research ethics, we show how a pragmatic approach can provide guidance not only for the day-to-day functioning of the IRB, but also for evaluation of policy standards, such as the one that addresses acceptable risks for healthy children in clinical research trials. We also show how pragmatic considerations might influence the debate about the use of deception in clinical research. Finally, we show how a pragmatic approach, by regarding the promotion of human research and the protection of human subjects as equally important values, helps to break down the false dichotomy between science and ethics in clinical research.

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http://bioethics.net (link may be outdated)

* Document 791
Willison, D.J.; Emerson, C.; Szala-Meneok, K.V.; Gibson, E.; Schwartz, L.; Weisbaum, K.M.; Fournier, F.; Brazil, K.; Coughlin, M.D.
Access to medical records for research purposes: varying perceptions across research ethics boards
Journal of Medical Ethics 2008 April; 34(4): 308-314
Abstract: Introduction: Variation across research ethics boards (REBs) in conditions placed on access to medical records for research purposes raises concerns around negative impacts on research quality and on human subject protection, including privacy. Aim: To study variation in REB consent requirements for retrospective chart review and who may have access to the medical record for data abstraction. Methods: Thirty 90-min face-to-face interviews were conducted with REB chairs and administrators affiliated with faculties of medicine in Canadian universities, using structured questions around a case study with open-ended responses. Interviews were recorded, transcribed and coded manually. Results: Fourteen sites (47%) required individual patient consent for the study to proceed as proposed. Three (10%) indicated that their response would depend on how potentially identifying variables would be managed. Eleven sites (38%) did not require consent. Two (7%) suggested a notification and opt-out process. Most stated that consent would be required if identifiable information was being abstracted from the record. Among those not requiring consent, there was substantial variation in recognising that the abstracted information could potentially indirectly re-identify individuals. Concern over access to medical records by an outside individual was also associated with requirement for consent. Eighteen sites (60%) required full committee review. Sixteen (53%) allowed an external research assistant to abstract information from the health record. Conclusions: Large variation was found across sites in the requirement for consent for research involving access to medical records. REBs need training in best practices for protecting privacy and confidentiality in health research. A forum for REB chairs to confidentially share concerns and decisions about specific studies could also reduce variation in decisions.

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http://www.jmedethics.com (link may be outdated)

* Document 792
Davies, H.; Wells, F.; Druml, C.
How can we provide effective training for research ethics committee members? A European assessment
Journal of Medical Ethics 2008 April; 34(4): 301-302
Abstract: Training for members of research ethics committees (RECs) varies from state to state in Europe. To follow this up, the European Forum for Good Clinical Practice organised a workshop in March 2007 to explore these issues and look for solutions. This article summarises the discussion, providing ways forward to develop REC training.

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http://www.jmedethics.com (link may be outdated)
Document 793
Atici, E.; Erdemir, A.D.
Ethics in a scientific approach: the importance of the biostatistician in research ethics committees
Journal of Medical Ethics 2008 April; 34(4): 297-300
Abstract: In medical practice and research it is necessary to consider the rights of the researcher or physician and of the subject or patient, to conform to scientific standards and to examine the appropriateness with respect to laws and moral values. Research ethics committees have an important role to play in ensuring the ethical standards and scientific merit of research on human subjects. Research of no scientific value is also against ethical principles. To obtain valid and reliable results from biomedical research, it is a scientific and ethical obligation to make use of the science of statistics. Therefore, for research to be evaluated using biostatistics intensively from ethical and scientific points of view, a biostatistics expert is necessary on research ethics committees. Developments in Turkey are used as examples.

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http://www.jmedethics.com (link may be outdated)

Document 794
Coleman, Carl H.; Bouésséau, Marie-Charlotte
How do we know that research ethics committees are really working? The neglected role of outcomes assessment in research ethics review
Abstract: Background: Countries are increasingly devoting significant resources to creating or strengthening research ethics committees, but there has been insufficient attention to assessing whether these committees are actually improving the protection of human research participants. Discussion: Research ethics committees face numerous obstacles to achieving their goal of improving research participant protection. These include the inherently amorphous nature of ethics review, the tendency of regulatory systems to encourage a focus on form over substance, financial and resource constraints, and conflicts of interest. Auditing and accreditation programs can improve the quality of ethics review by encouraging the development of standardized policies and procedures, promoting a common base of knowledge, and enhancing the status of research ethics committees within their own institutions. However, these mechanisms focus largely on questions of structure and process and are therefore incapable of answering many critical questions about ethics committees' actual impact on research practices. The first step in determining whether research ethics committees are achieving their intended function is to identify what prospective research participants and their communities hope to get out of the ethics review process. Answers to this question can help guide the development of effective outcomes assessment measures. It is also important to determine whether research ethics committees' guidance to investigators is actually being followed. Finally, the information developed through outcomes assessment must be disseminated to key decision-makers and incorporated into practice. This article offers concrete suggestions for achieving these goals. Conclusion: Outcomes assessment of research ethics committees should address the following questions: First, does research ethics committee review improve participants' understanding of the risks and potential benefits of studies? Second, does the process affect prospective participants' decisions about whether to participate in research? Third, does it change participants' subjective experiences in studies or their attitudes about research? Fourth, does it reduce the riskiness of research? Fifth, does it result in more research responsive to the local community's self-identified needs? Sixth, is research ethics committees' guidance to researchers actually being followed?

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http://www.biomedcentral.com/1472-6939/9/6 (link may be outdated)

Document 795
Saginur, Raphael; Dent, Susan F.; Schwartz, Lisa; Heslegrave, Ronald; Stacey, Sid; Manzo, Janet
Ontario Cancer Research Ethics Board: lessons learned from developing a multicenter regional institutional review board
**Document 796**

Spriggs, Merle P.; Gillam, Lynn H.
*Consent in paediatric research: an evaluation of the guidance provided in the 2007 NHMRC national statement on ethical conduct in human research*
Medical Journal of Australia 2008 March 17; 188(6): 360-362

Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 797**

Halpern, Sydney
*Hybrid design, systemic rigidity: institutional dynamics in human research oversight*
Regulation and Governance 2008 March; 2(1): 85-102

Georgetown users check [Georgetown Journal Finder](#) for access to full text

[http://www3.interscience.wiley.com/journal/119423162/issue](http://www3.interscience.wiley.com/journal/119423162/issue) (link may be outdated)

**Document 798**

Burris, Scott
*Regulatory innovation in the governance of human subjects research: a cautionary tale and some modest proposals*
Regulation and Governance 2008 March; 2(1): 65-84

Georgetown users check [Georgetown Journal Finder](#) for access to full text

[http://www3.interscience.wiley.com/journal/119423162/issue](http://www3.interscience.wiley.com/journal/119423162/issue) (link may be outdated)

**Document 799**

Gozzani, Judymarca Lauzi
*Ethics committee, conflict of interest, and registry of clinical assays.*
Revista Brasileira de Anestesiologia 2008 March-April; 58(2): 91-94

Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 800**

Johnson, Tara Star
*Qualitative research in question: a narrative of disciplinary power with/in the IRB.*
Qualitative Inquiry 2008 March; 14(2): 212-232

Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 801**
Committees for Ethics in Research involving human subjects


**Abstract:** In Brazil since October 1996 there have been guidelines for research involving human subjects. Now human subjects know when their treatment is part of research. Deceit is no longer tolerated. But is not enough to say we offer an explanation to the potential subject and we offer a choice before he or she is confronted with an informed consent form. As in all professional activity, scientific investigation needs social controls. In Brazil, the ultimate responsibility of an investigation lies on the investigator, but in every institution where research is carried out there is a Committee for Ethics in Research. All Committees are subordinated to the National Commission of Ethics in Research, which is submitted to the Brazilian Institute of Health. During 2005 around 17,000 protocols involving 700,000 human subjects were revised by 475 Committees distributed all over the country. Approximately 7,000 people are now working in these Committees.

Georgetown users check [Georgetown Journal Finder](http://www.lahey.org/Ethics/) for access to full text
Document 807
Maloney, Dennis M.
**A better way to report Adverse Events (AEs)**
Human Research Report 2008 March; 23(3): 3

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 808
Chamberlain, Barbara
**Ethical regulations in research.**
Clinical Nurse Specialist CNS 2008 March-April; 22(2): 59-60

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 809
Greenhalgh, Trisha; Wengraf, Tom
**Collecting stories: is it research? Is it good research? Preliminary guidance based on a Delphi study.**
Medical Education 2008 March; 42(3): 242-247

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 810
Forde, Kenneth A.
**Ethics of human research.**
Surgical Endoscopy 2008 March; 22(3): 577-579

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 811
Bassler, Dirk; Montori, Victor M.; Briel, Matthias; Glasziou, Paul; Guyatt, Gordon
**Early stopping of randomized clinical trials for overt efficacy is problematic.**
Journal of Clinical Epidemiology 2008 March; 61(3): 241-246

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 812
Intemann, Kristen K.; de Melo-Martín, Inmaculada
**Regulating scientific research: should scientists be left alone?**
FASEB Journal 2008 March; 22(3): 654-658

Georgetown users check [Georgetown Journal Finder](#) for access to full text
**Document 813**
Sarti, Cynthia Andersen

**A difficult dialogue**
Ciência and Saúde Coletiva 2008 March-April; 13(2): 315-318

Georgetown users check [Georgetown Journal Finder](http://www.scielo.br/) for access to full text

**Document 814**
Markman, Maurie

"Conflict-of-interest" and participation in IRB deliberations: an alternative perspective
Cancer Investigation 2008 March; 26(2): 115-117

Georgetown users check [Georgetown Journal Finder](http://www.scielo.br/) for access to full text

**Document 815**
Koski, Greg

Tipping point, over the top, or just noncompliance as usual?

Georgetown users check [Georgetown Journal Finder](http://www.scielo.br/) for access to full text

**Document 816**
Snyder, Lois; Mueller, Paul S.

Research in the physician's office: navigating the ethical minefield

Georgetown users check [Georgetown Journal Finder](http://www.scielo.br/) for access to full text

**Document 817**
Reeser, Jonathan C.; Austin, Diane M.; Jaros, Linda M.; Mukesh, Bickol N.; McCarty, Catherine A.

Investigating perceived institutional review board quality and function using the IRB Researcher Assessment Tool

Abstract: THE INSTITUTIONAL REVIEW BOARD-RESEARCHER ASSESSMENT TOOL (IRB-RAT) was designed to assess the relative importance of various factors to the effective functioning of IRBs. We employed the IRB-RAT to gain insight into the ways in which our IRB is perceived to be deficient by those who routinely interact with our Office of Research Integrity and Protections. Respondents ranked qualities thought to be characteristic of an "ideal" IRB and then compared our IRB to that internal standard. We observed that the rate of study participation varied by role. The composite relative ranking of the 45 items that comprise the IRB-RAT differed significantly from the rank order reported by Keith-Spiegel et al. Our data furthermore suggest that role influences scoring of the IRB-RAT (e.g., investigators awarded our IRB significantly higher scores in several areas than did research coordinators). Additional research is warranted to determine if the observed role-dependent differences in the perceived quality of our IRB simply reflect the local research culture or if they are indicative of a more fundamental and generalizable difference in outlook between investigators and research coordinators.

Georgetown users check [Georgetown Journal Finder](http://www.scielo.br/) for access to full text
**Document 818**

Salas, Halle Showalter; Aziz, Zuraya; Diekema, Douglas S.; Cho, Mildred K.; Tobin, Sara L.; Greely, Henry T.; McCormick, Jennifer; Boyce, Angie; Magnus, David

*The role of family liaisons in research ethics consultations [comment]*


Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text

**Document 819**

Fleming, David A.; Reynolds, Don; Cho, Mildred K.; Tobin, Sara L.; Greely, Henry T.; McCormick, Jennifer; Boyce, Angie; Magnus, David

*Being directly responsive and accountable to human-research participants [comment]*

American Journal of Bioethics 2008 March; 8(3): 24-25, author reply W4-W6

Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text

**Document 820**

Larkin, Philip J.; Dierckx de Casterlé, Bernadette; Schotsmans, Paul

*A relational ethical dialogue with research ethics committees*

Nursing Ethics 2008 March; 15(2): 234-242

**Abstract:** The aim of this article is to take relational ethics concepts and apply them to the context of application to research ethics committees for approval to carry out research. The process of a multinational qualitative research application is described. The article suggests that a relational ethics approach can address two issues: how qualitative proposals are interpreted by research ethics committees and how this safeguards potentially vulnerable respondents. In relational terms, the governance of a research project may be enhanced by shared ownership and willingness to engage in mutual dialogue. This challenges both researchers and research ethics committees to reframe their understanding of roles and functions in the assessment of research protocols, particularly those of a qualitative nature and those that address end-of-life issues.

Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text

**Document 821**

Miller, F.A.; Christensen, R.; Giacomin, M.; Robert, J.S.

*Duty to disclose what? Querying the putative obligation to return research results to participants*

Journal of Medical Ethics 2008 March; 34(3): 210-213

**Abstract:** Many research ethics guidelines now oblige researchers to offer research participants the results of research in which they participated. This practice is intended to uphold respect for persons and ensure that participants are not treated as mere means to an end. Yet some scholars have begun to question a generalised duty to disclose research results, highlighting the potential harms arising from disclosure and questioning the ethical justification for a duty to disclose, especially with respect to individual results. In support of this view, we argue that current rationales for a duty of disclosure do not form an adequate basis for an ethical imperative. We review policy guidance and scholarly commentary regarding the duty to communicate the results of biomedical, epidemiological and genetic research to research participants and show that there is wide variation in opinion regarding what should be disclosed and under what circumstance. Moreover, we argue that there is fundamental confusion about the notion of "research results," specifically regarding three core concepts: the distinction between aggregate and individual results, amongst different types of research, and across different degrees of result veracity. Even where policy guidance and scholarly commentary have been most forceful in support of an ethical imperative to disclose research results, we argue that the ethical rationale tends to fall short of a compelling prima facie duty.
results, ambiguity regarding what is to be disclosed confounds ethical action.

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http://www.jmedethics.com (link may be outdated)

*   Article   Document 822
Miller, F.G.; Wendler, D.
Is it ethical to keep interim findings of randomised controlled trials confidential?
Journal of Medical Ethics 2008 March; 34(3): 198-201

Abstract: Data monitoring committees often are employed to review interim findings of randomised controlled trials. Interim findings are kept confidential until the data monitoring committee finds that they provide sufficiently compelling evidence regarding efficacy, typically because they have crossed the pre-defined statistical boundaries, or they raise serious concerns about safety. While this practice is vital to maintaining the scientific integrity of controlled trials and thereby ensuring their social value, it has been criticised as unethical. Commentators argue that withholding interim findings from research participants is deceptive, inconsistent with valid informed consent, and a violation of respect for participants’ autonomy. The present article examines these arguments, focusing specifically on confidential data monitoring for efficacy. This practice need not be deceptive provided its use is disclosed to prospective research participants. In addition, confidential data monitoring does not make research participants worse off than they would be in the clinical setting and represents an acceptable limitation on the options available to prospective research participants. Taken together, these considerations suggest confidential data monitoring, subject to adequate safeguards, is ethically acceptable.

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http://www.jmedethics.com (link may be outdated)

*   Article   Document 823
Sumathipala, Athula; Siribaddana, Sisira; Hewege, Suwin; Lekamwattage, Manura; Athukorale, Manjula; Siriwardhana, Chesmal; Murray, Joanna; Prince, Martin
Ethics review committee approval and informed consent: an analysis of biomedical publications originating from Sri Lanka

Abstract: Background: International guidelines on research have focused on protecting research participants. Ethical Research Committee (ERC) approval and informed consent are the cornerstones. Externally sponsored research requires approval through ethical review in both the host and the sponsoring country. This study aimed to determine to what extent ERC approval and informed consent procedures are documented in locally and internationally published human subject research carried out in Sri Lanka. Methods: We obtained ERC approval in Sri Lanka and the United Kingdom. Theses from 1985 to 2005 available at the Postgraduate Institute of Medicine (PGIM) library affiliated to the University of Colombo were scrutinised using checklists agreed in consultation with senior research collaborators. A Medline search was carried out with MeSH major and minor heading 'Sri Lanka' as the search term for international publications originating in Sri Lanka during 1999 to 2004. All research publications from CMJ during 1999 to 2005 were also scrutinized. Results: Of 291 theses, 34% documented ERC approvals and 61% documented obtaining consent. From the international journal survey, 250 publications originated from Sri Lanka of which only 79 full text original research publications could be accessed electronically. Of these 38% documented ERC approval and 39% documented obtaining consent. In the Ceylon Medical Journal 36% documented ERC approval and 37% documented obtaining consent. Conclusion: Only one third of the publications scrutinized recorded ERC approval and procurement of informed consent. However, there is a positive trend in documenting these ethical requirements in local postgraduate research and in the local medical journal.

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http://www.biomedcentral.com/bmcmedethics/1472-6939/9/3 (link may be outdated)
Document 824
Wells, Robert J.
Secrecy and integrity in clinical trials
Journal of Clinical Oncology 2008 February 1; 26(4): 680-682
Georgetown users check Georgetown Journal Finder for access to full text

Document 825
Plantadosi, Steven
Rigor in monitoring clinical trials is ethical
Journal of Clinical Oncology 2008 February 1; 26(4): 683-685
Georgetown users check Georgetown Journal Finder for access to full text

Document 826
Council for International Organizations of Medical Sciences (CIOMS)
International ethical guidelines for epidemiological studies

Document 827
Demarez, Jean-Paul
De Nuremberg à aujourd'hui : les « Comités d’éthique » dans l’expérimentation humaine = From Nuremberg to the ethics committees in human experimentation
Médecine/Science 2008 February; 24(2): 208-212
Georgetown users check Georgetown Journal Finder for access to full text

http://www.edk.fr/reserve/recherche/e-docs/00/00/0C/07/document_article.md (link may be outdated)

Document 828
Mignot, A.
High-risk molecules or insufficient scientific data?
Clinical Pharmacology and Therapeutics 2008 February; 83(2): 365-367
Georgetown users check Georgetown Journal Finder for access to full text

Document 829
Markman, Maurie
Objective data rather than opinion in the interpretation of the legitimate goals of phase 1 oncology trials
Cancer Investigation 2008 February; 26(1): 11-12
Georgetown users check Georgetown Journal Finder for access to full text

Document 830
Horn, Lyn
Payment of clinical trial participants.
Document 831
Armitage, Jane; Souhami, Robert; Friedman, Lawrence; Hilbrich, Lutz; Holland, Jack; Muhlbaier, Lawrence H.; Shannon, Jane; Van Nie, Alison
The impact of privacy and confidentiality laws on the conduct of clinical trials.
Clinical Trials 2008 February; 5(1): 70-74

Document 832
Ajuwon, Ademola J.; Kass, Nancy
Outcome of a research ethics training workshop among clinicians and scientists in a Nigerian university
Abstract: Background: In Nigeria, as in other developing countries, access to training in research ethics is limited, due to weak social, economic, and health infrastructure. The project described in this article was designed to develop the capacity of academic staff of the College of Medicine, University of Ibadan, Nigeria to conduct ethically acceptable research involving human participants. Methods: Three in-depth interviews and one focus group discussion were conducted to assess the training needs of participants. A research ethics training workshop was then conducted with College of Medicine faculty. A 23-item questionnaire that assessed knowledge of research ethics, application of principles of ethics, operations of the Institutional Review Board (IRB) and ethics reasoning was developed to be a pre-post test evaluation of the training workshop. Ninety-seven workshop participants completed the questionnaire before and after the workshop; 59 of them completed a second post-test questionnaire one month after the workshop. Results: The trainees came from a multi-disciplinary background including medicine, nursing, pharmacy, social science and laboratory science. The mean scores for knowledge of the principles of research ethics rose from 0.67 out of 3 points at pre-test to 2.25 at post-test (p < 0.05). Also, 42% correctly mentioned one international guideline or regulation at pretest, with most of those knowing of the Declaration of Helsinki. Trainees' knowledge of the operations of an IRB increased from 6.05 at pre-test to 6.29 at post test out of 7 points. Overall, participants retained much of the knowledge acquired from the workshop one month after its completion. Conclusion: The training improved participants' knowledge of principles of research ethics, international guidelines and regulations and operations of IRBs. It thus provided an opportunity for research ethics capacity development among academic staff in a developing country institution.

Document 833
National Institute for Health Research (NIHR). National Health Service (NHS)
Transforming health research the first two years. National Institute for Health Research Progress Report 2006-2008
Call number: citation only
Document 834

O'Neil, Peter

**Ethics guidelines for clinical trials to be revised**


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Document 835

Schnaider, Taylor Brandão

**Etica e pesquisa [Ethics and research]**


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Document 836

Saisine reçue du Professeur Jean-Louis Bernard, Président du Comité de protection des personnes Sud-méditerranéen II, concernant la question de la recherche en urgence sur des personnes incapables de consentir en raison de leur état [Request for a ruling received from Professor Jean-Louis Bernard, Chair of the Committee for the Protection of People [IRB] concerning the question of research done in the emergency room on people unable to consent because of their condition]

Les Cahiers du Comité Consultatif National d'Éthique pour les Sciences de la Vie et de la Santé 2008 January-March; (54): 56-57

Georgetown users check [Georgetown Journal Finder](http://www.cmaj.ca) for access to full text

Document 837

Resnik, David B.

**Randomized controlled trials in environmental health research: ethical issues**


Georgetown users check [Georgetown Journal Finder](http://www.cmaj.ca) for access to full text

Document 838

Flicker, Sarah; Guta, Adrian

**Ethical approaches to adolescent participation in sexual health research**

Journal of Adolescent Health 2008 January; 42(1): 3-10

Georgetown users check [Georgetown Journal Finder](http://www.cmaj.ca) for access to full text

Document 839

Silverstein, Jeffrey H.; Bienstock, Carol

**Roles and actions of IRBs as it relates to the process of drug and device development.**

Document 840
Frank, Samuel A.; Wilson, Renee; Holloway, Robert G.; Zimmerman, Carol; Peterson, Derick R.; Kieburtz, Karl; Kim, Scott Y.H.
**Ethics of sham surgery: perspective of patients.**
Movement Disorders 2008 January; 23(1): 63-68

Document 841
Tharyan, Prathap
**Clinical trials registration in India: no longer a dream.**

Document 842
Griffith, Richard
**Legal requirements for conducting clinical trials.**
British Journal of Community Nursing 2008 January; 13(1): 41-42, 44-46

Document 843
McRae, Andrew; Weijer, Charles
**U.S. Federal Regulations for emergency research: a practical guide and commentary.**

Document 844
Lee, C.A.
**Best practice: protecting research subjects, patients and experimental animals**
Haemophilia 2008 January; 14(1): 111

Document 845
Wilcox, C. Mel
**Exploring the use of the sham design for interventional trials: implications for endoscopic research**
Gastrointestinal Endoscopy 2008 January; 67(1): 123-127
Article 1

Broyles, Lauren M.; Tate, Judith A.; Happ, Mary Beth

**Videorecording in clinical research: mapping the ethical terrain.**

Nursing Research 2008 January; 57(1); 59-63

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Article 2

Wicclair, Mark R.

**Ethics and research with deceased patients**

CQ: Cambridge Quarterly of Healthcare Ethics 2008 Winter; 17(1): 87-97

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Article 3

Ehni, Hans-Jörg; Wiesing, Urban

**International ethical regulations on placebo-use in clinical trials: a comparative analysis**

Bioethics 2008 January; 22(1): 64-74

**Abstract:** The ethical aspects of placebo control in clinical trials have been extensively and controversially debated in the last decade. However, a thorough analytical comparison of the different existing international regulations, their terminologies and their ethical principles concerning placebo, is still missing. The central issue in the ongoing controversy is the justification of placebo-use, if proven treatment exists. All present versions of the examined guidelines propose such justifications, but each guideline differs from the others in relevant details. Therefore the conditions justifying placebo-use according to each guideline are the focus of our attention. We will first propose a formalized general principle that defines the ethical acceptability of placebo-use. Then we will analyse three categories of conditions put forward by the different documents: the risk of harm or burden, compelling scientific reasons, and the availability of proven treatment. The analysis shows important normative discrepancies and contradictions between the examined guidelines. Especially striking is the fact that some guidelines allow the participants in clinical trials to be exposed to a risk of serious harm, while others do not. Finally, we try to show how the normative difference of each guideline could influence the decision of researchers or IRBs concerning the ethical acceptability of placebo-use.

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Article 4

Taylor, Holly A.; Currie, Peter; Kass, Nancy E.

**A study to evaluate the effect of investigator attendance on the efficiency of IRB review**


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Article 5

Smith, Lynn

**What does it take to get accredited?**

Protecting Human Subjects 2008; (17): 8

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[http://www.science.doe.gov/ober/humsubj/](http://www.science.doe.gov/ober/humsubj/) (link may be outdated)
Document 851

Speers, Marjorie

Environment of concern led to accreditation
Protecting Human Subjects 2008; (17): 6-7

Georgetown users check Georgetown Journal Finder for access to full text

http://www.science.doe.gov/ober/humsubj/ (link may be outdated)

Document 852

Hawkins, Becky; Ellis, Betsy; Greeley, Leigh

For Oak Ridge, one size does not fit all
Protecting Human Subjects 2008; (17): 5

Georgetown users check Georgetown Journal Finder for access to full text

http://www.science.doe.gov/ober/humsubj/ (link may be outdated)

Document 853

Davis, Sherry

What we learned
Protecting Human Subjects 2008; (17): 1, 3

Georgetown users check Georgetown Journal Finder for access to full text

http://www.science.doe.gov/ober/humsubj/ (link may be outdated)

Document 854

Tausig, Mark; Subedi, Janardan; Subedi, Sree

Sociological contributions to developing ethical standards for medical research in very poor countries: the example of Nepal
Call number: QH332 .B48 2008

Document 855

Gonorazky, Sergio E.

Independent ethics committees for clinical research in Argentina. An evaluation and a system to guarantee their independence = Comités de ética independientes para la investigación clínica en la Argentina.

Evaluación y sistema para garantizar su independencia.
Medicina 2008; 68(2): 113-119

Georgetown users check Georgetown Journal Finder for access to full text

Document 856

Ligocka, Danuta
Bioethical committees and data protection issues in Poland.
Environmental Health 2008; 7 Suppl 1: S4

Georgetown users check Georgetown Journal Finder for access to full text

* Article Document 857
Reis, M. Fátima; Segurado, Susana; Brantes, Ana; Simões, Helena Teresinha; Melim, J. Maurício; Geraldes, V.; Miguel, J. Pereira
Ethics issues experienced in HBM within Portuguese health surveillance and research projects.
Environmental Health 2008; 7 Suppl 1: S5

Georgetown users check Georgetown Journal Finder for access to full text

* Chapter Document 858
Hellenic National Bioethics Commission
Opinion on the establishment of ethics committees that review biomedical research
Call number: QH332 .R445 2008

* Chapter Document 859
Hellenic National Bioethics Commission
Report on biomedical experimentations involving human subjects and clinical trials of medicinal products
Call number: QH332 .R445 2008

* Chapter Document 860
Hellenic National Bioethics Commission
Opinion on clinical trials
Call number: QH332 .R445 2008

* Article Document 861
Bignamini, Angelo A.
La experimentación oncológica: medida de eficacia y seguridad para el cáncer avanzado = Clinical trials in oncology: measurements of efficacy and safety in advanced cancer
Medicina y Ética 2008; 19(1): 65-89

Georgetown users check Georgetown Journal Finder for access to full text

* Article Document 862
Planned Helsinki changes raise questions: is the historic declaration still useful, relevant?
Protecting Human Subjects 2008; (16): 18

Georgetown users check Georgetown Journal Finder for access to full text
Document 863
Marshall Clark, Mary
**Oral historian: IRB scrutiny often unnecessary**
Protecting Human Subjects 2008; (16): 9
Georgetown users check [Georgetown Journal Finder](http://www.science.doe.gov/ober/humsubj/) for access to full text

Document 864
Caplan, Art
**IRBs and research changes**
Protecting Human Subjects 2008; (16): 1-3
Georgetown users check [Georgetown Journal Finder](http://www.science.doe.gov/ober/humsubj/) for access to full text

Document 865
Linton, R.
**Applying for ethical approval from the MoD research ethics committee.**
Journal of the Royal Naval Medical Service 2008; 94(1): 41-46
Georgetown users check [Georgetown Journal Finder](http://www.science.doe.gov/ober/humsubj/) for access to full text

Document 866
Wang-Gillam, Andrea; Valentine, Jimmie; Sherman, Allen C.; Mehta, Paulette
**Experiences of institutional review board (IRB) and protocol review and monitoring committee (PRMC) rotations in hematology/oncology training.**
Journal of Cancer Education 2008; 23(2): 71-73
Georgetown users check [Georgetown Journal Finder](http://www.science.doe.gov/ober/humsubj/) for access to full text

Document 867
Wicher, Camille C.; Michalek, Arthur M.
**To expedite or not to expedite ...that is the question.**
Journal of Cancer Education 2008; 23(3): 140-114
Georgetown users check [Georgetown Journal Finder](http://www.science.doe.gov/ober/humsubj/) for access to full text

Document 868
Lexchin, Joel
**Clinical trials in Canada: whose interests are paramount?**
Marcee, Alice K.

**Expanded access to phase II clinical trials in oncology: a step toward increasing scientific validity and compassion.**


Winter, John D.

**Is it time to abandon FDA's no release from liability regulation for clinical studies?**

Food and Drug Law Journal 2008; 63(2): 525-536

Taylor, Holly A.

**Implementation of NIH inclusion guidelines: survey of NIH study section members.**

Clinical Trials 2008; 5(2): 140-146

Fleming, Thomas R.; Sharples, Katrina; McCall, John; Moore, Andrew; Rodgers, Anthony; Stewart, Ralph

**Maintaining confidentiality of interim data to enhance trial integrity and credibility.**

Clinical Trials 2008; 5(2): 157-167

Meinert, Curtis L.

**Long-term drug prevention trials.**

Clinical Trials 2008; 5(2): 168-176

Taylor, Holly A.; Chaisson, Lelia; Sugarman, Jeremy

**Enhancing communication among data monitoring committees and institutional review boards.**

Clinical Trials 2008; 5(3): 277-282
Document 875
Catania, Chiara; De Pas, Tommaso; Goldhirsch, Aron; Radice, Davide; Adamoli, Laura; Medici, Marta; Verri, Elena; Marenghi, Cristina; de Braud, Filippo; Nolè, Franco
Participation in clinical trials as viewed by the patient: understanding cultural and emotional aspects which influence choice
Oncology 2008; 74(3-4): 177-87
Georgetown users check Georgetown Journal Finder for access to full text

Document 876
Gillenwater, Gail E.
FDA's emergency research rule: an inch given, a yard taken.
Georgetown users check Georgetown Journal Finder for access to full text

Document 877
Freeman, Scott R.; Lundahl, Kristy; Schilling, Lisa M.; Jensen, J. Daniel; Dellavalle, Robert P.
Human research review committee requirements in medical journals.
Clinical and Investigative Medicine = Médecine clinique et experimentale 2008; 31(1): E49-E54
Georgetown users check Georgetown Journal Finder for access to full text

Document 878
Scherer, Martin; Trelle, Sven
Opinions on registering trial details: a survey of academic researchers
BMC Health Services Research 2008; 8: 18
http://www.biomedcentral.com/ (link may be outdated)

Document 879
King, Nancy M.P.
The healthy-patient paradox in clinical trials
Atrium 2008; 5: 9-11
http://www.medschool.northwestern.edu/mhb/atrium/index.html (link may be outdated)

Document 880
Beauchamp, Tom L.; Walters, LeRoy; Kahn, Jeffrey P.; Mastroianni, Anna C., eds.
Research involving humans and animals
In their: Beauchamp, Tom L.; Walters, LeRoy; Kahn, Jeffrey P.; Mastroianni, Anna C., eds. Contemporary Issues in
* Article  Document 881
Yank, Veronia; Rennie, Drummond; Bero, Lisa A.
**Financial ties and concordance between results and conclusions in meta-analyses: retrospective cohort study**
BMJ: British Medical Journal 2007 December 8; 335(7631): 1202-1205

Georgetown users check [Georgetown Journal Finder](https://www.bmj.com) for access to full text

http://www.bmj.com (link may be outdated)

---

Article  Document 882
Heath, Iona
**The road to hell... clinical trial evidence is shamelessly extrapolated across time, population subgroup, and condition**
BMJ: British Medical Journal 2007 December 8; 335(7631): 1185

Georgetown users check [Georgetown Journal Finder](https://www.bmj.com) for access to full text

http://www.bmj.com (link may be outdated)

---

* Article  Document 883
Garattini, Silvio; Bertelé, Vittorio
**Non-inferiority trials are unethical because they disregard patients’ interests**
Lancet 2007 December 1-7; 370(9602): 1875-1877

Georgetown users check [Georgetown Journal Finder](https://www.thelancet.com/journal) for access to full text

http://www.thelancet.com/journal (link may be outdated)

---

Article  Document 884
Legault, Georges A.; Patenaude, Johane
**Au-delà des critiques adressées aux comités d’éthique de la recherche: un choix de gouvernance. = Beyond the criticism addressed to research ethics committees: a choice of governance**

**Abstract:** In 1998 in Canada and Quebec, two policies regarding research ethics transformed the evaluation process of clinical research following the Code of Nuremberg and subsequent Declarations of the World Medical Association. Even after almost ten years of implementation, these policies still arouse debate in the research milieu. If for many, these debates essentially reflect the inherent difficulties in any implementation process, in which resistance to change and the modification of policies and action plans, we believe that there is a more fundamental stake, rarely mentioned or debated, that of the choice of governance. In this article we start by proposing a classification of the different modes of governance: professional deontology, and ethical and administrative rights. Secondly, we show how the debates and criticisms addressed to the Research Ethics Committee of Quebec and Canada attains their full meaning in light of this basic stake: the divergence of the mode of governance to favour ethics in research.

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**Document 885**
Markman, Jonathan R.; Markman, Maurie
*Running an ethical trial 60 years after the Nuremberg Code*
Lancet Oncology 2007 December; 8(12): 1139-1146
Georgetown users check [Georgetown Journal Finder](http://caliber.ucpress.net/loi/jer) for access to full text

**Document 886**
Drury, Vicki; Francis, Karen; Chapman, Ysanne
*Taming the rescuer: the therapeutic nature of qualitative research interviews*
Georgetown users check [Georgetown Journal Finder](http://caliber.ucpress.net/loi/jer) for access to full text

**Document 887**
Afifi, Raafat Y.
*Biomedical research ethics: an Islamic view part II.*
Georgetown users check [Georgetown Journal Finder](http://caliber.ucpress.net/loi/jer) for access to full text

**Document 888**
Pech, C.; Cob, N.; Cejka, J.T.
*Understanding institutional review boards: practical guidance to the IRB review process*
Nutrition in Clinical Practice 2007 December; 22(6): 618-628
Georgetown users check [Georgetown Journal Finder](http://caliber.ucpress.net/loi/jer) for access to full text

**Document 889**
Shenvi, Neeta V.; Gebhart, Suzanne S.P.
*The impact of minor adverse event tracking on subject safety: a web-based system*
Georgetown users check [Georgetown Journal Finder](http://caliber.ucpress.net/loi/jer) for access to full text

**Document 890**
Maloney, Dennis M.
*Guidance for institutional review boards (IRBs)*
Human Research Report 2007 December; 22(12): 9
Georgetown users check [Georgetown Journal Finder](http://caliber.ucpress.net/loi/jer) for access to full text
Document 891
Maloney, Dennis M.
**Two types of institutional review boards (IRBs) studied**
Human Research Report 2007 December; 22(12): 4

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Document 892
Maloney, Dennis M.
**Changes for expedited reviews by institutional review boards (IRBs)**

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Document 893
Napier, Stephen
**Belmont Revisited: Ethical Principles for Research with Human Subjects, Edited by James F. Childress, Eric M. Meslin, and Harold T. Shapiro [book review]**
National Catholic Bioethics Quarterly 2007 Winter; 7(4): 838-841

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 894
Tonti-Filippini, Nicholas
**The need for ethics committees, and their role and function**
National Catholic Bioethics Quarterly 2007 Winter; 7(4): 749-769

*Abstract:* The search for truth is not the sole end of science. Science serves humanity, not humanity science. Science must never forget that the human being is not a mere means to scientific ends, but the reason for and goal of research. The central function of bioethics committees is to guide the development of medical science so that it genuinely seeks knowledge within the context of recognizing that each human being is created in God's own image and likeness and that no member of the human family may be used or treated merely as an object of use.

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Document 895
Elsayed, Dya Eldin M.; Kass, Nancy E.
**Assessment of the ethical review process in Sudan**
Developing World Bioethics 2007 December; 7(3): 143-148

*Abstract:* The ethical review process is an important component of contemporary health research worldwide. Sudan started an ethical review process rather late in comparison with other countries. In this study, we evaluate the structure and functions of existing ethics review committees. We also explore the knowledge and attitudes of Sudanese researchers toward the ethical review process and their experience with existing ethics review committees. There are four ethics review committees in the country; these committees have no institutional regulations to govern their functions. Furthermore, Sudan also lacks national guidelines. Ethical reviews are carried out primarily for studies seeking international funding and are almost always governed by the funding agencies' requirements. Nearly half of respondents (46.3%) knew about the existence of research ethics committees in Sudan. Researchers reported a variety of experiences with the ethical review process; most of them were unable to define 'ethics committee'.

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**Document 896**

**Ethics committees in western and central Africa: concrete foundations**

Effa, Pierre; Massougbdji, Achillé; Ntoumi, Francine; Hirsch, François; Debois, Henri; Vicari, Marissa; Derme, Assetou; Ndemanga-Kamoune, Jacques; Ngoum, Joseph; Impouma, Benido; Akué, Jean-Paul; Ehouman, Armand; Diaye, Alioune; Kilama, Wen

*Abstract:* The involvement of developing countries in international clinical trials is necessary for the development of appropriate medicines for local populations. However, the absence of appropriate structures for ethical review represents a barrier for certain countries. Currently there is very little information available on existing structures dedicated to ethics in western and central Africa. This article briefly describes historical milestones in the development of networks dedicated to capacity building in ethical review in these regions and outlines the major conclusions of two workshops on this issue, which were held in September and October 2002 in Libreville, Gabon, and Paris, France. The workshops were the culmination of collaboration between the African Malaria Network Trust (AMANET) and the Pan African Bioethics Initiative (PABIN). They produced an update on ethics organizations with regard to mission, function, activities, members, and contact people, in eight countries within the regions discussed. As a result of the commitment of mandated delegates, a further prominent outcome followed these workshops: the creation of national structures, where none existed before, dedicated to the ethical review of clinical trials.

**Document 897**

**Need to strengthen ethics committees**

Karbwang, Juntra; Crawley, Francis P.


**Document 898**

**Hospital ethics approval for a population-based case-control study of very preterm birth.**

Watson, Lyndsey F.; Rayner, Jo-Anne; Lumley, Judith M.


**Document 899**

**Why healthy subjects volunteer for phase I studies and how they perceive their participation?**

Almeida, Luis; Azevedo, Benedita; Nunes, Teresa; Vaz-da-Silva, Manuel; Soares-da-Silva, Patricio

*European Journal of Clinical Pharmacology* 2007 November; 63(11): 1085-1094

**Document 900**

**First-in-Man (FIM) clinical trials post-TeGenero: a review of the impact of the TeGenero trial on the design,**

Nada, Adel; Somberg, John
**conduct, and ethics of FIM trials**

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**Clinical trials and medical care: defining the therapeutic misconception.**

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**Trustworthiness in evaluation practice: an emphasis on the relational.**
Evaluation and Program Planning 2007 November; 30(4): 404-409

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---

**Consequences of Directive 2001/20/EC for investigator-initiated trials in the paediatric population – a field report.**
European Journal of Pediatrics 2007 November; 166(11): 1169-1176

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[http://www.springerlink.com/content/100415/](http://www.springerlink.com/content/100415/) (link may be outdated)

---

**Tobacco industry research and protection of human subjects: a case study of R. J. Reynolds**
Nicotine and Tobacco Research 2007 November; 9(11): 1213-1225

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**Case study: institutional review board (IRB) must review hundreds of protocols--again**
Human Research Report 2007 November; 22(11): 6-7

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**Document 906**
**Document 907**

Maloney, Dennis M.

**Special IRB considerations in observational exposure studies**


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**Document 908**

Hunter, David

**Efficiency and the proposed reforms to the NHS research ethics system**

Journal of Medical Ethics 2007 November; 33(11): 651-654

*Abstract*: Significant changes are proposed for the research ethics system governing the review of the conduct of medical research in the UK. This paper examines these changes and whether they will meet the aimed-for goal of improving the efficiency of the research ethics system. The author concludes that, unfortunately, they will not and thus should be rejected.

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[http://www.jmedethics.com](http://www.jmedethics.com) (link may be outdated)

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**Document 909**

Gorovitz, Samuel

**Home plate, the cheese lady, and bad sonnets: on the limitations of regulation**


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[http://www.bioethicsforum.org](http://www.bioethicsforum.org) (link may be outdated)

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**Document 910**

Sutherland, E. Rand

**Sham procedure versus usual care as the control in clinical trials of devices: which is better?**


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**Document 911**

Rogers, Andy

**COREC and IRMER—is co-existence achievable?**

British Journal of Radiology 2007 October; 80(958): 774-777

Georgetown users check [Georgetown Journal Finder](#) for access to full text
Document 912

Bathum, Mary Elizabeth

**Global health research to promote social justice: a critical perspective.**

ANS. Advances in Nursing Science 2007 October-December; 30(4): 303-314

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---

Document 913

Richmond, Therese S.; Ulrich, Connie

**Ethical issues of recruitment and enrollment of critically ill and injured patients for research.**

AACN Advanced Critical Care 2007 October-December; 18(4): 352-355

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---

Document 914

Tannert, Christof; Elvers, Horst-Dietrich; Jandrig, Burkhard

**The ethics of uncertainty. In the light of possible dangers, research becomes a moral duty**

EMBO Reports 2007 October; 8(10): 892-896

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---

Document 915

Saunders, John; Wisely, Janet

**Promoting and facilitating ethical research**

Clinical Medicine 2007 October; 7(5): 433-435

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---

Document 916

Hofmeijer, J.; Amelink, G.J.; den Hertog, H.M.; Algra, A.; Kappelle, L.J.; van der Worp, H B.;

**Appreciation of the informed consent procedure in a randomised trial of decompressive surgery for space occupying hemispheric infarction.**


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---

Document 917

Christie, D.R.H.; Gabriel, G.S.; Dear, K.

**Adverse effects of a multicentre system for ethics approval on the progress of a prospective multicentre trial of cancer treatment: how many patients die waiting?**


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Document 918
Afifi, Raafat Y.
Biomedical research ethics: an Islamic view—part I.
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Document 919
DeVille, Kenneth A.
Georgetown users check [Georgetown Journal Finder](https://georgetownjournalfinder.georgetown.edu) for access to full text

Document 920
Kozanczyn, Christa; Collins, Katie; Fernandez, Conrad V.
Offering results to research subjects: U.S. institutional review board policy
Accountability in Research 2007 October-December; 14(4): 255-267
Georgetown users check [Georgetown Journal Finder](https://georgetownjournalfinder.georgetown.edu) for access to full text

Document 921
Maloney, Dennis M.
In court: legal principles for protecting human subjects
Human Research Report 2007 October; 22(10): 8
Georgetown users check [Georgetown Journal Finder](https://georgetownjournalfinder.georgetown.edu) for access to full text

Document 922
Maloney, Dennis M.
University explains how it will strengthen its support for institutional review boards (IRBs) [case study]
Human Research Report 2007 October; 22(10): 6-7
Georgetown users check [Georgetown Journal Finder](https://georgetownjournalfinder.georgetown.edu) for access to full text

Document 923
Maloney, Dennis M.
Another type of research review
Human Research Report 2007 October; 22(10): 5
Georgetown users check [Georgetown Journal Finder](https://georgetownjournalfinder.georgetown.edu) for access to full text
Document 924
Maloney, Dennis M.
Recommended changes on continuing reviews by IRBs
Human Research Report 2007 October; 22(10): 3
Georgetown users check Georgetown Journal Finder for access to full text

Document 925
Levinson, Daniel R.
The Food and Drug Administration's oversight of clinical trials

http://www.oig.hhs.gov/oei/reports/oei-01-06-00160.pdf (link may be outdated)

Document 926
Vaccaro, Alexander R.; Fehlings, Michael G.
The applicability of clinical equipoise and sham surgery in patients with symptomatic lumbar radiculopathy due to a herniated disc: the SPORT trial
Spine 2007 September 1; 32(19): 2039-2040
Georgetown users check Georgetown Journal Finder for access to full text

Document 927
Korczyn, Amos D.
Drug trials in dementia: challenging ethical dilemmas
Georgetown users check Georgetown Journal Finder for access to full text

Document 928
Kirk, Susan
Methodological and ethical issues in conducting qualitative research with children and young people: a literature review.
International Journal of Nursing Studies 2007 September; 44(7): 1250-1260
Georgetown users check Georgetown Journal Finder for access to full text

Document 929
de Melo-Martín, Inmaculada; Palmer, Larry I.; Fins, Joseph J.
Developing a research ethics consultation service to foster responsive and responsible clinical research
Academic Medicine 2007 September; 82(9): 900-904
Georgetown users check Georgetown Journal Finder for access to full text
Expanding responsible conduct of research instruction across the university
Bulger, Ruth Ellen; Heitman, Elizabeth
Academic Medicine 2007 September; 82(9): 876-878

Responding to challenges in educating for the responsible conduct of research
Kalichman, Michael W.
Academic Medicine 2007 September; 82(9): 870-875

Scientific societies and promotion of the responsible conduct of research: codes, policies, and education
Macrina, Francis L.
Academic Medicine 2007 September; 82(9): 865-869

The CITI program: an international online resource for education in human subjects protection and the responsible conduct of research
Braunschweiger, Paul; Goodman, Kenneth W.
Academic Medicine 2007 September; 82(9): 861-864

What do mentoring and training in the responsible conduct of research have to do with scientists’ misbehavior? Findings from a national survey of NIH-funded scientists
Anderson, Melissa S.; Horn, Aaron S.; Risbey, Kelly R.; Ronning, Emily A.; De Vries, Raymond; Martinson, Brian C.
Academic Medicine 2007 September; 82(9): 853-860
* Document 935
Kalichman, Michael W.; Plemmons, Dena K.
Reported goals for responsible conduct of research courses
Academic Medicine 2007 September; 82(9): 846-852
Georgetown users check Georgetown Journal Finder for access to full text

* Document 936
Vasgird, Daniel R.
Prevention over cure: the administrative rationale for education in the responsible conduct of research
Academic Medicine 2007 September; 82(9): 835-837
Georgetown users check Georgetown Journal Finder for access to full text

* Document 937
Steneck, Nicholas H.; Bulger, Ruth Ellen
The history, purpose, and future of instruction in the responsible conduct of research
Academic Medicine 2007 September; 82(9): 829-834
Georgetown users check Georgetown Journal Finder for access to full text

* Document 938
Miller, Paul B.; Weijer, Charles
Revisiting equipoise; a response to Gifford
Kennedy Institute of Ethics Journal 2007 September; 17(3): 227-246
Abstract: The authors respond to objections Fred Gifford has raised against their paper "Rehabilitating Equipoise." They situate this exchange in the wider context of recent debate over equipoise, highlighting substantial points of agreement between themselves and Gifford. The authors offer a brief restatement of "Rehabilitating Equipoise" in which they amplify some of its core arguments. They then assess Gifford's objections. Finding each to be unfounded, they argue that there is no justification for "pulling the plug" on clinical equipoise.

* Document 939
Gifford, Fred
Pulling the plug on clinical equipoise: a critique of Miller and Weijer
Kennedy Institute of Ethics Journal 2007 September; 17(3): 203-226
Abstract: As clinicians, researchers, bioethicists, and members of society, we face a number of moral dilemmas concerning randomized clinical trials. How we manage the starting and stopping of such trials—how we conceptualize what evidence is sufficient for these decisions—has implications for both our obligations to trial participants and for the nature and security of the resultant medical knowledge. One view of how this is to be done,
"clinical equipoise," recently has been given an extended defense by Paul Miller and Charles Weijer in their article "Rehabilitating Equipoise." The present paper critiques this position and Miller and Weijer's defense of it. I argue that their attempted rehabilitation fails. Their analysis suffers from a number of confusions, as well as a failure to make crucial distinctions, adequately to clarify key concepts, or to think through exactly what needs to be established to justify their claim. We are left with little reason to uphold the clinical equipoise criterion.

Kukla, Rebecca
Resituating the principle of equipoise: justice and access to care in non-ideal conditions
Kennedy Institute of Ethics Journal 2007 September; 17(3): 171-202

Abstract: The principle of equipoise traditionally is grounded in the special obligations of physician-investigators to provide research participants with optimal care. This grounding makes the principle hard to apply in contexts with limited health resources, to research that is not directed by physicians, or to non-therapeutic research. I propose a different version of the principle of equipoise that does not depend upon an appeal to the Hippocratic duties of physicians and that is designed to be applicable within a wider range of research contexts and types—including health services research and research on social interventions. I consider three examples of ethically contentious research trials conducted in three different social settings. I argue that in each case my version of the principle of equipoise provides more plausible and helpful guidance than does the traditional version of the principle.

MacNeil, S. Danielle; Fernandez, Conrad V.
Attitudes of research ethics board chairs toward disclosure of research results to participants: results of a national survey
Journal of Medical Ethics 2007 September; 33(9): 549-553

Abstract: Background: The offer of aggregate study results to research participants following study completion is increasingly accepted as a means of demonstrating greater respect for participants. The attitudes of research ethics board (REB) chairs towards this practice, although integral to policy development, are unknown. Objectives: To determine the attitudes of REB chairs and the practices of REBs with respect to disclosure of results to research participants. Design: A postal questionnaire was distributed to the chairs of English-language university-based REBs in Canada. In total, 88 REB chairs were eligible. The questionnaire examined respondents' attitudes towards offering participants completed study results, methods for delivering this information, and barriers to disclosing results. Findings: The response rate was 89.8%. Chairs were highly supportive (94.8%) of offering results to research participants. Only 19.5% of chairs responded that a policy or guideline that governed the return of research results to participants existed at their institution. Most chairs (72.0%) supported the idea of their REB instituting a set of guidelines recommending that researchers offer results to participants in a lay format. Chairs identified the major impediments to the implementation of programmes offering to return results to participants as being financial cost (57.5%) and retaining contact with research participants (78.1%). Conclusions: University-based REB chairs overwhelmingly support the offer of research results to participants. This is incongruent with the frequent lack of existing REB guidelines recommending this practice. REBs should support guidelines that diminish identified barriers and promote consistency in offering to return results.

Carlson, Robert V.; van Ginneken, Nadja H.; Pettigrew, Luisa M.; Davies, Alan; Boyd, Kenneth M.; Webb, David J.
The three official language versions of the Declaration of Helsinki: what's lost in translation?
Journal of Medical Ethics 2007 September; 33(9): 545-548
Abstract: Background: The Declaration of Helsinki, the World Medical Association's (WMA's) statement of ethical guidelines regarding medical research, is published in the three official languages of the WMA: English, French and Spanish. Methods: A detailed comparison of the three official language versions was carried out to determine ways in which they differed and ways in which the wording of the three versions might illuminate the interpretation of the document. Results: There were many minor linguistic differences between the three versions. However, in paragraphs 1, 6, 29, 30 and in the note of clarification to paragraph 29, there were differences that could be considered potentially significant in their ethical relevance. Interpretation: Given the global status of the Declaration of Helsinki and the fact that it is translated from its official versions into many other languages for application to the ethical conduct of research, the differences identified are of concern. It would be best if such differences could be eliminated but, at the very least, a commentary to explain any differences that are unavoidable on the basis of language or culture should accompany the Declaration of Helsinki. This evidence further strengthens the case for international surveillance of medical research ethics as has been proposed by the WMA.

http://www.jmedethics.com (link may be outdated)
Document 947
Ledford, Heidi
"Trial and error: the ethics committees that oversee research done in humans have been attacked from all sides"
Nature 2007 August 2; 448(7153): 530-532

Document 948
Friedman, Joseph H.
"IRBs and the private office"
Medicine and Health, Rhode Island 2007 August; 90(8): 230

Document 949
Thieren, Michel; Mauron, Alexandre
"Nuremberg code turns 60"

Document 950
Kass, N.E.; Myers, R.; Fuchs, E.J.; Carson, K.A.; Flexner, C.
"Balancing justice and autonomy in clinical research with healthy volunteers"
Clinical Pharmacology and Therapeutics 2007 August; 82(2): 219-227

Document 951
Maloney, Dennis M.
"IRBs and reporting of unanticipated problems"
Human Research Report 2007 August; 22(8): 4

Document 952
Maloney, Dennis M.
"Opportunity to seek changes to certain IRB requirements"
Maloney, Dennis M.

Researchers' supervisory duties are subject to review by IRBs

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Weijer, Charles; Miller, P.B.

Refuting the net risks test: a response to Wendler and Miller’s “Assessing research risks systematically”
Journal of Medical Ethics 2007 August; 33(8): 487-490

Abstract: Earlier in the pages of this journal (p 481), Wendler and Miller offered the "net risks test" as an alternative approach to the ethical analysis of benefits and harms in research. They have been vocal critics of the dominant view of benefit-harm analysis in research ethics, which encompasses core concepts of duty of care, clinical equipoise and component analysis. They had been challenged to come up with a viable alternative to component analysis which meets five criteria. The alternative must (1) protect research subjects; (2) allow clinical research to proceed; (3) explain how physicians may offer trial enrolment to their patients; (4) address the challenges posed by research containing a mixture of interventions and (5) define ethical standards according to which the risks and potential benefits of research may be consistently evaluated. This response argues that the net risks test meets none of these criteria and concludes that it is not a viable alternative to component analysis.

http://www.jmedethics.com (link may be outdated)

Wendler, D. Miller, F.G.

Assessing research risks systematically: the net risks test
Journal of Medical Ethics 2007 August; 33(8): 481-486

Abstract: Dual-track assessment directs research ethics committees (RECs) to assess the risks of research interventions based on the unclear distinction between therapeutic and non-therapeutic interventions. The net risks test, in contrast, relies on the clinically familiar method of assessing the risks and benefits of interventions in comparison to the available alternatives and also focuses attention of the RECs on the central challenge of protecting research participants.

http://www.jmedethics.com (link may be outdated)

Boyd, Ann

Respecting vulnerable persons

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Document 957
Thatte, Urmila; Kulkarni-Munshi, Renuka
Data Safety Monitoring Boards
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Document 958
Cordner, Christopher; Thomson, Colin
No need to go! Workplace studies and the resources of the revised National Statement
Monash Bioethics Review 2007 July; 26(3, Ethics Committee Supplement): 37-48
Georgetown users check Georgetown Journal Finder for access to full text

Document 959
Bamber, Greg J.; Sappey, Jennifer
Unintended consequences of human research ethics committees: Au revoir workplace studies?
Monash Bioethics Review 2007 July; 26(3, Ethics Committee Supplement): 26-36
Georgetown users check Georgetown Journal Finder for access to full text

Document 960
Shields, Linda; Pearn, John
Inducements for medical and health research: issues for the profession of nursing.
Journal of Clinical Nursing 2007 July; 16(7): 1196-1200
Georgetown users check Georgetown Journal Finder for access to full text

Document 961
Mehta, Samir; Myers, Thomas G.; Lonner, Jess H.; Huffman, G. Russell; Sennett, Brian J.
The ethics of sham surgery in clinical orthopaedic research.
Georgetown users check Georgetown Journal Finder for access to full text

Document 962
Singh, Ilina
Capacity and competence in children as research participants. Researchers have been reluctant to include children in health research on the basis of potentially naive assumptions
EMBO Reports 2007 July; 8(Special Number): S35-S39
Georgetown users check Georgetown Journal Finder for access to full text
* Article Document 963
Resnik, David B.; Tinkle, Sally S.
**Ethical issues in clinical trials involving nanomedicine**
Contemporary Clinical Trials 2007 July; 28(4): 433-441

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* Article Document 964
Dyrbye, Liselotte N.; Thomas, Matthew R.; Mechaber, Alex J.; Eacker, Anne; Harper, William; Massie, F. Stanford; Power, David V.; Shanafelt, Tait D.
**Medical education research and IRB review: an analysis and comparison of the IRB review process at six institutions**
Academic Medicine 2007 July; 82(7): 654-660

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[http://www.academicmedicine.org/](http://www.academicmedicine.org/) (link may be outdated)

* Article Document 965
Maloney, Dennis M.
**Case study: university says it is doing what it can to earn right to resume research**
Human Research Report 2007 July; 22(7): 6-7

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* Article Document 966
Maloney, Dennis M.
**Institutional review boards (IRBs), privacy rule, and subject recruitment**

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* Article Document 967
Musschenga, A.W.; van Luijn, H.E.M.; Keus, R.B.; Aaronson, N.K.
**Are risks and benefits of oncological research protocols both incommensurable and incompensable?**
Accountability in Research 2007 July-September; 14(3): 179-196

**Abstract:** Institutional review boards (IRBs) are legally required to determine whether the balance between the risks and benefits (the risk-benefit ratio or RBR) of a proposed study is "reasonable" or "proportional". This obligation flows from their duty to protect the interests of research subjects. It has been argued that it is difficult, perhaps even impossible for IRBs to determine the RBR of studies, because the risks and benefits are not only heterogeneous, but also incommensurable. After arguing that the relevant meaning of incommensurability is incomparability, we discuss whether the risks of participating in a trial and the benefits are comparable. We conclude that at least the risks and the benefits to participants are comparable. In the last section we show that the main problem of RBR analyses is that of interpersonal incompensability. IRBs have to assume that risks to research subjects be compensated by benefits to others. The question is: To what extent? When does it become unreasonable to ask that patients accept the risks of participating in a trial for the benefit of science and/or future patients?

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**Document 968**

Hadskis, Michael R.

**Giving voice to research participants: should IRBs hear from research participant representatives?**

*Accountability in Research* 2007 July-September; 14(3): 155-177

**Abstract:** The current decision-making model for the review of human research contains inadequate mechanisms to ensure that the interests and perspectives of research participants are considered by Institutional Review Boards, whose decisions may profoundly affect the safety and well-being of participants. As a result, this model is far from being optimized to realize Institutional Review Boards' principal mandate and undermines the credibility of the research review process. This article proposes a procedural mechanism that would ameliorate these systemic deficiencies by allowing "research participant representatives" to give voice to participants during the research review process.

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**Document 969**

Pentz, Rebecca D.; Flamm, Anne L.; Sugarman, Jeremy; Cohen, Marlene Z.; Xu, Zhiheng; Herbst, Roy S.; Abbruzzese, James L.

**Who should go first in trials with scarce agents? The views of potential participants**


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**Document 970**

Day, Michael

**Clinical trial results often overstate benefits of treatment**

*BMJ: British Medical Journal* 2007 June 30; 334(7608): 1341

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http://www.bmj.com (link may be outdated)

**Document 971**


**Ethical considerations related to the provision of care and treatment in vaccine trials**

*Vaccine* 2007 June 21; 25(26): 4863-4874

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**Document 972**

Goodman, Steven N.

**Stopping at nothing? Some dilemmas of data monitoring in clinical trials [commentary]**

*Annals of Internal Medicine* 2007 June 19; 146(12): 882-887

**Abstract:** This commentary reviews the argument that clinical trials with data monitoring committees that use statistical stopping guidelines should generally not be stopped early for large observed efficacy differences because efficacy estimates may be exaggerated and there is minimal information on treatment harms. Overall, the average of estimates from trials that use these boundaries differs minimally from the true value. Estimates from a given trial that seem implausibly high can be moderated by using Bayesian methods. Data monitoring committees are not ethically required to precisely estimate a large efficacy difference if that difference differs convincingly from zero, and the requirement to detect harms and balance efficacy against harm depends on whether the nature of the harm.
is known or unknown before the trial.

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http://www.annals.org (link may be outdated)

* Document 973
Mueller, Paul S.; Montori, Victor M.; Bassler, Dirk; Koenig, Barbara A.; Guyatt, Gordon H.

Ethical issues in stopping randomized trials early because of apparent benefit
Annals of Internal Medicine 2007 June 19; 146(12): 878-881

Abstract: Stopping randomized trials early because of an apparent benefit is becoming more common. To protect and promote the interests of trial participants, investigators may feel obligated to stop a trial early because of the apparent benefit of a study treatment (compared with placebo or other treatment). There are, however, serious ethical problems with doing so. Truncated trials systematically overestimate treatment effects; in cases where the number of accrued outcome events is small, the overestimation may be very large. Generating seriously inflated estimates of treatment effect violates the ethical research requirement of scientific validity. Subsequent use of inflated estimates to inform clinical decision making and practice guidelines violates the ethical requirements of social value and a favorable risk–benefit ratio. Researchers should ensure that a large number of outcome events accrues before stopping a trial and then continue recruitment to assess whether positive trends continue. This can balance the need to protect research participants with the ethical requirements of scientific validity, social value, and a favorable risk–benefit ratio.

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Laine, Christine; Horton, Richard

Clinical trial registration: looking back and moving ahead

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* Document 975
Krimsky, Sheldon; Simoncelli, Tania

Testing pesticides in humans: of mice and men divided by ten

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http://jama.ama-assn.org (link may be outdated)
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Document 976
Comité consultatif de Bioéthique de Belgique
Avis no. 40 du 12 février 2007 concernant le champ d'application de la loi du 7 mai 2004 relative aux expérimentations sur la personne humaine [Opinion no. 40 of February 12, 2007 concerning the scope of application of May 7, 2004 on human experimentation]
Bioetica Belgica 2007 June; (28): 6-14
Georgetown users check Georgetown Journal Finder for access to full text

Document 977
Benatar, S.R.; Fleischer, T.E.
Ethical issues in research in low-income countries.
International Journal of Tuberculosis and Lung Disease 2007 June; 11(6): 617-623
Georgetown users check Georgetown Journal Finder for access to full text

Document 978
Dowsing, T.; Kendall, M.J.
The Northwick Park tragedy—protecting healthy volunteers in future first-in-man trials.
Georgetown users check Georgetown Journal Finder for access to full text

Document 979
Kotzer, Anne Marie; Milton, Jerrod
An education initiative to increase staff knowledge of Institutional Review Board guidelines in the USA
Nursing and Health Sciences 2007 June; 9(2): 103-106
Georgetown users check Georgetown Journal Finder for access to full text

Document 980
Nelson, Robert M.
Minimal risk, yet again
Georgetown users check Georgetown Journal Finder for access to full text
Document 981
Wendler, David; Glantz, Leonard

A standard for assessing the risks of pediatric research: pro and con

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Fovargue, Sara

'Oh pick me, pick me' -- selecting participants for xenotransplant clinical trials

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Maloney, Dennis M.

Alternative models discussed for institutional review boards

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Maloney, Dennis M.

Huge study would impact institutional review boards

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Document 985
Maloney, Dennis M.

Required training for IRB chairs, members, and staff

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Document 986
O'Beirne; Maeve; Stingl, Michael; Hayward, Sarah

Who reviews the projects of unaffiliated researchers for ethics? A case study from Alberta
CQ: Cambridge Quarterly of Healthcare Ethics 2007 Summer; 16(3): 346-355

Georgetown users check Georgetown Journal Finder for access to full text

Document 987

*
Regulation of clinical research and bioethics in Portugal
Bioethics 2007 June; 21(5): 290-302

Abstract: This article presents an overview of the Portuguese transposition of the European Directive on Good Clinical Practice (2001/20/E) concerning scientific and academic debates on bioethics and clinical investigation. Since the Directive was transposed into Portuguese law by its National Assembly, the bureaucracy of clinical trials has been ever more complex. Despite demands for swift application processes by the Pharmaceutical industry, supported by the European Parliament, the Directive's transcription to the national law has not always delivered the expected outcome. However, this has led to an increased number of applications for clinical trials in Portuguese hospitals. In this article I revise bioethical publications and decree-laws enabling an informed appraisal of the anxieties and prospects for the implementation of the clinical trials Directive in Portugal. This article also places the European Directive in the field of sociology of bioethics, arguing that Portuguese bioethical institutions differ from those of the US, and also from Northern European counterparts. The main divergence is that those people in Portugal who claim expertise in 'legal' bioethics do not dominate either the bureaucratic structure of research or ethics committees for health. Even experts in the applied ethics field now claim that 'professional bioethicists do not exist'. The recent creation of a national Ethics Committee for Clinical Investigation (CEIC) in line with the European Directive on Good Clinical Practice (GCP) will not change the present imbalance between different professional jurisdictions in the national bioethical debate in Portugal.

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Document 988

Wittes, Janet; Barrett-Conner, Elizabeth; Braunwald, Eugene; Chesney, Margaret; Cohen, Harvey Jay; DeMets, David; Dunn, Leo; Dwyer, Johanna; Heaney, Robert P.; Vogel, Victor; Walters, LeRoy; Yusuf, Salim
Monitoring the randomized trials of the Women's Health Initiative: the experience of the data and safety monitoring board
Clinical Trials 2007 June; 4(3): 218-234

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 989

Ding, Eric L.; Powe, Neil R.; Manson, JoAnn E.; Sherber, Noëlle S.; Braunstein, Joel B.
Sex differences in perceived risks, distrust, and willingness to participate in clinical trials
Archives of Internal Medicine 2007 May 14; 167(9): 905-912

Abstract: Background: Multiple sex differences exist in cardiovascular disease burden and treatment efficacies; adequate participation of both sexes is crucial to clinical research. Methods: A multicenter, double-blind, randomized study evaluated sex and trial scenarios on willingness to participate (WTP) in cardiovascular prevention trials and examined sex differences in perceived risks and distrust. Hypothetical trial scenarios randomized multifactorial vignettes of adverse effects, trial durations, sponsors, financial incentives, and conflicts of interest. Results: With 783 participants across 13 clinical centers, women showed lower distrust of medical researchers, perceived greater risk of myocardial infarction, and perceived greater risk of harm from trial participation than men. Men had 15% greater WTP than women (33.1% vs 28.7%; relative risk [RR], 1.15; 95% confidence interval [CI], 1.02-1.31); adjusting for explanatory mediators, we found that sex differences in perceived risks and benefits explained the sex gap in WTP. Although greater perceived probability of harm (RR, 0.41; 95% CI, 0.23-0.72), health benefit (RR, 2.99; 95% CI, 1.63-5.46), and quality of care (RR, 1.71; 95% CI, 1.12-2.61) strongly predicted WTP (for perceived probabilities 80% vs <20%) similarly in both sexes, and perceptions of distrust and myocardial infarction risk predicted WTP differently between sexes (P.01 for interactions), age, history of coronary artery disease, hypertension, and diabetes mellitus increased WTP in men but not in women (P.05 for sex interactions). Compared with no financial conflict, disclosure of investigator patent ownership increased WTP in women, while it decreased WTP in men (P = .02 for sex interaction). Monetary incentives were overall more effective on WTP in women (P = .03 for sex interaction). Conclusions: In this multicenter study, women perceived greater risk of harm and myocardial infarction and showed lower WTP in cardiovascular prevention trials. Evidence underscores the importance of sex in influencing clinical trial enrollment.

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Falagas, Matthew E.; Pitsouni, Eleni I.

**Guidelines and consensus statements regarding the conduction and reporting of clinical research studies**

Archives of Internal Medicine 2007 May 14; 167(9): 877-878

Georgetown users check [Georgetown Journal Finder](http://archinte.amassn.org) for access to full text

McMichael, Anthony J.; Bambrick, Hilary J.

**Greenhouse-gas costs of clinical trials**

Lancet 2007 May 12–18; 369(9573): 1584-1585

Georgetown users check [Georgetown Journal Finder](http://www.thelancet.com/journals/lancet) for access to full text

Kohane, Isaac C.; Mandl, Kenneth D.; Taylor, Patrick L.; Holm, Ingrid A.; Nigrin, Daniel J.; Kunkel, Louis M.

**Reestablishing the researcher-patient compact**

Science 2007 May 11; 316(5826): 836-837

Georgetown users check [Georgetown Journal Finder](http://www.sciencemag.org) for access to full text

Hemelaar, Joris

**Minimising risk in first-in-man trials**

Lancet 2007 May 5-11; 369(9572): 1496-1497

Georgetown users check [Georgetown Journal Finder](http://www.thelancet.com/journals/lancet) for access to full text

Macrae, Duncan J.

**The Council for International Organizations and Medical Sciences (CIOMS) guidelines on ethics of clinical trials.**


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* Document 995
Silverman, Henry
**Ethical issues during the conduct of clinical trials.**
Georgetown users check **Georgetown Journal Finder** for access to full text

* Document 996
Rowell, Robert M.; Lawrence, Dana J.; Owens, Edward F.
**Process development for ethical recruitment of patients into simultaneous clinical studies in a chiropractic research clinic.**
Journal of Manipulative and Physiological Therapeutics 2007 May; 30(4): 295-300
Georgetown users check **Georgetown Journal Finder** for access to full text

* Document 997
Jansen, T.C.; Kompanje, E.J.O.; Druml, C.; Menon, D.K.; Wiedermann, C.J.; Bakker, J.
**Deferred consent in emergency intensive care research: what if the patient dies early? use the data or not?**
Intensive Care Medicine 2007 May; 33(5): 894-900
Georgetown users check **Georgetown Journal Finder** for access to full text

* Document 998
Dubray, Claude; Mailierre, Patricia; Spriet, Alain
**The conduct of clinical trials for medicinal products in europe in the light of the European clinical trials directive. review of regulatory and practical aspects in the different countries.**
Thérapie 2007 May-June; 62(3): 193-197, 199-202
Georgetown users check **Georgetown Journal Finder** for access to full text

* Document 999
Sleem, Hany Mohamed Safwat; Silverman, Henry
**Evaluation of ethics review procedures for research in Egypt [abstract]**
Eubios Journal of Asian and International Bioethics 2007 May; 17(3): 89
Georgetown users check **Georgetown Journal Finder** for access to full text

http://www.eubios.info/EJAIB52007.pdf (link may be outdated)

* Document 1000
Alaa, Abouzeid; Mohammad, Afzal; Henry, Silverman
**Adequacy of ethical review and informed consent documents submitted for funding to the Eastern Mediterranean region of WHO [abstract]**
Eubios Journal of Asian and International Bioethics 2007 May; 17(3): 89
Georgetown users check **Georgetown Journal Finder** for access to full text
Document 1001
Kiatying-Angsulee, Niyada; Haritavorn, Niphatra

Ethics in clinical trials for AIDS vaccine and antiretroviral drugs: patient perspectives in Thailand [abstract]
Eubios Journal of Asian and International Bioethics 2007 May; 17(3): 81

Georgetown users check Georgetown Journal Finder for access to full text

Document 1002
Harrington, Linda

Quality improvement, research, and the institutional review board.
Journal for Healthcare Quality 2007 May-June; 29(3): 4-9

Georgetown users check Georgetown Journal Finder for access to full text

Document 1003
Barratt, Monica J.; Norman, Josephine S.; Fry, Craig L.

Positive and negative aspects of participation in illicit drug research: implications for recruitment and ethical conduct
International Journal on Drug Policy 2007 May; 18(3): 235-238

Georgetown users check Georgetown Journal Finder for access to full text

Document 1004
Wise, Robert A.

Ethical issues confronted in pulmonary clinical trials

Georgetown users check Georgetown Journal Finder for access to full text

Document 1005
Rojas, Ariz; Kinder, Bill N.

Effects of completing sexual questionnaires in males and females with histories of childhood sexual abuse: implications for institutional review boards
Journal of Sex and Marital Therapy 2007 May-June; 33(3): 193-201

Georgetown users check Georgetown Journal Finder for access to full text

Document 1006
Lantos, John D.

Should institutional review board decisions be evidence-based?
Archives of Pediatrics and Adolescent Medicine 2007 May; 161(5): 516-517
Document 1007
West, Robert
Access to data from clinical trials sponsored by pharmaceutical companies.
Addiction 2007 May; 102(5): 682-683

Document 1008
Mitchell, Peter
Critics pan timid European response to TeGenero disaster

Document 1009
Maloney, Dennis M.
IRB members must receive continuing education on protection of human subjects
Human Research Report 2007 May; 22(5): 6-7

Document 1010
Maloney, Dennis M.
IRBs and the privacy of human research subjects
Human Research Report 2007 May; 22(5): 3

Document 1011
Maloney, Dennis M.
What should not be reported to institutional review boards (IRBs)

Document 1012
Kim, Kwang-Soo
Commentary: stem cell research continues in Korea beyond the Hwang scandal
Miller, Franklin G.; Wertheimer, Alan

**Facing up to paternalism in research ethics**
Hastings Center Report 2007 May-June; 37(3): 24-34

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---

Menikoff, Jerry

**Toward a general theory of research ethics**
Hastings Center Report 2007 May-June; 37(3): 3

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---

Slaven, Marcia Jacobson

**First impressions: the experiences of a community member on a research ethics committee**
IRB: Ethics and Human Research 2007 May-June; 29(3): 17-19

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---

Erwin, Cheryl; Hersch, Steven

Huntington Study Group. Event Monitoring Committee

**Monitoring reportable events and unanticipated problems: the PHAROS and PREDICT studies of Huntington disease**
IRB: Ethics and Human Research 2007 May-June; 29(3): 11-16

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---

Hausman, Daniel M.

**Third-party risks in research: should IRBs address them?**

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---

Schuppli, C.A.; Fraser, D.

**Factors influencing the effectiveness of research ethics committees**
Journal of Medical Ethics 2007 May; 33(5): 294-301

Abstract: Research ethics committees - animal ethics committees (AECs) for animal-based research and institutional research boards (IRBs) for human subjects - have a key role in research governance, but there has been little study of the factors influencing their effectiveness. The objectives of this study were to examine how the effectiveness of a research ethics committee is influenced by committee composition and dynamics, recruitment of members, workload, participation level and member turnover. As a model, 28 members of AECs at four universities...
in western Canada were interviewed. Committees were selected to represent variation in the number and type of
protocols reviewed, and participants were selected to include different types of committee members. We found that a
bias towards institutional or scientific interests may result from (1) a preponderance of institutional and scientist
members, (2) an intimidating atmosphere for community members and other minority members, (3) recruitment of
community members who are affiliated with the institution and (4) members joining for reasons other than to fulfil the
committee mandate. Thoroughness of protocol review may be influenced by heavy workloads, type of review
process and lack of full committee participation. These results, together with results from the literature on research
ethics committees, suggested potential ways to improve the effectiveness of research ethics committees.

McClure, Katie B.; Delorio, Nicole M.; Schmidt, Terri A.; Chiodo, Gary; Gorman, Paul
A qualitative study of institutional review board members' experience reviewing research proposals using
emergency exception from informed consent
Journal of Medical Ethics 2007 May; 33(5): 289-293

Abstract: BACKGROUND: Emergency exception to informed consent regulation was introduced to provide a venue
to perform research on subjects in emergency situations before obtaining informed consent. For a study to proceed,
institutional review boards (IRBs) need to determine if the regulations have been met. AIM: To determine IRB
members' experience reviewing research protocols using emergency exception to informed consent. METHODS:
This qualitative research used semistructured telephone interviews of 10 selected IRB members from around the US
in the fall of 2003. IRB members were chosen as little is known about their views of exception to consent, and part
of their mandate is the protection of human subjects in research. Interview questions focused on the length of review
process, ethical and legal considerations, training provided to IRB members on the regulations, and experience using
community consultation and notification. Content analysis was performed on the transcripts of interviews. To ensure
validity, data analysis was performed by individuals with varying backgrounds: three emergency physicians, an IRB
member and a layperson. RESULTS: Respondents noted that: (1) emergency exception to informed consent studies
require lengthy review; (2) community consultation and notification regulations are vague and hard to implement; (3)
current regulations, if applied correctly, protect human subjects; (4) legal counsel is an important aspect of reviewing
exception to informed-consent protocols; and (5) IRB members have had little or no formal training in these
regulations, but are able to access materials needed to review such protocols. CONCLUSIONS: This preliminary
study suggests that IRB members find emergency exception to informed consent studies take longer to review than
other protocols, and that community consultation and community notification are the most difficult aspect of the
regulations with which to comply but that they adequately protect human subjects.

States); Center for Biologics Evaluation and Research [CBER] (United States); Center for Devices and Radiological
Health [CDRH] (United States)
Protecting the Rights, Safety, and Welfare of Study Subjects -- Supervisory Responsibilities of Investigators.
Guidance for Industry [draft guidance]
Rockville, MD: Food and Drug Administration [FDA], 2007 May: [16 p.] [Online]. Accessed:
* Article  Document 1021
Freemantle, Nick; Calvert, Mel
Composite and surrogate outcomes in randomized controlled trials
BMJ: British Medical Journal 2007 April 14; 334(7597): 756-757

Georgetown users check Georgetown Journal Finder for access to full text

http://www.bmj.com (link may be outdated)

Article  Document 1022
Wilcken, Nicholas R.; Gebski, Val J.; Pike, Rhana; Keech, Anthony C.
Putting the results of a clinical trial into perspective
Medical Journal of Australia 2007 April 2; 186(7): 368-370

Georgetown users check Georgetown Journal Finder for access to full text

Article  Document 1023
Role of the data safety and monitoring board in an international trial.
AIDS 2007 April; 21 Suppl 2: S99-102

Georgetown users check Georgetown Journal Finder for access to full text

Article  Document 1024
Smith, Rachel
Finding your way through Research Ethics Committees.
Journal of Family Planning and Reproductive Health Care 2007 April; 33(2): 121-122

Georgetown users check Georgetown Journal Finder for access to full text

* Article  Document 1025
Carandang, Carlo; Santor, Darcy; Gardner, David M.; Carrey, Normand; Kutcher, Stan
Data safety monitoring boards and other study methodologies that address subject safety in "high-risk" therapeutic trials in youths.
Journal of the American Academy of Child and Adolescent Psychiatry 2007 April; 46(4): 489-492

Georgetown users check Georgetown Journal Finder for access to full text

Article  Document 1026
Twomey, John G.
Revisiting Belmont: a stroll down memory lane, auld lang syne, or an opportunity to revitalize a vital document [review of Belmont Revisited: Ethical Principles for Research with Human Subjects, edited by J. Childress, E. Meslin and H. Shapiro]
Ethics and Behavior 2007 April; 17(2): 207-210

Georgetown users check Georgetown Journal Finder for access to full text
van der Meer, J.W.M.; de Gier, A.M.; van Swaaij, W.P.M.; Katan, M.B.

Independent medical research
Netherlands Journal of Medicine 2007 April; 65(4): 124-126

Georgetown users check Georgetown Journal Finder for access to full text

Freshwater, Dawn
Discourse, responsible research and positioning the subject

Georgetown users check Georgetown Journal Finder for access to full text

Fowler, Susan B.; Stack, Katherine
Research and the clinical trials coordinator
Journal of Neuroscience Nursing 2007 April; 39(2): 120-123

Georgetown users check Georgetown Journal Finder for access to full text

Mansbach, Jonathan; Acholonu, Uchechi; Clark, Sunday; Camargo, Carlos A. Jr.
Variation in institutional review board responses to a standard, observational, pediatric research protocol.
Academic Emergency Medicine April; 14(4): 377-380

Georgetown users check Georgetown Journal Finder for access to full text

Bliss-Holtz, Jane
The flip of the coin: exempt, expedited, or full IRB review?
AACN Advanced Critical Care 2007 April-June; 18(2): 213-217

Georgetown users check Georgetown Journal Finder for access to full text

Maloney, Dennis M.
Reintroduced bill contains role for institutional review boards (IRBs)
Human Research Report 2007 April; 22(4): 9

Georgetown users check Georgetown Journal Finder for access to full text

Maloney, Dennis M.
Court says actions of institutional review board (IRB) members were ethically wrong
Human Research Report 2007 April; 22(4): 8
Georgetown users check Georgetown Journal Finder for access to full text

Document 1034
Maloney, Dennis M.
Researcher's ethical duty to human research subjects
Human Research Report 2007 April; 22(4): 5
Georgetown users check Georgetown Journal Finder for access to full text

Document 1035
Maloney, Dennis M.
Public comments on role of IRBs when consent is waived
Georgetown users check Georgetown Journal Finder for access to full text

Document 1036
Maloney, Dennis M.
Institutional review boards (IRBs) and reporting unanticipated problems
Georgetown users check Georgetown Journal Finder for access to full text

Document 1037
Hunter, D.
Proportional ethical review and the identification of ethical issues
Journal of Medical Ethics 2007 April; 33(4): 241-245
Abstract: Presently, there is a movement in the UK research governance framework towards what is referred to as proportional ethical review. Proportional ethical review is the notion that the level of ethical review and scrutiny given to a research project ought to reflect the level of ethical risk represented by that project. Relatively innocuous research should receive relatively minimal review and relatively risky research should receive intense scrutiny. Although conceptually attractive, the notion of proportional review depends on the possibility of effectively identifying the risks and ethical issues posed by an application with some process other than a full review by a properly constituted research ethics committee. In this paper, it is argued that this cannot be achieved and that the only appropriate means of identifying risks and ethical issues is consideration by a full committee. This implies that the suggested changes to the National Health Service research ethics system presently being consulted on should be strenuously resisted.
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http://www.jmedethics.com (link may be outdated)

Document 1038
United States. Food and Drug Administration [FDA]. Office of the Commissioner (OC) Center for Drug Evaluation and Research [CDER] (United States); Center for Biologics Evaluation and Research [CBER] (United States); Center for
Adverse Event Reporting -- Improving Human Subject Protection. Guidance for Clinical Investigators, Sponsors and IRBs [draft guidance]

http://www.clinicalresearchresources.com/images/fdaguidanceadvreport.pdf (link may be outdated)

Alternative Models of IRB Review Workshop Summary Report, November 17-18, 2005

http://www.hhs.gov/ohrp/sachrp/documents/AltModIRB.pdf (link may be outdated)

Towards sustainable clinical trials
BMJ: British Medical Journal 2007 March 31; 334(7595): 671-673

http://www.bmj.com (link may be outdated)

Update on the TGN1412 trial

http://www.bioethicsforum.org (link may be outdated)

Guidelines on requirements for first-in-man clinical trials for potential high-risk medicinal products [draft]. Released for consultation 2007 March 22

http://www.emea.eu.int/pdfs/human/swp/2836707en.pdf (link may be outdated)
Markman, Maurie
Informing prospective research subjects of the influence of regulatory requirements for drug approval on the design of clinical trials in oncology.
Cancer 2007 March 15; 109(6): 1003-1006
Georgetown users check [Georgetown Journal Finder](#) for access to full text

Kelman, Chris W.; Pearson, Sallie-Anne; Day, Richard O.; Holman, C. D'Arcy J.; Kliwer, Erich V.; Henry, David A.
Evaluating medicines: let's use all the evidence
Medical Journal of Australia 2007 March 5; 186(5): 249-252
Georgetown users check [Georgetown Journal Finder](#) for access to full text

Tremayne-Lloyd, Tracey; Srebrolow, Gary
Research ethics approval for human and animal experimentation: consequences of failing to obtain approval— including legal and professional liability.
The Journal of the Canadian Chiropractic Association 2007 Mar ; 51(1): 56-60
Georgetown users check [Georgetown Journal Finder](#) for access to full text

Mainetti, José Alberto
Bioética, ética en comisión. = Bioethics, ethics in commission
Abstract: Since the outset, bioethics has been organised as ethics in commission, then it developed as a two-faced academic discipline with one face open to society and the other turned towards culture. It thus forms a bridge between techno-science and social morals. Commission is literally "management in common "from which comes the manner of being ethical in the field of life sciences and health. Our aim is to draw up an overview of bioethics in commission in its theoretical, historical and prospective aspects.
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Montano, Pedro J.
Les comités de déontologie médicale dans le MERCOSUR. = Medical ethics committees in the MERCOSUR
Abstract: Do medical ethics committees exist in the MERCOSUR? What is their role and its constitution? How are patients' rights to be respected? Informed consent.
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Byk, Christian
Do ethics committees need a legal framework?

Abstract: The question "do ethics committees need a legal framework" may then raise fundamental discussion in the case of developing countries: will an ethical framework bring them a better capacity to assume their task? And what should this task be if we consider the particularities of clinical research conducted in developing countries?

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---

* Article Document 1049

Guidelines for the conduct of clinical trials for spinal cord injury as developed by the ICCP Panel: clinical trial inclusion/exclusion criteria and ethics.
Spinal Cord 2007 March; 45(3): 222-231

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---

* Article Document 1050
Decullier, Evelyne; Chapuis, François

Oral presentation bias: a retrospective cohort study.
Journal of Epidemiology and Community Health 2007 March; 61(3): 190-193

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

* Article Document 1051
Mullings, A.M.

Research ethics committees: preserving research integrity and the public trust.
West Indian Medical Journal 2007 March; 56(2): 105-107

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

* Article Document 1052
Morris, Marilyn C.; Nelson, Robert M.

Randomized, controlled trials as minimal risk: an ethical analysis.
Critical Care Medicine 2007 March; 35(3): 940-944

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

* Article Document 1053
Kahn, Jeffrey P.

Beyond disclosure: the necessity of trust in biomedical research.
Cleveland Clinic Journal of Medicine 2007 March; 74 Suppl 2(): S49-50; discussion S51-59

Georgetown users check [Georgetown Journal Finder](#) for access to full text
Schwetz, Bernard A.  
**Protecting subjects without hampering research progress: guidance from the office for human research protections.**  
Cleveland Clinic Journal of Medicine 2007 March; 74 Suppl 2(): S60-62; discussion S68-69

Irwin, Richard S.  
**Clinical trial registration promotes patient protection and benefit, advances the trust of everyone, and is required.**  
Chest 2007 March; 131(3): 639-641

Grünwald, Hans W.  
**Ethical and design issues of phase I clinical trials in cancer patients.**  
Cancer Investigation 2007 March; 25(2): 124-126

Fisk, John D.  
**Ethical considerations for the conduct of antidementia trials in Canada.**  
Canadian Journal of Neurological Sciences = Le Journal Canadien des Sciences Neurologiques 2007 March; 34 Suppl 1(): S32-36

Timmermann, Carsten  
**As depressing as it was predictable? Lung cancer, clinical trials, and the Medical Research Council in postwar Britain.**  

Ryan, Virginia M.  
**Belmont Revisited: Ethical Principles for Research with Human Subjects, edited by James F. Childress, Eric M. Meslin, and Harold T. Shapiro [book review]**  
Document 1060
Graham, Deborah G.; Spano, Mindy S.; Manning, Brian
Georgetown users check Georgetown Journal Finder for access to full text

Document 1061
Maloney, Dennis M.
Better protection for human research subjects and for the general public
Human Research Report 2007 March; 22(3): 9
Georgetown users check Georgetown Journal Finder for access to full text

Document 1062
Maloney, Dennis M.
Court says institutional review boards (IRBs) are not objective enough to protect human subjects
Human Research Report 2007 March; 22(3): 8
Georgetown users check Georgetown Journal Finder for access to full text

Document 1063
Maloney, Dennis M.
Requirements for IRBs' written documentation
Human Research Report 2007 March; 22(3): 4
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Document 1064
Maloney, Dennis M.
Final guidance on adverse events for institutional review boards (IRBs)
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Document 1065
Kesselheim, Aaron S.; Mello, Michelle M.
Confidentiality laws and secrecy in medical research: improving public access to data on drug safety. Concealing clinical trial data from public scrutiny has implications for Americans' health
Health Affairs 2007 March-April; 26(2): 483-491
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http://www.healthaffairs.org (link may be outdated)
Document 1066
McDonald, Katherine; Hernandez, Brigida; Plemmons, Dena; Simmerling, Mary
Privacy in organizational research
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Document 1067
Falusi, Adeyinka G.; Olopade, Olufunmilayo I.; Olopade, Christopher O.
Establishment of a standing ethics/institutional review board in a Nigerian university: a blueprint for developing countries
Abstract: An ethics/institutional review board (IRB) was established according to International standards at the University of Ibadan in Nigeria. To achieve this, a private-public partnership was developed to support a review of prevailing practice and the development of necessary infrastructure for an effective IRB. An internationally registered and well-constituted IRB with a federal-wide assurance (FWA) from the National Institute of Health in the United States was established within a year. Over a 3-year period, the number of proposals reviewed increased by 150% while time to approval decreased by 62%. International collaboration and external research funding has increased substantially. These findings support our initial supposition that the development of a properly functioning IRB can be a catalyst for increased research productivity at academic centers in developing countries while ensuring the protection of vulnerable human research subjects. The University of Ibadan is now assisting other academic Institutions in Nigeria and sub-Saharan Africa with the establishment of their own IRBs.
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Document 1068
Mann, Howard
Deception in the single-blind run-in phase of clinical trials [commentary]
IRB: Ethics and Human Research 2007 March-April; 29(2): 14-17
Georgetown users check Georgetown Journal Finder for access to full text

Document 1069
Speckman, Jeanne L.; Byrne, Margaret M.; Gerson, Jason; Getz, Kenneth; Wangsmo, Gary; Muse, Carianne T.; Sugarman, Jeremy
Consortium to Examine Clinical Research Ethics
Determining the costs of institutional review boards
Georgetown users check Georgetown Journal Finder for access to full text

Document 1070
Slutsman, Julia; Buchanan, David; Grady, Christine
Ethical issues in cancer chemoprevention trials: considerations for IRBs and investigators
IRB: Ethics and Human Research 2007 March-April; 29(2): 1-6
Georgetown users check Georgetown Journal Finder for access to full text
The irrelevance of equipoise

Abstract: It is commonly believed in research ethics that some form of equipoise is a necessary condition for justifying randomized clinical trials, that without it clinicians are violating the moral duty to do what is best for the patient. Recent criticisms have shown how complex the concept of equipoise is, but often retain the commitment to some form of equipoise for randomization to be justified. This article rejects that claim. It first asks for what one should be equally poised (scientific or clinical equipoise), then asks who should be equally poised (scientist, clinician, or subject), and finally asks why any of these players need be equally poised between treatment options. The article argues that only the subject's evaluation of the options is morally relevant and that even the subject need not be equally poised or indifferent between the options in order to volunteer for randomization. All that is needed is adequately informed, free, and unexploited consent. It concludes equipoise is irrelevant.

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Clinical equipoise and the incoherence of research ethics

Abstract: The doctrine of clinical equipoise is appealing because it appears to permit physicians to maintain their therapeutic obligation to offer optimal medical care to patients while conducting randomized controlled trials (RCTs). The appearance, however, is deceptive. In this article we argue that clinical equipoise is defective and incoherent in multiple ways. First, it conflates the sound methodological principle that RCTs should begin with an honest null hypothesis with the questionable ethical norm that participants in these trials should never be randomized to an intervention known to be inferior to standard treatment. Second, the claim that RCTs preserve the therapeutic obligation of physicians misrepresents the patient-centered orientation of medical care. Third, the appeal to clinical equipoise as a basic principle of risk-benefit assessment for RCTs is incoherent. Finally, the difficulties with clinical equipoise cannot be resolved by viewing it as a presumptive principle subject to exceptions. In the final sections of the article, we elaborate on the non-exploitation framework for the ethics clinical research and indicate issues that warrant further inquiry.

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So-called "clinical equipoise" and the argument from design

Abstract: In this article, I review and expand upon arguments showing that Freedman's so-called "clinical equipoise" criterion cannot serve as an appropriate guide and justification for the moral legitimacy of carrying out randomized clinical trials. At the same time, I try to explain why this approach has been given so much credence despite compelling arguments against it, including the fact that Freedman's original discussion framed the issues in a misleading way, making certain things invisible: Clinical equipoise is conflated with community equipoise, and several versions of each are also conflated. But a misleading impression is given that, rather than distinct criteria being arbitrarily conflated, a puzzle is solved and a number of features unified. Various issues are pushed under the rug, hiding flaws of the "clinical equipoise" approach and thus deceiving us into thinking that we have a solution when we do not. Particularly significant is the ignoring of the crucial distinction between the individual patient decision and the policy decision.

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**Document 1074**

Miller, Paul B.; Weijer, Charles

*Equipoise and the duty of care in clinical research: a philosophical response to our critics*


**Abstract:** Franklin G. Miller and colleagues have stimulated renewed interest in research ethics through their work criticizing clinical equipoise. Over three years and some twenty articles, they have also worked to articulate a positive alternative view on norms governing the conduct of clinical research. Shared presuppositions underlie the positive and critical dimensions of Miller and colleagues' work. However, recognizing that constructive contributions to the field ought to enjoy priority, we presently scrutinize the constructive dimension of their work. We argue that it is wanting in several respects.

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**Document 1075**

Djulbegovic, Benjamin

*Articulating and responding to uncertainties in clinical research*


**Abstract:** This paper introduces taxonomy of clinical uncertainties and argues that the choice of scientific method should match the underlying level of uncertainty. Clinical trial is one of these methods aiming to resolve clinical uncertainties. Whenever possible these uncertainties should be quantified. The paper further shows that the still ongoing debate about the usage of "equipoise" vs. "uncertainty principle" vs. "indifference" as an entry criterion to clinical trials actually refers to the question "whose uncertainty counts". This question is intimately linked to the control of research agenda, which is not quantifiable and hence is not solvable to equal acceptability to all interested parties. The author finally shows that there is a predictable relation between [acknowledgement of] uncertainty (the moral principle) on which trials are based and the ultimate outcomes of clinical trials. That is, [acknowledgement of] uncertainty determines a pattern of success in medicine and drives clinical discoveries.

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**Document 1076**

Davies, Hugh

*Ethical reflections on Edward Jenner's experimental treatment*

Journal of Medical Ethics 2007 March; 33(3): 174-176

**Abstract:** In 1798 Dr Edward Jenner published his famous account of "vaccination". Some claim that a Research Ethics Committee, had it existed in the 1790s, might have rejected his work. I provide the historical context of his work and argue that it addressed a major risk to the health of the community, and, given the devastating nature of smallpox and the significant risk of variolation, the only alternative preventative measure, Jenner's study had purpose, justification and a base in the practice of the day.

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**Document 1077**

Wisely, J.; Lilleyman, J.

*Implementing the district hospital recommendations for the National Health Service Research Ethics Service in England*

Journal of Medical Ethics 2007 March; 33(3): 168

Georgetown users check [Georgetown Journal Finder](http://www.jmedethics.com) for access to full text
Contesting the science/ethics distinction in the review of clinical research

Abstract: Recent policy in relation to clinical research proposals in the UK has distinguished between two types of review: scientific and ethical. This distinction has been formally enshrined in the recent changes to research ethics committee (REC) structure and operating procedures, introduced as the UK response to the EU Directive on clinical trials. Recent reviews and recommendations have confirmed the place of the distinction and the separate review processes. However, serious reservations can be mounted about the science/ethics distinction and the policy of separate review that has been built upon it. We argue here that, first, the science/ethics distinction is incoherent, and, second, that RECs should not only be permitted to consider a study's science, but that they have an obligation to do so.

Catholic principles and guidelines for clinical research

Catholic Medical Association; National Catholic Bioethics Center

Phase 0 trials: are they ethically challenged?

Monopolizing clinical trial data: implications and trends

A cure for dyslexia?
* Document 1083
Parvizi, Javad; Tarity, T. David; Conner, Kyle; Smith, J. Bruce
**Institutional review board approval: why it matters**
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* Document 1084
Perkins, Alexis C.; Choi, Joanna Mimi; Kimball, Alexa B.
**Reporting of ethical review of clinical research submitted to the Journal of the American Academy of Dermatology**
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* Document 1085
Appleton, J.; Caan, W.; Cowley, S.; Kendall, S.
**Busting the bureaucracy: lessons from research governance in primary care**
Community Practitioner 2007 February; 80(2): 29-32
Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Document 1086
Schonfeld, Toby; Gordon, Bruce; Amoura, Jean; Brown, Joseph Spencer
**Money matters**
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http://bioethics.net (link may be outdated)

* Document 1087
Mann, Howard
**Evaluation of research design by research ethics committees: misleading reassurance and the need for substantive reforms**
American Journal of Bioethics 2007 February; 7(2): 84-86
Georgetown users check [Georgetown Journal Finder](#) for access to full text

http://bioethics.net (link may be outdated)

* Document 1088
Maloney, Dennis M.
**Institutional review board (IRB) accused of relying too much on subcommittee [case study]**
Human Research Report 2007 February; 22(2): 6-7
Agency's internal IRB finds many problems
Maloney, Dennis M.
Human Research Report 2007 February; 22(2): 4

IRBs likely to receive more drug protocols
Maloney, Dennis M.
Human Research Report 2007 February; 22(2): 4

Charging in clinical trials has ethical implications
Maloney, Dennis M.

Managing conflicts of interest: a survival guide for biotechs
Werner, Michael J.; Price, Elizabeth
Nature Biotechnology 2007 February; 25(2): 161-163

Assessment of the ethical review process for non-pharmacological multicentre studies in Germany on the basis of a randomised surgical trial
Seiler, C.M.; Kellmeyer, P.; Kienle, P.; Büchler, M.W.; Knaebel, H.-P.
Journal of Medical Ethics 2007 February; 33(2): 113-118

Abstract: OBJECTIVE: To examine the current ethical review process (ERP) of ethics committees in a non-pharmacological trial from the perspective of a clinical investigator. DESIGN: Prospective collection of data at the Study Centre of the German Surgical Society on the duration, costs and administrative effort of the ERP of a randomised controlled multicentre surgical INSECT Trial (INterrupted or continuous Slowly absorbable sutures-Evaluation of abdominal Closure Techniques Trial, ISRCTN 24023541) between November 2003 and May 2005. SETTING: Germany. PARTICIPANTS: 18 ethics committees, including the ethics committee handling the primary approval, responsible overall for 32 clinical sites throughout Germany. 8 ethics committees were located at university medical schools (MSU) and 10 at medical chambers. Duration was measured as days between submission and receipt of final approval, costs in euros and administrative effort by calculation of the product of the total number of different types of documents and the mean number of copies required (primary approval acting as the reference standard). RESULTS: The duration of the ERP ranged from 1 to 176 (median 31) days. The median...
duration was 26 days at MSUs compared with 34 days at medical chambers. The total cost was euro2947. 1 of 8 ethics committees at universities (euro250) and 8 of 10 at medical chambers charged a median fee of euro162 (mean euro269.70). The administrative effort for primary approval was 30. Four ethics committees required a higher administrative effort for secondary approval (37, 39, 42 and 104). CONCLUSION: The ERP for non-pharmacological multicentre trials in Germany needs improvement. The administrative process has to be standardised: the application forms and the number and content of the documents required should be identical or at least similar. The fees charged vary considerably and are obviously too high for committees located at medical chambers. However, the duration of the ERP was, with some exceptions, excellent. A centralised ethics committee in Germany for multicentre trials such as the INSECT Trial can simplify the ERP for clinical investigators in and outside the country.

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http://www.jmedethics.com (link may be outdated)

* Article Document 1094
Moerman, C.J.; Haafkens, J.A.; Söderström, M.; Rásky, É.; Maguire, P.; Maschewsky-Schneider, U.; Norstedt, M.; Hahn, D.; Reinerth, H.; McKevitt, M.
Gender equality in the work of local research ethics committees in Europe: a study of practice of five countries
Journal of Medical Ethics 2007 February; 33(2): 107-112
Abstract: BACKGROUND: Funding organisations and research ethics committees (RECs) should play a part in strengthening attention to gender equality in clinical research. In the research policy of European Union (EU), funding measures have been taken to realise this, but such measures are lacking in the EU policy regarding RECs. OBJECTIVE: To explore how RECs in Austria, Germany, Ireland, The Netherlands and Sweden deal with gender equality issues by asking two questions: (1) Do existing procedures promote representation of women and gender expertise in the committee? (2) How are sex and gender issues dealt with in protocol evaluation? METHODS: Two RECs were selected from each country. Data were obtained through interviews with key informants and content analysis of relevant documents (regulations, guidelines and review tools in use in 2003). RESULTS: All countries have rules (mostly informal) to ensure the presence of women on RECs; gender expertise is not required. Drug study protocols are carefully evaluated, sometimes on a formal basis, as regards the inclusion of women of childbearing age. The reason for excluding either one of the sexes or including specific groups of women or making a gender-specific risk-benefit analysis are investigated by some RECs. Such measures are, however, neither defined in the regulations nor integrated in review tools. CONCLUSIONS: The RECs investigated in five European member states are found to pay limited attention to gender equality in their working methods and, in particular in protocol evaluation. Policy and regulations of EU are needed to strengthen attention to gender equality in the work of RECs.

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http://www.jmedethics.com (link may be outdated)

* Article Document 1095
Sinclair, Andrew H.; Schofield, Peter R.
Human embryonic stem cell research: an Australian perspective
Cell 2007 January 26; 128(2): 221-223

Georgetown users check Georgetown Journal Finder for access to full text

http://www.jmedethics.com (link may be outdated)

* Article Document 1096
Moodley, Kaymanthri; Myer, Landon
Health research ethics committees in South Africa 12 years into democracy
Document 1097
Office for Human Research Protections [OHRP]
Guidance on Continuing Review

http://www.hhs.gov/ohrp/humansubjects/guidance/contrev0107.htm (link may be outdated)

Document 1098
Anderson, Emily E; DuBois, James M
The need for evidence-based research ethics: a review of the substance abuse literature.
Drug and Alcohol Dependence 2007 January 12; 86(2-3): 95-105

Document 1099

http://www.scotland.gov.uk/Resource/Doc/89021/0021244.pdf (link may be outdated)

Document 1100
Edwards, Sarah J.L.; Stone, Tracey; Swift, Teresa
Differences between research ethics committees
International Journal of Technology Assessment in Health Care 2007 Winter; 23(1): 17-23

Document 1101
Allen, Gary
Mind the gap: Griffith University's approach to the governance of ethical conduct in human research

Document 1102
Davies, Grant; Gillam, Lynn
Articulation and transparency of decision-making by human research ethics committees
De Ville, Kenneth; Hassler, Gregory; Lewis, Michael J.
Rejuvenating a foundering institutional review board: one institution’s story
Academic Medicine 2007 January; 82(1): 11-17

Newcombe, J.P.; Kerridge, I.H.
Assessment by human research ethics committees of potential conflicts of interest arising from pharmaceutical sponsorship of clinical research
Internal Medicine Journal 2007 January; 37(1): 12-17

Branson, Richard D.; Davis, Kenneth, Jr.; Butler, Karyn L.
African Americans' participation in clinical research: importance, barriers, and solutions

Van Denend, Toni; Finlayson, Marcia
Ethical decision making in clinical research: application of CELIBATE
American Journal of Occupational Therapy 2007 January-February; 61(1): 92-95

Epstein, M.; Wingate, D.L.
Is the NHS research ethics committees system to be outsourced to a low-cost offshore call centre?
Reflections on human research ethics after the Warner Report.
Journal of Medical Ethics 2007 January; 33(1): 45-47

Abstract: The recently published Report of the AHAG on the Operation of NHS Research Ethics Committees (the Warner Report) advocates major reforms of the NHS research ethics committees system. The main implications of the proposed changes and their probable effects on the major stakeholders are described.
Should research ethics committees be told how to think?

Abstract: Research ethics committees (RECs) are charged with providing an opinion on whether research proposals are ethical. These committees are overseen by a central office that acts for the Department of Health and hence the State. An advisory group has recently reported back to the Department of Health, recommending that it should deal with (excessive) inconsistency in the decisions made by different RECs. This article questions the desirability and feasibility of questing for consistent ethical decisions.

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http://www.jmedethics.com (link may be outdated)

* Article

Document 1109

Macduff, Colin; McKie, Andrew; Martindale, Sheelagh; Rennie, Anne Marie; West, Bernice; Wilcock, Sylvia

A novel framework for reflecting on the functioning of research ethics review panels
Nursing Ethics 2007 January; 14(1): 99-116

Abstract: In the past decade structures and processes for the ethical review of UK health care research have undergone rapid change. Although this has focused users' attention on the functioning of review committees, it remains rare to read a substantive view from the inside. This article presents details of processes and findings resulting from a novel structured reflective exercise undertaken by a newly formed research ethics review panel in a university school of nursing and midwifery. By adopting and adapting some of the knowledge to be found in the art and science of malt whisky tasting, a framework for critical reflection is presented and applied. This enables analysis of the main contemporary issues for a review panel that is primarily concerned with research into nursing education and practice. In addition to structuring the panel's own literary narrative, the framework also generates useful visual representation for further reflection. Both the analysis of issues and the framework itself are presented as of potential value to all nurses, health care professionals and educationalists with an interest in ethical review.

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Maloney, Dennis M.

University says its institutional review board (IRB) policies and procedures were just misunderstood

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Maloney, Dennis M.

Federal office clarifies who is not covered by protection regulations

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* Article

Document 1112

van Luijn, H.E.M.; Musschenga, A.W.; Keus, R.B.; Aaronson, N.K.

Evaluating the risks and benefits of phase II and III clinical cancer trials: a look at institutional review board members in the Netherlands

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**Document 1113**
Wolf, Leslie E.; Zandecki, Jolanta

*Conflicts of interest in research: how IRBS address their own conflicts*

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**Document 1114**
Weinfurt, Kevin P.; Allsbrook, Jennifer S.; Friedman, Joëlle Y.; Dinan, Michaela A.; Hall, Mark A.; Schulman, Kevin A.; Sugarman, Jeremy

*Developing model language for disclosing financial interests to potential clinical research participants*

Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 1115**
Kass, Nancy E.; Hyder, Adnan Ali; Ajuwon, Ademola; Appiah-Poku, John; Barsdorf, Nicola; Elsayed, Dya Eldin; Mokhachane, Mantoa; Mupenda, Bavon; Ndebele, Paul; Ndossi, Godwin; Sikateyo, Bornwell; Tangwa, Godfrey; Tindana, Pauline

*The structure and function of research ethics committees in Africa: a case study*

Georgetown users check [Georgetown Journal Finder](#) for access to full text

http://medicine.plosjournals.org/archive/1549-1676/4/1/pdf/10.1371_journal.pmed.0040003-S.pdf (link may be outdated)

**Document 1116**
Royal College of Physicians of London

*Guidelines on the Practice of Ethics Committees in Medical Research with Human Participants*

Call number: [R853.H8 R69 2007](#)

**Document 1117**
Amdur, Robert J. and Bankert, Elizabeth A.

*Institutional Review Board: Member Handbook*

Call number: [R852.5.A463 2007](#)

**Document 1118**
Mazur, Dennis J.

*Evaluating the Science and Ethics of Research on Humans: A Guide for IRB Members*

Call number: [R853.H8 M39 2007](#)
Document 1119
Page, Stacey; Godlovitch, Glenys
Tremayne-Lloyd T, Srebrolow G. Research ethics approval for human and animal experimentation: consequences of failing to obtain approval—including legal and professional liability JCCA 2007; 51(1): 56-60.
The Journal of the Canadian Chiropractic Association 2007 51(3): 186; author reply 186-7
Georgetown users check Georgetown Journal Finder for access to full text

Document 1120
Jorge, Miguel Tanús; Pegoraro, Bruno Leonardo; Ribeiro, Lindioneza Adriano
Abrangência de ação do Comitê de Ética em Pesquisa da Universidade Federal de Uberlândia
Georgetown users check Georgetown Journal Finder for access to full text

Document 1121
Kottow, Miguel
El medico y la investigación clínica
Revista Bioética 2007; 15(2): 218-228
Georgetown users check Georgetown Journal Finder for access to full text

Document 1122
Kipper, Délio José; dos Santos, Aline Gançalves
Sistema gerencial de acompanhamento de protocolos de pesquisa envolvendo ensaios clínicos
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Document 1123
de Freitas, Corina Bomtempo Duca; Novaes, Hillegonda Maria Dutilh
Posicionamentos de lideranças do sistema de avaliação de ética em pesquisa no Brasil - consensos e divergências
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* Document 1124
Reid, Lynette; Krahm, Timothy
Minimal risk in the Tri-Council policy statement
Georgetown users check Georgetown Journal Finder for access to full text
Document 1125
Tilburt, Jon; Ford, Jean G.; Howerton, Mollie W.; Gary, Tiffany L.; Lai, Gabriel Y.; Bolen, Shari; Baffi, Charles; Wilson, Renee F.; Tanpitukpongse, Teerath Peter; Powe, Neil R.; Bass, Eric B.; Sugarman, Jeremy
Applying justice in clinical trials for diverse populations.
Clinical Trials 2007; 4(3): 264-269

Georgetown users check Georgetown Journal Finder for access to full text

Document 1126
Kahn, Jeffrey
Comments on 'applying justice in clinical trials for diverse population' by J. Tilburt et al.
Clinical Trials 2007; 4(3): 270; discussion 271

Georgetown users check Georgetown Journal Finder for access to full text

Document 1127
Burnett, Leslie; McQueen, Matthew J.; Jonsson, Jon Johannes; Torricelli, Francesca;
IFCC position paper: report of the IFCC taskforce on ethics: introduction and framework.
Clinical Chemistry and Laboratory Medicine 2007; 45(8): 1098-1104

Georgetown users check Georgetown Journal Finder for access to full text

Document 1128
Cook, Margaret; Cook, Glenda; Hodgson, Philip; Reed, Jan; Clarke, Charlotte; Inglis, Pamela
The impact of research governance in the United Kingdom on research involving a national survey.

Georgetown users check Georgetown Journal Finder for access to full text

Document 1129
Gravel, Jocelyn; Opatrny, Lucie; Shapiro, Stan
The intention-to-treat approach in randomized controlled trials: are authors saying what they do and doing what they say?
Clinical Trials 2007; 4(4): 350-356

Georgetown users check Georgetown Journal Finder for access to full text

Document 1130
Walker, Wendy
Ethical considerations in phenomenological research
Nurse Researcher 2007; 14(3): 36-45

Georgetown users check Georgetown Journal Finder for access to full text
**Document 1131**
Wilmshurst, Peter

*Dishonesty in medical research*

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**Document 1132**
Barlow, M. Rose

*Researching dissociative identity disorder: practical suggestions and ethical implications*
Journal of Trauma and Dissociation 2007; 8(1): 81-96

Georgetown users check [Georgetown Journal Finder](#) for access to full text.

**Document 1133**
Rothstein, William G.; Phuong, Linh H.

*Ethical attitudes of nurse, physician, and unaffiliated members of institutional review boards*
Journal of Nursing Scholarship 2007; 39(1): 75-81

Georgetown users check [Georgetown Journal Finder](#) for access to full text.

**Document 1134**
Dowrick, Christopher F.; Hughes, John G.; Hiscock, Julia J.; Wigglesworth, Mark; Walley, Thomas J.

*Considering the case for an antidepressant drug trial involving temporary deception: a qualitative enquiry of potential participants.*
BMC Health Services Research 2007; 7(): 64

Georgetown users check [Georgetown Journal Finder](#) for access to full text.

**Document 1135**
Madsen, S.M.; Holm, S.; Riis, P.

*Participating in a cancer clinical trial? the balancing of options in the loneliness of autonomy: a grounded theory interview study.*

Georgetown users check [Georgetown Journal Finder](#) for access to full text.

**Document 1136**
Ikingura, J.K.B.; Kruger, M.; Zeleke, W.

*Health research ethics review and needs of institutional ethics committees in Tanzania*
Tanzania Health Research Bulletin 2007 September; 9(3): 154-158

Georgetown users check [Georgetown Journal Finder](#) for access to full text.
Dobbins, Kirk; Scanlon, Kay
Medicare's revised clinical trail policy and clinical trial-related provisions of FDAAA: what is a sponsor to do?
Georgetown users check Georgetown Journal Finder for access to full text

UK Clinical Research Collaboration [UKCRC]
Clinical trials: what they are and what they're not

http://www.ukcrc.org/pdf/CT%20leaflet%20for%20web.pdf (link may be outdated)

Miller, Paul B.; Weijer, Charles
Evaluating benefits and harms in clinical research
Call number: R724 .P69 2007

Clarke, Mike
The ethical requirement for systematic reviews for randomized trials
Call number: R724 .P69 2007

Ashcroft, Richard E.
The ethics of governance of medical research
Call number: R724 .P69 2007

Wichman, Alison
Institutional review boards
Call number: R850 .G35 2007

* Document 1143
Schwartz, Joan P.  
**Integrity in research: individual and institutional responsibility**  
Call number: R850 .G35 2007

Levanon, Ayelet  
**Conducting international clinical trials in Israel: benefits, opportunities and the unique role of pharmacists**  
Journal of Biolaw and Business 2007; 10(1): 31-34

Moreno, Jonathan D.  
**Stumbling toward bioethics: human experiments policy and the early Cold War**  
Call number: R853 .H8 D37 2007

Hyman, David A.  
**Institutional review boards: is this the least we can do?**  

Kulynych, Jennifer J.  
**The regulation of MR neuroimaging research: disentangling the Gordian knot**  

Akabayshi, Akira; Slingsby, Brian T.; Nagao, Noriko; Kai, Ichiro; Sato, Hajime  
**An eight-year follow-up national study of medical school and general hospital ethics committees in Japan**  

**Abstract:** BACKGROUND: Ethics committees and their system of research protocol peer-review are currently used worldwide. To ensure an international standard for research ethics and safety, however, data is needed on the quality and function of each nation's ethics committees. The purpose of this study was to describe the characteristics and developments of ethics committees established at medical schools and general hospitals in Japan. METHODS: This study consisted of four national surveys sent twice over a period of eight years to two separate samples. The first target was the ethics committees of all 80 medical schools and the second target was all general hospitals with over 300 beds in Japan (n = 1457 in 1996 and n = 1491 in 2002). Instruments contained four sections: (1) committee structure, (2) frequency of annual meetings, (3) committee function, and (4) existence of a set of guidelines for the
refusal of blood transfusion by Jehovah's Witnesses. RESULTS: Committee structure was overall interdisciplinary. Frequency of annual meetings increased significantly for both medical school and hospital ethics committees over the eight years. The primary activities for medical school and hospital ethics committees were research protocol reviews and policy making. Results also showed a significant increase in the use of ethical guidelines, particularly those related to the refusal of blood transfusion by Jehovah's Witnesses, among both medical school and hospital ethics committees. CONCLUSION: Overall findings indicated a greater recognized degree of responsibilities and an increase in workload for Japanese ethics committees.

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http://www.biomedcentral.com/1472-6939/8/8 (link may be outdated)

* Chapter Document 1149
Gifford, Fred
Taking equipoise seriously: the failure of clinical or community equipoise to resolve the ethical dilemmas in randomized clinical trials
Call number: R723 .E87 2007

* News Document 1150
Brainard, Jeffrey
Study finds conflicts of interest on many research-review boards
Chronicle of Higher Education 2006 December 8; 53(16): A22
Georgetown users check Georgetown Journal Finder for access to full text

http://chronicle.com (link may be outdated)

* Article Document 1151
Marcovitch, Harvey
Research misconduct: Can Australia learn from the UK's stuttering system?
Medical Journal of Australia 2006 December 4-18; 185(11-12): 616-618
Georgetown users check Georgetown Journal Finder for access to full text

* Article Document 1152
Hall, Bruce M.
Australia needs an office of academic integrity
Medical Journal of Australia 2006 December 4-18; 185(11-12): 619-622
Georgetown users check Georgetown Journal Finder for access to full text

* Article Document 1153
Poustie, Stephanie J.; Taylor, David McD; Forbes, Andrew B.; Skiba, Marina A.; Nelson, Mark R.; McNeil, John J.
Implementing a research governance framework for clinical and public health research
Medical Journal of Australia 2006 December 4-18; 185(11-12): 623-626
Georgetown users check Georgetown Journal Finder for access to full text
Document 1154

**Risperidone and mania: unethical trials.**
Prescrire International 2006 December; 15(86): 219

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 1155

Ferguson, Linda M.; Flo, Myrick; Yonge, Olive

**Ethically involving students in faculty research.**
Nurse Education Today 2006 December; 26(8): 705-711

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Document 1156

United States. Food and Drug Administration [FDA]


Call number: [citation only](#)

[http://www.fda.gov/cber/gdlns/childclininv.pdf](http://www.fda.gov/cber/gdlns/childclininv.pdf) (link may be outdated)

Document 1157

Corbie-Smith, Giselle M.; Durant, Raegan W.; St George, Diane Marie M.

**Investigators' assessment of NIH mandated inclusion of women and minorities in research**
Contemporary Clinical Trials 2006 December; 27(6): 571-579

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Document 1158

Maloney, Dennis M.

**National group criticizes lack of IRB appeal step**
Human Research Report 2006 December; 21(12): 4

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Document 1159

Maloney, Dennis M.

**More public awareness of IRB role in research review**
Human Research Report 2006 December; 21(12): 3

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Document 1160
Maloney, Dennis M.

Institutional review boards (IRBs) must be given adequate information

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Document 1161
van den Hooanaard, Will C.

Trends in Canadian sociology master’s theses in relation to research ethics review, 1995-2004

Abstract: THIS PAPER EXAMINES TRENDS IN CANADIAN Master’s theses in sociology, 1995-2004, in the course of the implementation of Canada’s national research-ethics guidelines (2001), using data available from ProQuest Dissertations. While there has been no decline in the number of theses completed during this period, nearly 1/4 fewer theses now involve research participants. The proportion of theses using quantitative methods shows decline; theses using qualitative methods, however, have increased significantly over time. A closer inspection qualitative theses shows an impressive increase in the proportion of theses using interviews, while the decrease in theses using field work is even more dramatic, from 40% to 5%. The decrease of theses involving field work is particularly alarming for a significant segment of sociology that must derive its material mainly from field work. Data drawn from a larger study supplement the findings in this article.

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Document 1162
Yentis, S.M.; Dawson, A.J.

Medical studies with ‘no material ethical issues’ — an unhelpful, confusing and potentially unethical suggestion
Clinical Ethics 2006 December; 1(4): 234-236

Georgetown users check Georgetown Journal Finder for access to full text

Document 1163
Buchanan, D.R.; Miller, F.G.

A public health perspective on research ethics
Journal of Medical Ethics 2006 December; 32(12): 729-733

http://www.jmedethics.com (link may be outdated)

Document 1164
Schroter, S.; Plowman, R.; Hutchings, A.; Gonzalez, A.

Reporting ethics committee approval and patient consent by study design in five general medical journals
Journal of Medical Ethics 2006 December; 32(12): 718-723

http://www.jmedethics.com (link may be outdated)
* Document 1165

Expert Scientific Group on Phase One Clinical Trials

Expert scientific group on phase one clinical trials: final report

http://www.dh.gov.uk/prod_consum_dh/idcplg?IdcService=GET_FILE&dID=136063&Rendition=Web (link may be outdated)

* Document 1166

Flum, David R.

Interpreting surgical trials with subjective outcomes: avoiding unSPORTsmanlike conduct
JAMA: The Journal of the American Medical Association 2006 November 22-29; 296(20): 2483-2485

Georgetown users check Georgetown Journal Finder for access to full text

http://jama.ama-assn.org (link may be outdated)

* Document 1167

Howard, Jennifer

Oral history under review
Chronicle of Higher Education 2006 November 10; 53(12): A14-A17

Georgetown users check Georgetown Journal Finder for access to full text

http://chronicle.com (link may be outdated)

* Document 1168

Hutt, Leah E.

Protecting the protectors: indemnification agreements for REB members
CMAJ/JAMC Canadian Medical Association Journal 2006 November 7; 175(10): 1229-1230

Georgetown users check Georgetown Journal Finder for access to full text

* Document 1169

Green, David; Cushman, Mary; Dermond, Norma; Johnson, Eric A.; Castro, Cecilia; Amett, Donna; Hill, Joel; Manolio, Teri A.

Obtaining informed consent for genetic studies: the multiethnic study of atherosclerosis
American Journal of Epidemiology 2006 November 1; 164(9): 845-851

Georgetown users check Georgetown Journal Finder for access to full text

* Document 1170

Angelos, Peter; Murphy, Timothy F.; Sampson, Heather; Hollings, Darius D.; Kshettry, Varun

Informed consent, capitation, and conflicts of interest in clinical trials: views from the field.
Buchanan, David

**Moral reasoning as a model for health promotion.**

Social Science and Medicine 2006 November; 63(10): 2715-2726

Mitra, Analava; Bhattacharyya, D.

**Ethical problems faced in villages of rural Bengal while conducting researches on chronic diseases like diabetes**

Indian Journal of Medical Sciences 2006 November; 60-11): 475-484

Mano, Max S.; Rosa, Daniela D.; Dal Lago, Lissandra

**Multinational clinical trials in oncology and post-trial benefits for host countries: where do we stand?**

European Journal of Cancer 2006 November; 42(16): 2675-2677


**TuBaFrost 3: regulatory and ethical issues on the exchange of residual tissue for research across Europe**

European Journal of Cancer 2006 November; 42(17): 2914-2923

Fuchs, Thomas

**Ethical issues in neuroscience**
Document 1177
Colt, Henri G.; Mulnard, Ruth A.
Writing an application for a human subjects institutional review board
Chest 2006 November; 130(5): 1605-1607

Document 1178
Singer, Eleanor; Bossarte, Robert M.
Incentives for survey participation when are they "coercive"?

Document 1179
Mayers, Douglas L.; Chung, Jain; Kohlbrenner, Veronika M.; Hall, David B.; DeMasi, Ralph A.; Neubacher, Dietmar; Buss, Neil E.; Salgo, Miklos P.
Seeking ethical designs for HIV clinical trials in treatment-experienced patients: an industry perspective
AIDS Research and Human Retroviruses 2006 November; 22(11): 1110-1112

Document 1180
Shweder, Richard A.
Protecting human subjects and preserving academic freedom: prospects at the University of Chicago

Document 1181
Maloney, Dennis M.
Case study: institutional review board fails to follow numerous regulations
Human Research Report 2006 November; 21(11): 6-7

Document 1182
Maloney, Dennis M.
Proposal to ease burdens of IRBs
Human Research Report 2006 November; 21(11): 4
**Document 1183**
Maloney, Dennis M.

**Institutional review boards (IRBs) and their role in community consultation**

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---

**Document 1184**
Beskow, Laura M.; Sandler, Robert S.; Weiberger, Morris

**Research recruitment through U.S. central cancer registries: balancing privacy and scientific issues**

**Abstract:** Cancer registries are a valuable resource for recruiting participants for public health-oriented research, although such recruitment raises potentially competing concerns about patient privacy and participant accrual. We surveyed US central cancer registries about their policies for research contact with patients, and results showed substantial variation. The strategy used most frequently (37.5% of those that allowed patient contact), which was among the least restrictive, was for investigators to notify patients' physicians and then contact patients with an opt-out approach. The most restrictive strategy was for registry staff to obtain physician permission and contact patients with an opt-in approach. Population-based studies enhance cancer control efforts, and registry policies can affect researchers' ability to conduct such studies. Further discussion about balanced recruitment approaches that protect patient privacy and encourage beneficial research is needed.

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**Document 1185**
Malone, Ruth E.; Yerger, Valerie B.; McGruder, Carol; Froelicher, Erika

"It's like Tuskegee in reverse": a case study of ethical tensions in institutional review board review of community-based participatory research

**Abstract:** Community-based participatory research (CBPR) addresses the social justice dimensions of health disparities by engaging marginalized communities, building capacity for action, and encouraging more egalitarian relationships between researchers and communities. CBPR may challenge institutionalized academic practices and the understandings that inform institutional review board deliberations and, indirectly, prioritize particular kinds of research. We present our attempt to study, as part of a CBPR partnership, cigarette sales practices in an inner-city community. We use critical and communitarian perspectives to examine the implications of the refusal of the university institutional review board (in this case, the University of California, San Francisco) to approve the study. CBPR requires expanding ethical discourse beyond the procedural, principle-based approaches common in biomedical research settings. The current ethics culture of academia may sometimes serve to protect institutional power at the expense of community empowerment.

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---

**Document 1186**
Jaspers, Patricia; van der Arend, Arie; Wanders, Rinus

**Inclusion practice in lung cancer trials**
Nursing Ethics 2006 November; 13(6): 649-660

[Find in a Library](http://www.journals.cambridge.org/)
Document 1187

King, Nancy M.P.

**Learning how to learn: a review of the ethics and regulation of research with human subjects** by Carl H. Coleman, Jerry A. Menikoff, Jesse A. Goldner, and Nancy Neveloff Dubler [book review]


Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text

Document 1188

Wolf, Leslie E.; Zandecki, Jolanta

**Sleeping better at night: investigators' experiences with certificates of confidentiality**


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Document 1189

Rothstein, Mark A.

**Tiered disclosure options promote the autonomy and well-being of research subjects**


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http://bioethics.net (link may be outdated)

Document 1190

*Angell, E.; Sutton, A.J.; Windridge, K.; Dixon-Woods, M.*

**Consistency in decision making by research ethics committees: a controlled comparison**

Journal of Medical Ethics 2006 November; 32(11): 662-664

**Abstract:** There has been longstanding interest in the consistency of decisions made by research ethics committees (RECs) in the UK, but most of the evidence has come from single studies submitted to multiple committees. A systematic comparison was carried out of the decisions made on 18 purposively selected applications, each of which was reviewed independently by three different RECs in a single strategic health authority. Decisions on 11 applications were consistent, but disparities were found among RECs on decisions on seven applications. An analysis of the agreement between decisions of RECs yielded an overall measure of agreement of kappa = 0.286 (95% confidence interval -0.06 to 0.73), indicating a level of agreement that, although probably better than chance, may be described as "slight". The small sample size limits the robustness of these findings. Further research on reasons for inconsistencies in decision making between RECs, and on the importance of such inconsistencies for a range of arguments, is needed.

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http://www.jmedethics.com (link may be outdated)

Document 1191

Kuehn, Bridget M.

**Industry, FDA warm to "adaptive" trials**

Agulnik, Mark; Oza, Amit M.; Pond, Gregory R.; Siu, Lillian L.
Impact and perceptions of mandatory tumor biopsies for correlative studies in clinical trials of novel anticancer agents
Journal of Clinical Oncology 2006 October 20; 24(30): 4801-4807

Kenter, M.J.H.; Cohen, A.F.
Establishing risk of human experimentation with drugs: lessons from TGN1412
Lancet 2006 October 14-20; 368(9544): 1387-1391

Comité consultatif de Bioéthique de Belgique
Avis no. 36 du 11 septembre 2006 relatif à l'évaluation éthique des recherches dans certains domaines des sciences humaines [Opinion no. 36 of September 11, 2006 on the ethical evaluation of certain areas of human sciences research]
Bioetica Belgica 2006 October; (26): 28-39

Johnson, Nate; Vermeulen, Lee; Smith, Kelly M.
A survey of academic medical centers to distinguish between quality improvement and research activities.

Shamoo, Adil E.; Woeckner, Elizabeth
Research ethics boards: no data on quality of for-profit or non-profit IRBs.
PLoS Medicine 2006 October; 3(10): e459; author reply e460, e471
**Document 1197**

Dingwall, Robert

*An exercise in fatuity: research governance and the emasculation of HSR*


Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

**Document 1198**

Griffin, Joan M.; Struve, James K.; Collins, Dorothea; Liu, An; Nelson, David B.; Bloomfield, Hanna E.

*Long term clinical trials: how much information do participants retain from the informed consent process?*

Contemporary Clinical Trials 2006 October; 27(5): 441-448

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

**Document 1199**

Maloney, Dennis M.

*Safety of human subjects and drug-drug interaction*

Human Research Report 2006 October; 21(10): 5

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---

**Document 1200**

Maloney, Dennis M.

*IRBs must review use of humanitarian use devices*

Human Research Report 2006 October; 21(10): 5

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

**Document 1201**

Dinan, Michaela A.; Weinfurt, Kevin P.; Friedman, Joëlle Y.; Allsbrook, Jennifer S.; Gottlieb, Julie; Schulman, Kevin A.; Hall, Mark A.; Dhillon, Jatinder K.; Sugarman, Jeremy

*Comparison of conflict of interest policies and reported practices in academic medical centers in the United States*

Accountability in Research 2006 October-December; 13(4): 325-342

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

**Document 1202**

Merritt, Maria; Grady, Christine

*Reciprocity and post-trial access for participants in antiretroviral therapy trials*

AIDS 2006 September 11; 20(14): 1791-1794

Georgetown users check [Georgetown Journal Finder](#) for access to full text
Document 1203
Giacinti, L.; Lopez, M.; Giordano, A.
Clinical trials
Frontiers in Bioscience 2006 September 1; 11: 2918-2923
Georgetown users check Georgetown Journal Finder for access to full text

Document 1204
Bonell, Christopher; Hargreaves, James; Strange, Vicki; Pronyk, Paul; Porter, John
Should structural interventions be evaluated using RCTs? The case of HIV prevention.
Social Science and Medicine 2006 September; 63(5): 1135-1142
Georgetown users check Georgetown Journal Finder for access to full text

Document 1205
Boemer, M.R.; Correa, A.K.
Qualitative investigation: zeal for rigor and ethics.
Revista da Escola de Enfermagem da USP 2006 September; 40(3): 317-320
Georgetown users check Georgetown Journal Finder for access to full text

Document 1206
Byrne, Margaret M.; Thompson, Peter
Collective equipoise, disappointment, and the therapeutic misconception: on the consequences of selection for clinical research
Medical Decision Making 2006 September-October; 26(5): 467-479
Georgetown users check Georgetown Journal Finder for access to full text

Document 1207
Cvetkovski, Stefan; Fry, Craig L.
Science, ethics and the regulation of alcohol and other drug research
International Journal of Drug Policy 2006 September; 17(5): 450-452
Georgetown users check Georgetown Journal Finder for access to full text

Document 1208
Pace, Christine; Grady, Christine; Wendler, David; Bebchuk, Judith D.; Tavel, Jorge A.; McNay, Laura A.; Forster, Heidi P.; Killen, Jack; Emanuel, Ezekiel J.
Espirit Group
Post-trial access to tested interventions: the views of IRB/REC chair, investigators, and research participants in a multinational HIV/AIDS study
AIDS Research and Human Retroviruses 2006 September; 22(9): 837-841
Georgetown users check Georgetown Journal Finder for access to full text
* Article  Document 1209
Turale, Sue
Reflections on the ethics involved in international research
Nursing & Health Sciences 2006 September; 8(3): 131-132

Georgetown users check Georgetown Journal Finder for access to full text

* Article  Document 1210
Moran, Maureen B.
Ethical issues in research with human subjects
Journal of the American Dietetic Association 2006 September; 106(9): 1346, 1348

Georgetown users check Georgetown Journal Finder for access to full text

* Article  Document 1211
Lubowitz, James H.
Randomize, then consent: a strategy for improving patient acceptance of participation in randomized controlled trials

Georgetown users check Georgetown Journal Finder for access to full text

* Article  Document 1212

Checklists? Two views being debated: a dangerously comfortable substitute for protection or the best guarantee both to protect subjects and limit overzealous IRBs
Protecting Human Subjects 2006 Fall; (14): 19, 22

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* Article  Document 1213

Lessons to be learned. Devastating illnesses for six research subjects "could happen again"
Protecting Human Subjects 2006 Fall; (14): 17

Georgetown users check Georgetown Journal Finder for access to full text

* Article  Document 1214

Surprises? How researchers view IRBs. Report suggests that the way review boards see themselves and the way researchers see them may be very, very different
Protecting Human Subjects 2006 Fall; (14): 12-14

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* Article  Document 1215
Conflicts of interest threaten trust. Who should discuss which conflicts? When? Where? How?
Protecting Human Subjects 2006 Fall; (14): 9-10
Georgetown users check Georgetown Journal Finder for access to full text

Protecting people "to death"? Are people needlessly being kept from promising drugs? Alternative forms of access, combined with appropriate protective mechanisms may be needed
Protecting Human Subjects 2006 Fall; (14): 4-5
Georgetown users check Georgetown Journal Finder for access to full text

Weinfurt, Kevin P.; Friedman, Joëlle Y.; Allsbrook, Jennifer S.; Dinan, Michaela A.; Hall, Mark A.; Sugarman, Jeremy
Views of potential research participants on financial conflicts of interest: barriers and opportunities for effective disclosure
JGIM: Journal of General Internal Medicine 2006 September; 21(9): 901-906
Georgetown users check Georgetown Journal Finder for access to full text

http://www.pubmedcentral.nih.gov (link may be outdated)

Fisher, Jill A.
Co-ordinating 'ethical' clinical trials: the role of research coordinators in the contract research industry
Sociology of Health and Illness 2006 September; 28(6): 678-694
Call number: Special Issue shelf
Georgetown users check Georgetown Journal Finder for access to full text

Liddell, Kathleen; Bion, Julian; Chamberlain, Douglas; Druml, Christiane; Kompanje, Erwin; Lemaire, Francois; Menon, David; Vrhovac, Bozidar; Wiedermann, Christian J.
Medical research involving incapacitated adults: implications of the EU Clinical Trials Directive 2001/20/EC
Georgetown users check Georgetown Journal Finder for access to full text

Bhat, S.B.; Hegde, T.T.
Ethical international research on human subjects research in the absence of local institutional review boards
Journal of Medical Ethics 2006 September; 32(9): 535-536
Abstract: International health-related research on human subjects entails unique ethical responsibilities and difficulties. Often, these difficulties are augmented by the lack of a local ethical review infrastructure. In a recent cross-national study conducted by us, three critical components of ethical regulation were identified--external oversight, local oversight and subject involvement--and integrated into the study design. These three concepts are outlined and established as an important aspect of ensuring ethical coherence in the local context, particularly when reviews by the local institutional review boards cannot practically be obtained. The three levels of ethical oversight
identified are suggested to be the framework within which future field studies on human subjects are developed and a standard for maintaining ethical rigorousness in research on humans.

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http://www.jmedethics.com (link may be outdated)

* Article  Document 1221

de Champlain, J.; Patenaude, J.

Review of a mock research protocol in functional neuroimaging by Canadian research ethics boards
Journal of Medical Ethics 2006 September; 32(9): 530-534

Abstract: To examine how research ethics boards (REBs) review research projects in emerging disciplines such as functional neuroimaging. DESIGN: To compare the criteria applied and the decisions reached by REBs that reviewed the same mock research protocol in functional neuroimaging. PARTICIPANTS: 44 Canadian biomedical REBs, mostly working in public university or hospital settings. MAIN MEASUREMENTS: The mock research protocol "The Neurobiology of Social Behavior" included several ethical issues operating at all three levels: personal, institutional and social. Data consisting of responses to closed questions were analysed quantitatively. Qualitative analysis of open-question responses used mixed classification. RESULTS: Similar criteria were used by most participating REBs. Yet the project was unconditionally approved by 3 REBs, approved conditionally by 10 and rejected by 30. CONCLUSIONS: The results point to the difficulty for REBs of reviewing all kinds of research projects, regardless of field, by relying on international and national norms framed in general terms and a possible variation between REBs in the interpretation of their mandate for the protection of research subjects.

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http://www.jmedethics.com (link may be outdated)

* Article  Document 1222

Slovenko, R.

Milestones in the evolution of standards for experimental treatment or research

Abstract: The abuses in experimentation that marked the 20th century has resulted in regulations. Standards for experimental treatment or for research involving human subjects has been a major development of the twentieth century, coming about in response to the horrendous experiments carried out by Nazi Germany and also in the United States and elsewhere. How these regulations have fared is discussed herein.

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* Article  Document 1223

Research agenda

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* Article  Document 1224

Morreim, E. Haavi; Webb, George E.; Gordon, Harvey L.; Brody, Baruch; Casarett, David; Rosenfield, Ken; Sabin, James; Lantos, John D.; Morenz, Barry; Krouse, Robert; Goodman, Stan

Innovation in human research protection: the AbioCor artificial hearth trial

Georgetown users check Georgetown Journal Finder for access to full text

http://www.jmedethics.com (link may be outdated)
Document 1225

de Grey, A.D.

**Has Hippocrates had his day?**
Rejuvenation Research 2006 Fall; 9(3): 371-373

Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text

Document 1226

Maloney, Dennis M.

**Postmarketing safety research is not a top priority at agency**
Human Research Report 2006 September; 21(9): 4

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Document 1227

Maloney, Dennis M.

**Institutional review boards and humanitarian devices**
Human Research Report 2006 September; 21(9): 3

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* Document 1228

Grady, Christine; Horstmann, Elizabeth; Sussman, Jeffrey S.; Hull, Sara Chandros

**The limits of disclosure: what research subjects want to know about investigator financial interests**
Journal of Law, Medicine and Ethics 2006 Fall; 34(3): 592-599

**Abstract:** Research participants' views about investigator financial interests were explored. Reactions ranged from concern to acceptance, indifference, and even encouragement. Although most wanted such information, some said it did not matter, was private, or was burdensome, and other factors were more important to research decisions. Very few said it would affect their research decisions, and many assumed that institutions managed potential conflicts of interest. Although disclosure of investigator financial interest information to research participants is often recommended, its usefulness is limited, especially when participation is desired because of illness.

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* Document 1229

Weinfurt, Kevin P.; Friedman, Joëlle Y.; Dinan, Michaela A.; Allsbrook, Jennifer S.; Hall, Mark A.; Dhillon, Jatinder K.; Sugarman, Jeremy

**Disclosing conflicts of interest in clinical research: views on institutional review boards, conflict of interest committees, and investigators**
Journal of Law, Medicine and Ethics 2006 Fall; 34(3): 581-591

**Abstract:** Strategies for disclosing investigators' financial interests to potential research participants have been adopted by many research institutions. However, little is known about how decisions are made regarding disclosures of financial interests to potential research participants, including what is disclosed and the rationale for making these determinations. We sought to understand the attitudes, beliefs, and practices of institutional review board chairs, conflict of interest committee chairs, and investigators regarding disclosure of financial interests to potential
Several themes emerged, including general attitudes toward conflicts of interest, circumstances in which financial interests should be disclosed, rationales and benefits of disclosure, what should be disclosed, negative effects of and barriers to disclosure, and timing and presentation of disclosure. Respondents cited several rationales for disclosure, including enabling informed decision making, promoting trust in researchers and research institutions, and reducing legal liability. There was general agreement that disclosure should happen early in the consent process. Respondents disagreed about whether to disclose the amounts of particular financial interests. Clarifying the goals of disclosure and understanding how potential research participants use the information will be critical in efforts to ensure the integrity of clinical research and to protect the rights and interests of participants.
Document 1234
Hewison, Jenny; Haines, Andy
Confidentiality and consent in medical research: overcoming barriers to recruitment in health research
BMJ: British Medical Journal 2006 August 5; 333(7562): 300-302
Georgetown users check Georgetown Journal Finder for access to full text
http://www.bmj.com (link may be outdated)

Document 1235
Kimmelman, Jonathan
Research ethics [review of Belmont Revisited: Ethical Principles for Research With Human Subjects, edited by James F. Childress, Eric M. Meslin, and Harold T. Shapiro]
JAMA: The Journal of the American Medical Association 2006 August 2; 296(5): 589-590
Georgetown users check Georgetown Journal Finder for access to full text
http://jama.ama-assn.org (link may be outdated)

Document 1236
Gallagher-Thompson, Dolores; Rabinowitz, Yaron; Tang, Paulette C.Y.; Tse, Collins; Kwo, Elizabeth; Hsu, Shannon; Wang, Peng-Chih; Leung, Laurie; Tong, Hui-Qi; Thompson, Larry W.
Recruiting Chinese Americans for dementia caregiver intervention research: suggestions for success
American Journal of Geriatric Psychiatry 2006 August; 14(8): 676-683
Georgetown users check Georgetown Journal Finder for access to full text

Document 1237
Racine, Eric; Illes, Judy
Neuroethical responsibilities
Canadian Journal of Neurological Sciences 2006 August; 33(3): 269-277, 260-268
Georgetown users check Georgetown Journal Finder for access to full text

Document 1238
Watt, G.
Using patient records for medical research
British Journal of General Practice 2006 August; 56(529): 630-631
Georgetown users check Georgetown Journal Finder for access to full text

Document 1239
Greene, Sarah M.; Geiger, Ann M.
A review finds that multicenter studies face substantial challenges but strategies exist to achieve Institutional Review Board approval
Journal of Clinical Epidemiology 2006 August; 59(8): 784-790
Document 1240
Adamson, Joy; Cockayne, Sarah; Puffer, Suezann; Torgerson, David J.
*Review of randomised trials using the post-randomised consent (Zelen's) design*
Contemporary Clinical Trials 2006 August; 27(4): 305-319

Document 1241
Heaven, Ben; Murtagh, Madeleine; Rapley, Tim; May, Carl; Graham, Ruth; Kaner, Eileen; Thomson, Richard
*Patients or research subjects? A qualitative study of participation in a randomised controlled trial of a complex intervention*

Document 1242
Sherwood, Mylaina L.; Buchinsky, Farrel J.; Quigley, Matthew R.; Donfack, Joseph; Choi, Sukgi S.; Conley, Stephen F.; Derkay, Craig S.; Myer, Charles M. III; Ehrlich, Garth D.; Post, J. Christopher
*Unique challenges of obtaining regulatory approval for a multicenter protocol to study the genetics of RRP and suggested remedies*
Otolaryngology – Head and Neck Surgery 2006 August; 135(2): 189-196

Document 1243
Sade, Robert M.
*Reports of clinical trials: ethical aspects*
Journal of Thoracic and Cardiovascular Surgery 2006 August; 132(2): 245-246

Document 1244
Rabin, Cheryl; Tabak, Nili
*Healthy participants in phase I clinical trials: the quality of their decision to take part*

Document 1245
Byrne, Margaret M.; Speckman, Jeanne; Getz, Ken; Sugarman, Jeremy
*Variability in the costs of institutional review board oversight*
Academic Medicine 2006 August; 81(8): 708-712
Document 1246
Hedgecoe, A.; Carvalho, F.; Lobmayer, P.; Raka, F.
Research ethics committees in Europe: implementing the directive, respecting diversity
Journal of Medical Ethics 2006 August; 32(8): 483-486
Abstract: With the recent Clinical Trials Directive, a degree of harmonisation into research ethics committees (RECs) across Europe, including the time taken to assess a trial proposal and the kinds of issues a committee should take into account, has been introduced by the European Union (EU). How four different member states - Hungary, Portugal, Sweden and the UK - have chosen to implement the directive is shown. Although this has resulted in four very different ways of structuring RECs, similar themes are present in all four cases, such as centralisation of control over RECs within member states, harmonisation of REC procedures across the EU and increased role of political decision making with regard to such committees.

Document 1247
Maloney, Dennis M.
University finally can resume human subjects research again [case study]
Human Research Report 2006 August; 21(8): 6-7

Document 1248
Maloney, Dennis M.
Risky research with humans and continuing requirements
Human Research Report 2006 August; 21(8): 4

Document 1249
Maloney, Dennis M.
Major agency will support costs for human subjects
Human Research Report 2006 August; 21(8): 4

Document 1250
Maloney, Dennis M.
Institutional Review Board (IRB) requirements are key
Human Research Report 2006 August; 21(8): 3
**Document 1251**

Markman, Maurie

"Therapeutic intent" in phase 1 oncology trials: a justifiable objective
Archives of Internal Medicine 2006 July 24; 166(14): 1446-1448

Georgetown users check Georgetown Journal Finder for access to full text

http://archinte.ama-assn.org (link may be outdated)

---

**Document 1252**

Khandekar, Jarardan; Khandekar, Melin

Phase 1 clinical trials: not just for safety anymore?
Archives of Internal Medicine 2006 July 24; 166(14): 1440-1441

Georgetown users check Georgetown Journal Finder for access to full text

http://archinte.ama-assn.org (link may be outdated)

---

**Document 1253**

Joffe, Steven; Miller, Franklin G.

Rethinking risk-benefit assessment for Phase I cancer trials
Journal of Clinical Oncology 2006 July 1; 24(19): 2987-2990

Georgetown users check Georgetown Journal Finder for access to full text

---

**Document 1254**

Establishing transparency to restore trust in clinical trials

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---

**Document 1255**

Block, Mark I.; Khitin, Lev M.; Sade, Robert M.

Ethical process in human research published in thoracic surgery journals

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---

**Document 1256**


Is it ethical to use placebos in osteoporosis trials?

Georgetown users check Georgetown Journal Finder for access to full text
Schwab, Abraham P.  
**Splitting the difference position**  
American Journal of Bioethics 2006 July-August; 6(4): 74-76

Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text

http://bioethics.net (link may be outdated)

---

Trachtman, Howard  
**The law of mass action**  
American Journal of Bioethics 2006 July-August; 6(4): 72-74

Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text

http://bioethics.net (link may be outdated)

---

Lindsay, Ronald A.  
**Role-differentiated morality: the need to consider institutions, not just individuals**  
American Journal of Bioethics 2006 July-August; 6(4): 70-72

Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text

http://bioethics.net (link may be outdated)

---

Thompson, Dan R.  
**What do I tell my patient?**  

Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text

http://bioethics.net (link may be outdated)

---

Litton, Paul  
**Defending the distinctions between research and medical care**  

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http://bioethics.net (link may be outdated)

---

Paradis, Carmen  
**Equipoise in the real world**  
Georgetown users check Georgetown Journal Finder for access to full text

http://bioethics.net (link may be outdated)

*   Document 1269
Miller, Franklin G.
**Equipoise and the ethics of clinical research revisited [comment]**

Georgetown users check Georgetown Journal Finder for access to full text

http://bioethics.net (link may be outdated)

*   Document 1270
Wasserman, David; Hellman, Deborah S.; Wachbroit, Robert
**Physicians as researchers: difficulties with the "similarity position" [comment]**

Georgetown users check Georgetown Journal Finder for access to full text

http://bioethics.net (link may be outdated)

*   Document 1271
Veatch, Robert M.
**Why researchers cannot establish equipoise [comment]**

Georgetown users check Georgetown Journal Finder for access to full text

http://bioethics.net (link may be outdated)

*   Document 1272
Appelbaum, Paul S.; Lidz, Charles W.
**Clinical ethics versus clinical research [comment]**

Georgetown users check Georgetown Journal Finder for access to full text

http://bioethics.net (link may be outdated)

*   Document 1273
Brody, Howard
**Are there three or four distinct types of medical practice? [comment]**

Georgetown users check Georgetown Journal Finder for access to full text

http://bioethics.net (link may be outdated)
**Document 1274**

Chiong, Winston  
**The real problem with equipoise**  

Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text

---

**Document 1275**

Maloney, Dennis M.  
**Case study: inadequate university response leads to shutdown of human research projects**  
Human Research Report 2006 July; 21(7): 6-7

Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text

---

**Document 1276**

Maloney, Dennis M.  
**Massive study would affect numerous IRBs**  
Human Research Report 2006 July; 21(7): 5

Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text

---

**Document 1277**

Palmlund, Ingar  
**Loyalties in clinical research on drugs: the case of hormone replacement therapy**  
Social Science and Medicine 2006 July; 63(2): 540-551

Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text

---

**Document 1278**

Chalmers, Iain  
**From optimism to disillusion about commitment to transparency in the medico-industrial complex**  
Journal of the Royal Society of Medicine 2006 July; 99(7): 337-341

Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text

---

**Document 1279**

Jansen, Lynn A.  
**The problem with optimism in clinical trials**  

Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text
Protecting third parties in human subjects research

Resnik, David B.; Sharp, Richard R.


Supported by: RS; R01-HG002498

A bill to amend the Public Health Service Act with respect to the protection of human subjects in research.


http://thomas.loc.gov (link may be outdated)

An outlook on research ethics committees worldwide and in Iran

Larijani, Badger; Zahedi, Farzaneh


Family patterns of decision-making in pediatric clinical trials

Snethen, J.A.; Broome, M.E.; Knafli, K.; Deatrick, J.A.; Angst, D.B.

Research in Nursing and Health 2006 June; 29(3): 223-232

Enacting a theory of caring to recruit and retain vulnerable participants for sensitive research

Kavanaugh, K.; Moro, T.T.; Savage, T.; Mehendale, R.

Research in Nursing and Health 2006 June; 29(3): 244-252

Outcome measures: linking science and ethics in clinical research

O'Lonergan, T.A.; Milgrom, H.

Current Opinion in Allergy and Clinical Immunology 2006 June; 6(3): 139-143
Document 1286

De Lemos, Mário L.

Defining the clinical improvement in cancer drug therapy: implications for priority setting in healthcare

Georgetown users check Georgetown Journal Finder for access to full text

Document 1287

Pemberton, John

Medical experiments carried out in Sheffield on conscientious objectors to military service during the 1939-45 war

Georgetown users check Georgetown Journal Finder for access to full text

Document 1288

Commentary: guinea-pigs' private war
International Journal of Epidemiology 2006 June; 35(3): 558-560

Georgetown users check Georgetown Journal Finder for access to full text

Document 1289

Jester, Penelope M.; Tilden, Samuel J.; Li, Yufen; Whitley, Richard J.; Sullender, Wayne M.

Regulatory challenges: lessons from recent West Nile virus trials in the United States
Contemporary Clinical Trials 2006 June; 27(3): 254-259

Georgetown users check Georgetown Journal Finder for access to full text

Document 1290

Silverman, David I.; Cirullo, Lisanne; DeMartinis, Nicholas A.; Damato, Kathryn; DeMeo, Margaret; Fernandez, Gustavo A.; Glynn, Laura; Hegde, Upendra; Laskay, Elizabeth; Leger, Robin; Abu-Hasaballah, Khamis; Caron, Joan M.

Systematic identification and classification of adverse events in human research
Contemporary Clinical Trials 2006 June; 27(3): 295-303

Georgetown users check Georgetown Journal Finder for access to full text

Document 1291

Appendix: submission made by FoA to the expert working group studying the TGN1412 incident
ALTA (Alternatives to Laboratory Animals) 2006 June; 34(3): 354-356

Georgetown users check Georgetown Journal Finder for access to full text
* Document 1292
Bhogal, Nirmala; Combes, Robert
An update on TGN1412 [comment]
ALTA (Alternatives to Laboratory Animals) 2006 June; 34(3): 351-353
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1293
Evans, Emily L.; London, Alex John
Equipoise and the criteria for reasonable action
Journal of Law, Medicine & Ethics 2006 Summer; 34(2): 441-450
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1294
Corrigan, Oonagh; Tutton, Richard
What's in a name? Subjects, volunteers, participants and activists in clinical research
Clinical Ethics 2006 June; 1(2): 101-104
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1295
Staley, Kristina; Minogue, Virginia
User involvement leads to more ethically sound research
Clinical Ethics 2006 June; 1(2): 95-100
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1296
Scott, Timothy
Tricks of the trade
Ethical Human Psychology and Psychiatry 2006 Summer; 8(2): 133-146
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1297
Brown, Stephen D.; Daly, Jennifer C.; Kalish, Leslie A.; McDaniel, Samuel A.
Financial disclosures of scientific papers presented at the 2003 RSNA Annual Meeting: association with reporting of non-Food and Drug Administration-approved uses of industry products
Radiology 2006 June; 239(3): 849-855
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1298
Becker, Gary J.
Financial relationships with industry and device research involving non-Food and Drug Administration-approved use: a perspective
Radiology 2006 June; 239(3): 626-628

Georgetown users check Georgetown Journal Finder for access to full text

Ruel, Michael D.
Using race in clinical research to develop tailored medications: is the FDA encouraging discrimination or eliminating traditional disparities in health care for African Americans?

Georgetown users check Georgetown Journal Finder for access to full text

Salako, S.E.
The declaration of Helsinki 2000: ethical principles and the dignity of difference

Abstract: The first detailed regulations about nontherapeutic research were promulgated by the Prussian Government in 1900. In 1947, the Nuremberg Code was decreed. Since then, the Declaration of Helsinki (DOH) was adopted in 1964 and has been revised five times. The object of this article is to evaluate the 2000 Revision of the DOH and discuss three problems of concern. These problems are: (1) If, unlike its predecessors, the DOH (2000) has recast itself as a minimum set of international standards 'binding' on physicians worldwide, from where does it derive its authority? (2) The wording of the DOH is incongruent with the underlying ethical principles. (3) The projection of the DOH into the realms of social justice raises the issue of human dignity. Finally, the feasibility or desirability of a theory of justice privileging human dignity as one of its guiding principles and the future of the DOH are examined.

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Document 1301
Maclean, Alasdair
The Law and Ethics of Medical Research: International Bioethics and Human Rights by Aurora Plomer [book review]
Medical Law Review 2006 Summer; 14(2): 284-290
Georgetown users check Georgetown Journal Finder for access to full text

Document 1302
Faden, Ruth
Response: reflections on Jay Katz's legacy
Yale Journal of Health Policy, Law and Ethics 2006 Summer; 6(2): 451-454
Georgetown users check Georgetown Journal Finder for access to full text

Document 1303
Capron, Alexander M.
Experimentation with human beings: light or only shadows?
Yale Journal of Health Policy, Law and Ethics 2006 Summer; 6(2): 431-449
Georgetown users check Georgetown Journal Finder for access to full text

Document 1304
Rao, Mahendra S.
Embryonic stem cell research and U.S. policy
Stem Cells 2006 June; 24(6): 1412-1413
Georgetown users check Georgetown Journal Finder for access to full text

Document 1305
University's defense against noncompliance charges begin to fail [case study]
Human Research Report 2006 June; 21(6): 6-7
Georgetown users check Georgetown Journal Finder for access to full text
**Document 1306**

*Yet another alternative to IRB reviews of research*


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---

**Document 1307**

*Some extra steps to protect research subjects*


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---

**Document 1308**

*Government evaluation of fundamental IRB functions*

Human Research Report 2006 June; 21(6): 4

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---

**Document 1309**

Childress, Herb

*The anthropologist and the crayons: changing our focus from avoiding harm to doing good*


**Abstract:** THE ETHICAL REVIEW PROCESS is aimed at protecting research participants, evaluating risk in relation to benefit, and, where possible, reducing risk to research participants (and by extension, to the sponsoring organizations). In practice, however, there is usually much focus on risk and little on benefit. However, social research presents an opportunity to give active benefits to many constituents: the research participants, the host community, the researcher and research team members, the sponsoring institution and funding agency, the academic community, and society at large. Even when benefits are considered, the proximal benefits—those that actually accrue during (and because of) the investigator's presence—are too often overlooked by both investigators and ethics committees in favor of the more distal benefits related to the contribution to knowledge. The research design and review processes can both be redirected to focus more centrally on imagining, creating and extending the benefits of our work.

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**Document 1310**

Burris, Scott; Moss, Kathryn

*U.S. health researchers review their ethics review boards: a qualitative study*


**Abstract:** Virtually all research involving human subjects in the United States must be reviewed by an institutional review board, a form of research ethics review board. This article reports the results of qualitative research on how investigators regard this regulatory regime. Interviews were conducted with forty investigators conducting health-related research. Most respondents shared the regulations’ goals, but doubted that the regulations, as implemented, promoted these goals efficiently, effectively and fairly. The interviews suggest that efforts to raise researchers' ethical consciousness have been, over time, quite successful, but that implementation of the regulations remains problematic. Research aimed at better defining the problem to be solved by the regulatory system, and at assessing the effectiveness of the regulatory tools for solving properly defined problems, could guide a more productive debate about human subject protection.

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**Document 1311**

Sidle, John E.; Were, Edwin; Wools-Kaloustian, Kara; Chuani, Christine; Salmon, Karen; Tierney, William M.; Meslin, Eric M.

**A needs assessment to build international research ethics capacity**


**Abstract:** INTERNATIONAL COLLABORATORS IN BIOMEDICAL sciences face ethical challenges in the design, review, and conduct of research. Challenges include differences in research ethics capacity, cultural differences in interpretation and application of ethical principles, and cooperation between ethics review boards at collaborating institutions. Indiana University School of Medicine (Indianapolis, USA) and Moi University Faculty of Health Sciences (Eldoret, Kenya) developed a Memorandum of Understanding (MOU) to establish greater cooperation between their ethics review boards, followed by a joint needs assessment to assess barriers to implementing the MOU. Focus groups and interviews at each institution revealed that while each side verbalized understanding and respect for the other's culture, there were misunderstandings deeply rooted in each culture that could potentially derail the collaboration. Although the participants at each university agreed on the major principles and issues in research ethics and on the importance attributed to them, a more in-depth evaluation of the responses revealed important differences. Methods to address these misunderstandings are outlined in the recommended Best Practices.

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---

**Document 1312**

Chan, An-Wen; Upshur, Ross; Singh, Jerome A.; Ghersi, Davina; Chapuis, François; Altman, Douglas G.

**Research protocols: waiving confidentiality for the greater good**

BMJ: British Medical Journal 2006 May 6; 332(7549): 1086-1089

Georgetown users check [Georgetown Journal Finder](#) for access to full text

[http://www.bmj.com](http://www.bmj.com) (link may be outdated)

---

**Document 1313**

Krousel-Wood, Marie; Muntner, Paul; Jannu, Ann; Hyre, Amanda; Breault, Joseph

**Does waiver of written informed consent from the institutional review board affect response rate in a low-risk research study?**

Journal of Investigative Medicine 2006 May; 54(4): 174-179

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

**Document 1314**

Boudoulas, Harisios

**Ethics in biomedical research**

Hellenic Journal of Cardiology 2006 May-June; 47(3): 193

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

**Document 1315**

Carson, P.A.; Holt, J.

**Ethics of studies involving human volunteers. I. Historical background**
* Document 1316
Shamoo, Adil E.; Resnik, David B.
**Strategies to minimize risks and exploitation in phase one trials on healthy subjects**

* Document 1317
Magnus, David C.
**Blood, sweat and tears**

* Document 1318
Wichman, Alison, Kalyan, Dev N.; Abbott, Lura J.; Wesley, Robert; Sandler, Alan L.
**Protecting human subjects in the NIH's Intramural Research Program: a draft instrument to evaluate convened meetings of its IRBs**
IRB: Ethics and Human Research 2006 May-June; 28(3): 7-10

* Document 1319
Maloney, Dennis M.
**Institutional review board (IRB) did not know about subject problem until after study**
Human Research Report 2006 May; 21(5): 6-7

* Document 1320
Maloney, Dennis M.
**Earlier contacts with agency and safety of human subjects**
Human Research Report 2006 May; 21(5): 5

* Document 1321
Maloney, Dennis M.
**Risk assessment and human subject safety**

Human Research Report 2006 May; 21(5): 4

Georgetown users check [Georgetown Journal Finder](#) for access to full text.

---

**Document 1322**

Maloney, Dennis M.

*When ethical studies cannot be conducted*

Human Research Report 2006 May; 21(5): 3

Georgetown users check [Georgetown Journal Finder](#) for access to full text.

---

**Document 1323**

Maloney, Dennis M.

*Better protection for human subjects is outcome of very early clinical trials*


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---

**Document 1324**

Valdez-Martinez, Edith; Turnbull, Bernardo; Garduno-Espinosa, Juan; Porter, John D.H.

*Descriptive ethics: a qualitative study of local research ethics committees in Mexico*

Developing World Bioethics 2006 May; 6(2): 95-105

Abstract: Objective: To describe how local research ethics committees (LRECs) consider and apply research ethics in the evaluation of biomedical research proposals. Design: A qualitative study was conducted using purposeful sampling, focus groups and a grounded theory approach to generate data and to analyse the work of the LRECs. Setting and participants: 11 LRECs of the Mexican Institute of Social Security (IMSS). Results: LRECs considered ethics to be implicit in all types of research, but that ethics reviews were only necessary for projects that included the direct participation of human beings. The LRECs appeared to understand the importance of consent, as in the completion of a consent form, but did not emphasise the importance of the process of acquiring 'informed' consent. The committees considered their main roles or functions to be: (a) to improve the methodological quality of research and to verify - if applicable - the ethical aspects; (b) to encourage personnel to undergo research training; (c) to follow-up research to oversee the adherence to norms and compliance with a specified research timetable. Conclusions: This study provides a valuable insight into how these LRECs understand the ethical review process. The emphasis of the committees was on rules, regulations, improving research methodology and research training, rather than a focus on efforts to protect the rights and well being of research subjects. The results encourage further normative and descriptive lines of investigation concerning education and the development of LRECs.

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---

**Document 1325**

Hobbs, F.D. Richard; Stewart, Paul M.

*How should we rate research? The UK's current system can be improved but shouldn't be discarded*

BMJ: British Medical Journal 2006 April 29; 332(7548): 983-984

Georgetown users check [Georgetown Journal Finder](#) for access to full text.

http://www.bmj.com (link may be outdated)
**Document 1326**
Levine, Carol; Sugarman, Jeremy

*After the TGN1412 tragedy: addressing the right questions at the right time for early phase testing*

Georgetown users check [Georgetown Journal Finder](http://www.bioethicsforum.org) for access to full text

**Document 1327**
Marshall, Eliot

*Accident prompts a closer look at antibody trials*
Science 2006 April 14; 312(5771): 172

Georgetown users check [Georgetown Journal Finder](http://www.sciencemag.org) for access to full text

**Document 1328**
Mangan, Katherine S.

*Researchers raise concerns about secrecy in company-sponsored clinical trials*
Chronicle of Higher Education 2006 April 7; 52(31): A39

Georgetown users check [Georgetown Journal Finder](http://chronicle.com) for access to full text

**Document 1329**
Gillam, Lynn; Guillemin, Marlys; Rosenthal, Doreen

*‘Obstructive and power hungry’?: the Australian human research ethics process*

Abstract: tba

Georgetown users check [Georgetown Journal Finder](http://www.bioethicsforum.org) for access to full text

**Document 1330**
Liddell, Kathleen; Chamberlain, Douglas; Menon, David K; Bion, Julian; Kompanje, Erwin J.O.; Lemaire, François; Druml, Christiane; Vrhovac, Bozidar; Wiedermann, Christian J.; Sterz, Fritz

*The European Clinical Trials Directive revisited: the VISEAR recommendations.*
Resuscitation 2006 April; 69(1): 9-14

Georgetown users check [Georgetown Journal Finder](http://www.bioethicsforum.org) for access to full text

**Document 1331**
Barden, J.; Derry, S.; McQuay, H.J.; Moore, R.A.

*Bias from industry trial funding? A framework, a suggested approach, and a negative result*
* Document 1332
Gluud, L.L.
Unravelling industry bias in clinical trials
Pain 2006 April; 121(3): 175-176
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1333
Yoder, L.H.
The basics of human subjects protection
Medsurg Nursing 2006 April; 15(2): 95-98; quiz 99
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1334
Bramstedt, Katrina A.; Ford, Paul J.
Protecting human subjects in neurosurgical trials: the challenge of psychogenic dystonia
Contemporary Clinical Trials 2006 April; 27(2): 161-164
Georgetown users check Georgetown Journal Finder for access to full text

Document 1335
Beskow, L.M.; Millikan, R.C.; Sandler, R.S.; Godley, P.A.; Weiner, B.J.; Weinberger, M.
The effect of physician permission versus notification on research recruitment through cancer registries (United States)
Cancer causes & control: CCC 2006 April; 17(3): 315-323
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1336
Nilstun, Tore; Cartwright Colleen; Löfmark Rurik; Deliens Luc; Fischer Susanne; Miccinesi Guido; Norup, Michael; Van Der Heide, Agnes
EURELD [European End-of-Life Decision] Consortium
Access to death certificates: what should research ethics committees require for approval?
Annals of Epidemiology 2006 April; 16(4): 281-284
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1337
Greene, Sarah M.; Geiger, Ann M.; Harris, Emily L.; Altschuler, Andrea; Nekhlyudov, Larissa; Barton, Mary B.; Rolnick, Sharon J.; Elmore, Joann G.; Fletcher, Suzanne
Impact of IRB requirements on a multicenter survey of prophylactic mastectomy outcomes
Document 1338

Kietinun, Somboon

Research ethics review in government and academic institutions in Thailand
Indian Journal of Medical Ethics 2006 April-June; 3(2): 67-68

Document 1339

Ploem, M.C.

Towards an appropriate privacy regime for medical data research
European Journal of Health Law 2006 April; 13(1): 41-64

Document 1340

Drew, Nancy

Bridging the distance between the objectivism of research and the subjectivity of the researcher
 Advances in Nursing Science 2006 April-June; 29(2): 181-191

Document 1341

Ogle, Kaye Robyn; Glass, Nel

Mobile subjectivities: positioning the nonunitary self in critical feminist and postmodern research
 Advances in Nursing Science 2006 April-June; 29(2): 170-180

Document 1342

Chen, Donna T.; Moreno, Jonathan D.

Ethics of medication-free research in schizophrenia

Document 1343

Jeste, Dilip V.

Can medication-free research ever be ethical in older people with psychotic disorders?
Document 1344
Jayson, Gordon; Harris, John
How participants in cancer trials are chosen: ethics and conflicting interests
Georgetown users check Georgetown Journal Finder for access to full text

Document 1345
Maloney, Dennis M.
Agency says institutional review board (IRB) did not fulfill duties so agency investigation expands
Human Research Report 2006 April; 21(4): 6-7
Georgetown users check Georgetown Journal Finder for access to full text

Document 1346
Maloney, Dennis M.
Safety of human subjects and postmarket assessment
Human Research Report 2006 April; 21(4): 5
Georgetown users check Georgetown Journal Finder for access to full text

Document 1347
Maloney, Dennis M.
Centralized institutional review boards (CIRBs)
Human Research Report 2006 April; 21(4): 4
Georgetown users check Georgetown Journal Finder for access to full text

Document 1348
Maloney, Dennis M.
Alternatives to local institutional review board (IRB) system debated
Georgetown users check Georgetown Journal Finder for access to full text

Document 1349
Anderson, Emily E.
A qualitative study of non-affiliated, non-scientist institutional review board members
Accountability in Research 2006 April-June; 13(2): 135-155
Abstract: In addition to outlining criteria for the approval of human subjects research, federal regulations provide guidance regarding local institutional review boards (IRB) membership. IRBs are mandated to include "at least one member whose primary concerns are in nonscientific areas" and "at least one member who is not otherwise affiliated
with the institution." Often a single individual serves both of these roles simultaneously. Although there have been calls for increased representation of lay community members in IRBs, little is known regarding their experiences or their perceptions of human subject protections and the IRB process. Using an ethnographic interview approach, this study seeks to gain a perspective from non-affiliated, non-scientist (NA/NS) IRB members about the process in which they participated. Findings suggest a need for clarification regarding whom NA/NS IRB members represent. They also suggest that NA/NS IRB members' experiences could be improved by an increased show of respect from the IRB chair, other members, and staff; efforts to make participation more convenient for these volunteer members; and training tailored specifically to NA/NS members. Further research on this important and understudied topic is needed to determine best practice and policy recommendations.

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* Document 1350
Goodyear, Michael
Closing the gaps: moving closer to a collaborative culture; comments on disclosure timing: balancing increased transparency and competitive advantage; submission to WHO International Clinical Trials Registry Platform [ICTRP]

http://www.who.int/ictrp/007-Michael_Goodyear_31March06.pdf (link may be outdated)

* Document 1351
Bell, Chaim M.; Urbach, David R.; Ray, Joel G.; Bayoumi, Ahmed; Rosen, Allison B.; Greenberg, Dan; Newmann, Peter J.
Bias in published cost effectiveness studies: systematic review
BMJ 2006 March 25; 332(7543): 699-701

http://www.bmj.com (link may be outdated)

* Document 1352
Wadman, Meredith
Drive for drugs leads to baby clinical trials

http://www.nature.com (link may be outdated)

Document 1353
Johnson, L.; Barrett-Lee, P.; Ellis, P.; Bliss J.
How do patients want to learn of results of clinical trials? - results of a survey of 1431 breast cancer patients taking part in the TACT trial [abstract]
**Document 1354**
Masterton, George

**Two decades on an ethics committee [opinion]**
BMJ: British Medical Journal 2006 March 11; 332(7541): 615

Georgetown users check [Georgetown Journal Finder](http://www.bmj.com) for access to full text

---

**Document 1355**

Clinical trials = Essais cliniques


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---

**Document 1356**

Goldberg, Mark

**Case vignette: the recruitment of subjects from medical care facilities into observational epidemiological studies**

NCEHR Communique CNERH 2006 Spring; 14(1): 27-31

Georgetown users check [Georgetown Journal Finder](http://www.ncehr.medical.org) for access to full text

---

**Document 1357**

Bauer, Kristen

**A preventable death—a contribution to research**

NCEHR Communique CNERH 2006 Spring; 14(1): 26-27

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---

**Document 1358**

Poff, Deborah

**Community-based REBS: the experience of the British Columbia medical services foundation**

NCEHR Communique CNERH 2006 Spring; 14(1): 24-25

Georgetown users check [Georgetown Journal Finder](http://www.ncehr.medical.org) for access to full text
**Document 1359**

Shragge, Jeremy E.

**A graduate student perspective on the accreditation of programs ensuring ethical research with humans**

NCEHR Communiqué CNERH 2006 Spring; 14(1): 21-22

Georgetown users check [Georgetown Journal Finder](http://www.ncehr.medical.org) for access to full text

**Document 1360**

Janovec, Nancy

**Ethics and oral history**

NCEHR Communiqué CNERH 2006 Spring; 14(1): 16-17

Georgetown users check [Georgetown Journal Finder](http://www.ncehr.medical.org) for access to full text

**Document 1361**

Vanderwel, Marianne

**Accreditation: the application of quality principles to the protection of human research subjects**

NCEHR Communiqué CNERH 2006 Spring; 14(1): 9-11

Georgetown users check [Georgetown Journal Finder](http://www.ncehr.medical.org) for access to full text

**Document 1362**

Davey, Ken

**Why did NCEHR take the lead? A personal view**

NCEHR Communiqué CNERH 2006 Spring; 14(1): 8

Georgetown users check [Georgetown Journal Finder](http://www.ncehr.medical.org) for access to full text

**Document 1363**

Dinsdale, Henry B.

**Accreditation and research involving humans in Canada: background and prospects**

NCEHR Communiqué CNERH 2006 Spring; 14(1): 4-7

Georgetown users check [Georgetown Journal Finder](http://www.ncehr.medical.org) for access to full text

**Document 1364**
Brewer, Sherry
Networking resources for IRBs
Protecting Human Subjects 2006 Spring; (13): 14-15
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1365
Brewer, Sherry
When things go wrong...
Protecting Human Subjects 2006 Spring; (13): 13-14
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1366
No regulations for "IRB shopping"
Protecting Human Subjects 2006 Spring; (13): 12
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1367
Research in developing countries
Protecting Human Subjects 2006 Spring; (13): 7
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1368
Reconsidering ethics in research
Protecting Human Subjects 2006 Spring; (13): 6
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1369
Miller, Franklin G.
Revisiting the Belmont Report: the ethical significance of the distinction between clinical research and medical care
APA Newsletters: Newsletter on Philosophy and Medicine 2006 Spring; 05(2): 10-14
Georgetown users check Georgetown Journal Finder for access to full text

http://www.apaonline.org/publications/onlinesubscriptions/ (link may be outdated)

* Document 1370
London, Alex John
Justice in the Belmont Report & the social division of labor
APA Newsletters: Newsletter on Philosophy and Medicine 2006 Spring; 05(2): 5-10
**Document 1371**

Macklin, Ruth

*The Belmont principle of justice: an idea whose time has come*

APA Newsletters: Newsletter on Philosophy and Medicine 2006 Spring; 05(2): 4-5

Georgetown users check [Georgetown Journal Finder](http://www.apaonline.org/publications/onlinesubscriptions/) for access to full text

**Document 1372**

Beauchamp, Tom L.

*Assessing the Belmont Report*

APA Newsletters: Newsletter on Philosophy and Medicine 2006 Spring; 05(2): 2-3

Georgetown users check [Georgetown Journal Finder](http://www.apaonline.org/publications/onlinesubscriptions/) for access to full text

**Document 1373**

van Luijn, H.E.M.; Aaronson, N.K.; Keus, R.B.; Musschenga, A.W.

*The evaluation of the risks and benefits of phase II cancer clinical trials by institutional review boards (IRB) members: a case study*

Journal of Medical Ethics 2006 March; 32(3): 170-176

Abstract: There are indications that institutional review board (IRB) members do not find it easy to assess the risks and benefits in medical experiments, although this is their principal duty. This study examined how IRB members assessed the risk/benefit ratio (RBR) of a specific phase II breast cancer clinical trial. Participants and METHODS: The trial was evaluated by means of a questionnaire administered to 43 members of IRBs at six academic hospitals and specialised cancer centres in the Netherlands. The questionnaire addressed: identification and estimation of inconvenience, toxicity, psychosocial distress, and benefits of trial participation to patients; identification and estimation of benefits to future patients and medical science; assessment of the trial's RBR; and assessment of its ethical acceptability. RESULTS: Most IRB members expected trial participation to involve fairly or very serious inconvenience, fairly severe to sometimes life-threatening toxicity, and serious psychological and social consequences. Conversely, the perceived likelihood of benefits to patients was modest. Most regarded the study as important, and the balance between risks and benefits to be favourable, and believed that the protocol should be approved. The IRB members' final judgement on the trial's ethical acceptability was significantly correlated with their RBR assessment of the protocol. CONCLUSIONS: Because most patients who participate in clinical trials hope this will prolong their lives, it is suggested that patient information should better describe the anticipated benefits-for example, the likelihood of prolonging life. This would allow patients to make decisions regarding participation based on realistic expectations.

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**Document 1374**

United States. Food and Drug Administration [FDA]. Good Clinical Practice Program, Office of the Commissioner (OC) Center for Drug Evaluation and Research [CDER] (United States); Center for Biologics Evaluation and
Research [CBER] (United States); United States. Food and Drug Administration [FDA]. Office of Regulatory Affairs [ORA]

Using a centralized IRB review process in multicenter clinical trials. Guidance for industry

http://www.fda.gov/cber/gdlns/irbclintrial.pdf (link may be outdated)

Document 1375
Center for Biologics Evaluation and Research [CBER] (United States) Center for Drug Evaluation and Research [CDER] (United States); Center for Devices and Radiological Health [CDRH] (United States)

Establishment and operation of clinical trial data monitoring committees. Guidance for clinical trial sponsors

http://www.fda.gov/cber/gdlns/clintrialdmc.pdf (link may be outdated)

* Document 1376
Keith-Spiegal, Patricia; Koocher, Gerald P.; Tabachnick, Barbara

What scientists want from their research ethics committee

Abstract: Whereas investigators have directed considerable criticism against Institutional Review Boards (IRBs), the desirable characteristics of IRBs have not previously been empirically determined. A sample of 886 experienced biomedical and social and behavioral scientists rated 45 descriptors of IRB actions and functions as to their importance. Predictions derived from organizational justice research findings in other work settings were generally borne out. Investigators place high value on the fairness and respectful consideration of their IRBs. Expected differences between biomedical and social behavioral researchers and other variables were unfounded. Recommendations are offered for educating IRBs to accord researchers greater respect and fair treatment.

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* Document 1377
Andrews, Stuart

The Law and Ethics of Medical Research: International Bioethics and Human Rights, by Aurora Plomer [book review]

Georgetown users check Georgetown Journal Finder for access to full text

* Document 1378
Cipolle, Christina L.; Cipolle, Robert J.; Strand, Linda M.

Consistent standards in medication use: the need to care for patients from research to practice
Journal of the American Pharmacists Association 2006 March-April; 46(2): 205-212

Georgetown users check Georgetown Journal Finder for access to full text

Document 1379
Maloney, Dennis M.

**Local and centralized institutional review boards (IRBs and CIRBs) to work together**

Human Research Report 2006 March; 21(3): 9

*Georgetown Journal Finder* for access to full text

---

Maloney, Dennis M.

**Agency says institutional review board (IRB) failed to warn subjects of significant problems**

Human Research Report 2006 March; 21(3): 6-7

*Georgetown Journal Finder* for access to full text

---

Maloney, Dennis M.

**Agency can make surprise investigation of researchers**

Human Research Report 2006 March; 21(3): 5

*Georgetown Journal Finder* for access to full text

---

Maloney, Dennis M.

**Waiver of institutional review board (IRB) requirements**

Human Research Report 2006 March; 21(3): 5

*Georgetown Journal Finder* for access to full text

---

Maloney, Dennis M.

**Inspecting institutional review boards (IRBs)**

Human Research Report 2006 March; 21(3): 4

*Georgetown Journal Finder* for access to full text

---

Maloney, Dennis M.

**Guidances for institutional review boards (IRBs)**

Human Research Report 2006 March; 21(3): 4

*Georgetown Journal Finder* for access to full text

---

Maloney, Dennis M.

**IRBs and DMCs -- a close relationship**

Human Research Report 2006 March; 21(3): 3

*Georgetown Journal Finder* for access to full text
Document 1386
Milford, Cecilia; Wassenaar, Douglas; Slack, Catherine
Resources and needs of research ethics committees in Africa: preparations for HIV vaccine trials
Georgetown users check Georgetown Journal Finder for access to full text

Document 1387
Daniels, Norman
Toward ethical review of health system transformations
Abstract: Efforts to transform health systems constitute social experiments on a population. Like clinical research, they deploy measures that are unproven in the context of the reform, and they often impose significant risks on some people in order to achieve a social goal: the improvement of health delivery. The rationale for proactively evaluating clinical experimentation on human subjects also applies to these social experiments. We used the "benchmarks of fairness" methodology to illustrate the elements such an evidence-based review should encompass, leaving open the question of who should perform it. The review must include the ethical objectives of reform, namely, an integrated approach to equity, accountability, and efficiency; the fit between measures taken and these objectives; and the governance of the reform.
Georgetown users check Georgetown Journal Finder for access to full text
http://www.ajph.org (link may be outdated)

Document 1388
Oberle, Kathleen; Allen, Marion
Ethical considerations for nurses in clinical trials
Nursing Ethics 2006 March; 13(2): 180-186
Abstract: Ethical issues arise for nurses involved in all phases of clinical trials regardless of whether they are caregivers, research nurses, trial co-ordinators or principal investigators. Potential problem areas centre on nurses' moral obligation related to methodological issues as well as the notions of beneficence/non-maleficence and autonomy. These ethical concerns can be highly upsetting to nurses if they are not addressed, so it is imperative that they are discussed fully prior to the initiation of a trial. Failure to resolve these issues can place both the conduct and the results of research in jeopardy.
Georgetown users check Georgetown Journal Finder for access to full text

Document 1389
Koski, Greg
Writing Clinical Research Protocols: Ethical Considerations, by Evan Derenko and Joel Moss [book review]
Georgetown users check Georgetown Journal Finder for access to full text
http://jama.ama-assn.org (link may be outdated)

Document 1390
Incidental findings in brain imaging research
Science 2006 February 10; 311(5762): 783-784

Georgetown users check Georgetown Journal Finder for access to full text

http://www.sciencemag.org (link may be outdated)

Document 1391

Canada. Royal Commission on Aboriginal Peoples

Appendix E: ethical guidelines for research
Call number: citation only

http://www.ainc-inac.gc.ca/ap/pubs/sg/cg/cka5di-eng.pdf (link may be outdated)

Document 1392

United States. Environmental Protection Agency [EPA]

Protections for Subjects in Human Research: Final Rule
Federal Register 2006 February 6; 71(24): 6138-6176

Georgetown users check Georgetown Journal Finder for access to full text

http://www.gpoaccess.gov/fr/ (link may be outdated)

Document 1393

Benham, Bryan; Francis, Leslie

Revisiting the guiding principles of research ethics [review of Belmont Revisited: Ethical Principles for Research with Human Subjects, edited by James F. Childress, Eric M. Meslin, and Harold Shapiro]
Lancet 2006 February 4-10; 367(9508): 387-388

Georgetown users check Georgetown Journal Finder for access to full text

http://www.thelancet.com/journal (link may be outdated)

Document 1394


Paediatric medicines: proposed EU regulation

http://www.publications.parliament.uk/pa/id200506/Idselect/Idcom/101/101.pdf (link may be outdated)

* Document 1395

Weinfurt, Kevin P.; Dinan, Michaela A.; Allsbrook, Jennifer S.; Friedman, Joëlle Y.; Hall, Mark A.; Schulman, Kevin
A.; Sugarman, Jeremy
Policies of academic medical center for disclosing financial conflicts of interest to potential research participants
Academic Medicine 2006 February; 81(2): 113-118

* Document 136
Karunaratne, A.S.; Myles P.S.; Ago M.J.; Komesaroff, P.A.
Communication deficiencies in research and monitoring by ethics committees
Internal Medicine Journal 2006 February; 36(2): 86-91

* Document 1396
Georgetown users check Georgetown Journal Finder for access to full text

Document 1397
Academy of Medical Sciences
Personal data for public good: using health information in medical research
Bulletin of Medical Ethics 2006 February-March; (213): 10-13

* Document 1398
Mills, Edward J.; Seely, Dugald; Rachlis, Beth; Griffith, Lauren; Wu, Ping; Wilson, Kumanan; Ellis, Peter; Wright, James R.
Barriers to participation in clinical trials of cancer: a meta-analysis and systematic review of patient-reported factors
Lancet Oncology 2006 February; 7(2): 141-148

* Document 1399
Uys, Leana R.
Are ethics committees always ethical?

* Document 1400
Propst, Evan J.; Hales, Sarah; Masellis, Mario; Adejumo, Adebayo O.; Godkin, M. Dianne
The beginning of one’s real ethical development
Clinical and Investigative Medicine 2006 February; 29(1): 7-9

* Document 1397
Georgetown users check Georgetown Journal Finder for access to full text

http://www.bullmedeth.info (link may be outdated)
* Document 1401
Thomson, Colin
Protecting health information privacy in research: what's an ethics committee like yours doing in a job like this?
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1402
Mosconi, Paola; Colombo, Cinzia; Labianca, Roberto; Apolone, Giovanni
Oncologists' opinions about research ethics committees in Italy: an update, 2004
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1403
Slowther, Anne; Boynton, Petra; Shaw, Sara
Research governance: ethical issues
Journal of the Royal Society of Medicine 2006 February; 99(2): 65-72
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1404
Green, Lee A.; Lowery, Julie C.; Kowalski, Christine P.; Wyszewianski, Leon
Impact of institutional review board practice variation on observational health services research
Health Services Research 2006 February; 41(1): 214-230
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1405
Maloney, Dennis M.
Research subject says institutional review board (IRB) would not answer her questions
Human Research Report 2006 February; 21(2): 7
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1406
Maloney, Dennis M.
Proposal withdrawn for institutional review boards
Human Research Report 2006 February; 21(2): 5
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1407
Anderson, James A.
The ethics and science of placebo-controlled trials: assay sensitivity and the Duhem-Quine thesis

Abstract: The principle of clinical equipoise requires that, aside from certain exceptional cases, second generation treatments ought to be tested against standard therapy. In violation of this principle, placebo-controlled trials (PCTs) continue to be used extensively in the development and licensure of second-generation treatments. This practice is typically justified by appeal to methodological arguments that purport to demonstrate that active-controlled trials (ACTs) are methodologically flawed. Foremost among these arguments is the so called assay sensitivity argument. In this paper, I take a closer look at this argument. Following Duhem, I argue that all trials, placebo-controlled or not, rely on external information for their meaningful interpretation. Pending non-circular empirical evidence that we can trust the findings of PCTs to a greater degree than the findings of ACTs, I conclude that the assay sensitivity argument fails to demonstrate that placebo-controlled trials are preferable, methodologically or otherwise, to active-controlled trials. Contrary to the intentions of its authors, the fundamental lesson taught by the assay sensitivity argument is Duhemian: the validity of all clinical trials depends on external information.

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* Document 1408
Dixon-Woods, Mary; Jackson, Clare; Windridge, Kate C.; Kenyon, Sara
Receiving a summary of the results of a trial: qualitative study of participants' views

Georgetown users check Georgetown Journal Finder for access to full text

http://www.bmj.com (link may be outdated)

Document 1409
McGee, Glenn; Philpott, Sean; Carroll, Emily
A risky business [review of Lesser Harms: The Morality of Risk in Medical Research, by Sydney A. Halpern]
Lancet 2006 January 28-February 3; 367(9507): 294

Georgetown users check Georgetown Journal Finder for access to full text

http://www.thelancet.com/journal (link may be outdated)

Document 1410
Ehringhaus, Susan; Kom, David
Association of American Medical Colleges [AAMC]
Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials

http://www.aamc.org/research/clinicaltrialsreporting/clinicaltrialsreporting.pdf (link may be outdated)

Document 1411
Milton, Constance L.
Research ethics standards: are they significant or only symbolic?

Georgetown users check Georgetown Journal Finder for access to full text
Feasibility of a national fatal asthma registry: more evidence of IRB variation in evaluation of a standard protocol.

Cost-benefit assessment in medical researches [sic; research]

Ethics committees and externally sponsored research in Iran

Recruiting and enrolling pregnant adolescents for research

Academic research record-keeping: best practices for individuals, group leaders, and institutions
The concept of quality in clinical research
Switula, Dorota
Georgetown users check Georgetown Journal Finder for access to full text

The protection of patients' rights in clinical trials
Czarkowski, Marek
Georgetown users check Georgetown Journal Finder for access to full text

Uncertainty and the ethics of clinical trials
Hansson, Sven Ove
Theoretical Medicine and Bioethics 2006; 27(2): 149-167
Georgetown users check Georgetown Journal Finder for access to full text

Cross-cultural perspectives on research participation and informed consent
Barata, Paula C.; Gucciardi, Enza; Ahmad, Farah; Stewart, Donna E.
Social Science and Medicine 2006 January; 62(2): 479-490
Georgetown users check Georgetown Journal Finder for access to full text

Institutional review boards: friend, not foe
Schmelzer, Marilee
Georgetown users check Georgetown Journal Finder for access to full text

Waiver of IRB requirements for drug and biological product studies. Information sheet guidance for sponsors, clinical investigators, and IRBs
United States. Food and Drug Administration [FDA]

http://www.fda.gov/oc/ohrt/irbs/waiver.pdf (link may be outdated)

Informing research participants of research results: analysis of Canadian university based research ethics
MacNeil, S.D.; Fernandez, C.V.
Abstract: BACKGROUND: Despite potential benefits of the return of research results to research participants, the TriCouncil Policy Statement (TCPS), which reflects Canadian regulatory ethical requirements, does not require this. The policies of Canadian research ethics boards (REBs) are unknown. OBJECTIVES: To examine the policies of Canadian university based REBs regarding returning results to research participants, and to ascertain if the presence/absence of a policy may be influenced by REB member composition. DESIGN: Email survey of the coordinators of Canadian university based REBs to determine the presence/absence of a policy on return of research results to research participants both during an ongoing study and at conclusion. REB coordinators were asked to return a copy of the policy or guidelines and to describe the member composition of their REB. Findings: Of 50 REBs that were contacted, 34 (68%) responded and 22 (64.7%) met the inclusion criteria. Two (9.1%) had a policy that governed the return of research results while on a study, and seven (31.8%) following the completion of a study. Presence of an ethicist or a lawyer on the REB did not influence the presence/absence of such policies. No REBs had specific guidelines describing how participants should be informed of results. CONCLUSIONS: Most REBs did not require researchers to disclose study results to research participants either during or following a study. Thus this study identifies an ethical shortcoming in the conduct of human research in Canada. It has also demonstrated that there are no clear recommendations by REBs to facilitate the return of results to participants following research projects.

http://www.jmedethics.com (link may be outdated)
Document 1428
Maloney, Dennis M.
Research subject says institutional review board (IRB) was no help
Georgetown users check Georgetown Journal Finder for access to full text

Document 1429
Maloney, Dennis M.
Federal agency has options when it investigates IRBs
Human Research Report 2006 January; 21(1): 4
Georgetown users check Georgetown Journal Finder for access to full text

Document 1430
Maloney, Dennis M.
How institutional review boards (IRBs) can handle adverse event reports
Georgetown users check Georgetown Journal Finder for access to full text

Document 1431
Resnik, David B.; Shamoo, Adil E.; Krimsky, Sheldon
Fraudulent human embryonic stem cell research in South Korea: lessons learned
Georgetown users check Georgetown Journal Finder for access to full text

Document 1432
Downie, Jocelyn
The Canadian agency for the oversight of research involving humans: a reform proposal
Accountability in Research 2006 January-March; 13(1): 75-100
Abstract: In this paper, I propose the creation of a Canadian agency for the oversight of research involving humans. I describe first a series of significant problems with Canada's current system of oversight. I then argue for the creation of a national-level agency, covering all research involving humans, with three branches (policy and standards, education, and compliance). Of particular note, the proposed compliance branch consists of a number of independent national and regional Research Ethics Boards (i.e., REBs no longer reside within institutions). There is also an Audit Committee and a Non-compliance Committee (with supporting staff of auditors and compliance officers) to ensure compliance with the policies and standards set by the Policy and Standards Branch. Finally, I answer a series of "frequently asked questions" about the proposed agency design such as "What about 'local context'?” and "Why not have a system of accreditation of institutional REBs instead?” In sum, radical reform is needed and, in this paper, I present a proposal for such reform.
Georgetown users check Georgetown Journal Finder for access to full text
Nowak, Kristin S.; Bankert, Elizabeth A.; Nelson, Robert M.
Reforming the oversight of multi-site clinical research: a review of two possible solutions
Accountability in Research 2006 January-March; 13(1): 11-24

Abstract: The current system for the ethical oversight of clinical research suffers from structural, procedural, and performance assessment problems. Initially conceived primarily to handle local investigator-initiated single-site studies, the system of institutionally-based committee review has become progressively more inefficient given the increased prevalence of commercially or federally sponsored multi-center trials. To date, proposed solutions do not adequately address these problems. Beginning with a review of these structural, procedural, and performance assessment problems, this article will then consider two proposals for addressing these deficiencies: (a) regional ethics organizations; and (b) IRBNet, a newly developed web-based program for cooperative IRB review. The strengths and weaknesses of these two approaches will be evaluated in light of recent experience with centralized review. The proposal to establish a system of regional ethics organizations presents a comprehensive approach to many of the problems faced by the current system. However, IRBNet offers an immediate and feasible solution to many of the problems faced by the review of multi-site clinical studies.

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Document 1434
Mann, Howard; Shamoo, Adil E.
Introduction to special issue of Accountability in Research on the review and approval of biomedical research proposals

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Document 1435
Shaw, Sara; Barrett, Geraldine
Research governance: regulating risk and reducing harm?

Georgetown users check Georgetown Journal Finder for access to full text

Document 1436
Brown, Joseph S.; Schonfeld, Toby L.; Gordon, Bruce G.
"You may have already won...": an examination of the use of lottery payments in research [case study]

Georgetown users check Georgetown Journal Finder for access to full text

Document 1437
Candilis, Philip J.; Lidz, Charles W.; Arnold, Robert M.
The need to understand IRB deliberations

Georgetown users check Georgetown Journal Finder for access to full text
Document 1438
Stone, Judy
CONDUCTING CLINICAL RESEARCH: A PRACTICAL GUIDE FOR PHYSICIANS, NURSES, STUDY COORDINATORS, AND INVESTIGATORS
Call number: R853.C55 S76 2006

Document 1439
Bankert, Elizabeth A. and Amdur, Robert J.
INSTITUTIONAL REVIEW BOARD: MANAGEMENT AND FUNCTION
Sudbury, MA: Jones and Bartlett, 2006. 530 p.
Call number: R852.5.A46 2006

Document 1440
Rosmini, Francesco; Ferrigno, Luigina; D'Angelo, Franca; Poltronieri, Elisabetta
Annali dell'Istituto Superiore di Sanità 2006; 42(4): 485-490
Georgetown users check Georgetown Journal Finder for access to full text

Document 1441
Simonsen, Sigmund; Nylenna, Magne
Basic ethical, professional and legal principles of biomedical research.
Scandinavian Journal of Work, Environment and Health 2006; (Supplement 2): 5-14
Georgetown users check Georgetown Journal Finder for access to full text

Document 1442
Califf, Robert M.
Clinical trials bureaucracy: unintended consequences of well-intentioned policy
Clinical Trials 2006; 3(6): 496-502
Georgetown users check Georgetown Journal Finder for access to full text

Document 1443
Yusuf, Salim; Bosch, Jackie
Independent design and conduct of clinical trials
Clinical Trials 2006; 3(6): 503-507
Georgetown users check Georgetown Journal Finder for access to full text
Document 1444

Pocock, Stuart J.

**Current controversies in data monitoring for clinical trials**

Clinical Trials 2006; 3(6): 513-521

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 1445

Demets, David L.

**Futility approaches to interim monitoring by data monitoring committees**

Clinical Trials 2006; 3(6): 522-529

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 1446

UK Clinical Research Collaboration

**Clinical trials: what they are and what they're not**


[http://www.ukcrc.org/pdf/CT%20leaflet%20for%20web.pdf](http://www.ukcrc.org/pdf/CT%20leaflet%20for%20web.pdf) (link may be outdated)

Document 1447

UK Clinical Research Collaboration [UKCRC]

**Understanding clinical trials**


Call number: [citation only](#)

[http://www.ukcrc.org/PDF/CT%20Booklet%20August%2007%20for%20web.pdf](http://www.ukcrc.org/PDF/CT%20Booklet%20August%2007%20for%20web.pdf) (link may be outdated)

Document 1448

DeMets, David L.; Fost, Norman; Powers, Madison

**An Institutional Review Board dilemma: responsible for safety monitoring but not in control**

Clinical Trials 2006; 3(2): 142-148

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 1449

Mayer, Musa

**Listen to all the voices: an advocate's perspective on early access to investigational therapies**

Clinical Trials 2006; 3(2): 149-153

Georgetown users check [Georgetown Journal Finder](#) for access to full text
* Document 1450
Huang, David T.; Hadian, Mehrnaz
**Bench-to-bedside review: human subjects research -- are more standards needed?**
Critical Care 2006; 10(6): 244
Georgetown users check [Georgetown Journal Finder](https://journal.finder.georgetown.edu/) for access to full text

* Document 1451
Hardy, Pollyahanna.; Clemens, Felicity
**Stopping a randomized trial early: from protocol to publication. Commentary to Thome at al.: outcome of extremely preterm infants randomized at birth to different PaCO2 targets during the first seven days of life** *(Biology of the Neonate 2006; 90: 218-225)*
Biology of the Neonate 2006; 90(4): 226-228
Georgetown users check [Georgetown Journal Finder](https://journal.finder.georgetown.edu/) for access to full text

* Document 1452
Chalmers, Iain
**Biased underreporting of research is unethical and should be outlawed**
Zeitschrift für Ärztliche Fortbildung und Qualitätssicherung 2006; 100(7): 531-535
Georgetown users check [Georgetown Journal Finder](https://journal.finder.georgetown.edu/) for access to full text

* Document 1453
Dixon, Dennis O.; Freedman, Ralph S.; Herson, Jay; Hughes, Michael; Kim, KyungMann; Silverman, Michael H.; Tangen, Catherine M.
SCT Working Group on Data Monitoring
**Guidelines for data and safety monitoring for clinical trials not requiring traditional data monitoring committees**
Georgetown users check [Georgetown Journal Finder](https://journal.finder.georgetown.edu/) for access to full text

* Document 1454
Clarke, Amanda
**Qualitative interviewing: encountering ethical issues and challenges**
Nurse Researcher 2006; 13(4): 19-29
Georgetown users check [Georgetown Journal Finder](https://journal.finder.georgetown.edu/) for access to full text

* Document 1455
Stone, Judy
**Ethical issues in human subjects research**
Call number: [R853 .C55 S76 2006](https://library.finder.georgetown.edu/)
International medical research regulation: from ethics to law
Chalmers, Don
Call number: K3601 .F57 2006

Ethical issues in drug user treatment research
Pimple, Kenneth D.
In: Kleinig, John; Einstein, Stanley, eds. Ethical Challenges for Intervening in Drug Use: Policy, Research and Treatment Issues. Huntsville, TX: Office of International Criminal Justice: Sam Houston State University, Criminal Justice Center, 2006: 205-216
Call number: HV4998 .E74 2006

Research on human subjects: academic freedom and the Institutional Review Board
Thomson, Judith Jarvis; Elgin, Catherine; Hyman, David A.; Rubin, Philip E.; Knight, Jonathan
American Association of University Professors [AAUP]. Committee A

Belmont as parable: research leadership and the spirit of integrity
Gabriele, Edward F.
In: Kulakowski, Elliott C.; Chronister, Lynne U., eds. Research Administration and Management. Sudbury, MA: Jones and Bartlett, 2006: 473-480
Call number: Q180 .U5 R3816 2006

Legal issues in clinical trials
Slocum, J. Michael
In: Kulakowski, Elliott C.; Chronister, Lynne U., eds. Research Administration and Management. Sudbury, MA: Jones and Bartlett, 2006: 189-206
Call number: Q180 .U5 R3816 2006

Clinical research: pharmaceutical manufacturer sponsoring terminated clinical trial not obligated to continue providing drug to volunteers—Abney v. Amgen, Inc.
Blonigan, William
**Document 1462**
Gatter, Robert
**Conflicts of interest in international human drug research and the insufficiency of international protections**

**Document 1463**
Khin-Moung-Gyi, Felix A.; Whalen, Matthew
**Ethics and human subjects protection.**
Call number: **R853 .C55 R47 2006**

**Document 1464**
Birmingham, Karen; Frumston, Michael
**Avon longitudinal study of parents and children (ALSPAC): ethical process**
Call number: **BJ1581.2 .E85 2005 v.2**

**Document 1465**
Patenaude, Johane; Cabanac, Julien; de Champlain, Johane
**Pan-Canadian study on variations in research ethics boards' reviews of a research project involving placebo use**

**Document 1466**
Ar-Rashid, Harun
**Regional perspectives in research ethics: a report from Bangladesh**

**Document 1467**
Sheikh, Abdul Latif
**Pharmaceutical research: paradox, challenge or dilemma?**
**Document 1468**
Cash, Richard A.

*What is owed to the community before, during and following research: an ethical dialogue*


**Document 1469**
Pluhar, Evelyn B.

*Experimentation on humans and nonhumans*

Theoretical Medicine and Bioethics 2006; 27(4): 333-355

**Abstract:** In this article, I argue that it is wrong to conduct any experiment on a nonhuman which we would regard as immoral were it to be conducted on a human, because such experimentation violates the basic moral rights of sentient beings. After distinguishing the rights approach from the utilitarian approach, I delineate basic concepts. I then raise the classic "argument from marginal cases" against those who support experimentation on nonhumans but not on humans. After next replying to six important objections against that argument, I contend that moral agents are logically required to accord basic moral rights to every sentient being. I conclude by providing criteria for distinguishing ethical from unethical experimentation.

**Document 1470**
Yancey, Antronette K.; Ortega, Alexander N.; Kumanyika, Shiriki K.

*Effective recruitment and retention of minority research participants*


**Document 1471**
Farrell, Kristen

*Human experimentation in developing countries: improving international practices by identifying vulnerable populations and allocating fair benefits [comment]*


**Document 1472**
Shamoo, Adil E.; Resnik, David B.

*Ethical issues for clinical research managers*

* Document 1473
Gaba, Aline
**Face transplants and the difficulties of obtaining research approval**
Journal of Biolaw and Business 2006; 9(1): 54-55

* Document 1474
Luu, Arlene D.
**Research examines the minimal risk standard for pediatric research**

* Document 1475
Goldstein, Nathan
**Financial conflict of interest in biomedical human subject research**

* Document 1476
Finn, Peter B.
**The negotiation and development of a clinical trial agreement**

* Document 1477
Willison, Donald J.; Kapral, Moira K.; Peladeau, Pierrot; Richards, Janice R.A.; Fang, Jiming; Silver, Frank L.
**Variation in recruitment across sites in a consent-based clinical data registry: lessons from the Canadian Stroke Network**

**Abstract:** Background: In earlier work, we found important selection biases when we tried to obtain consent for participation in a national stroke registry. Recognizing that not all registries will be exempt from requiring consent for participation, we examine here in greater depth the reasons for the poor accrual of patients from a systems perspective with a view to obtaining as representative sample as possible. Methods: We determined the percent of eligible patients who were approached to participate and, among those approached, the percent who actually consented to participate. In addition we examined the reasons why people were not approached or did not consent and the variation across sites in the percent of patients approached and consented. We also considered site variation in restrictions on the accrual and data collection process imposed by either the local research ethics board or the hospital. Results: Seventy percent of stroke patients were approached, with wide variations in approach rates across sites (from: 41% to 86%), and considerable inter-site variation in hospital policies governing patient accrual. Chief reasons for not approaching were discharge or death before being approached for consent. Seventeen percent
of those approached refused to participate (range: 5% to 75%). Finally, 11% of those approached did not participate due to language or communication difficulties. Conclusion: We found wide variation in approach and agree rates across sites that were accounted for, in part, by different approaches to accrual and idiosyncratic policies of the hospitals. This wide variation in approach and agree rates raises important challenges for research ethics boards and data protection authorities in determining when to waive consent requirements, when to press for increased quality control, when to permit local adaptation of the consent process, and when to permit alternatives to individual express consent. We offer several suggestions for those registries that require consent for participation.
Documents:

1. Thall, Peter F.; Estey, Elihu H. Some ethical issues in phase II trials in acute leukemia. Clinical Advances in Hematology and Oncology 2005 December; 3(12): 943-948


5. Maloney, Dennis M. Research subject complains about how she was treated by an institutional review board (IRB) [case study]. Human Research Report 2005 December; 20(12): 7

Document 1489
Maloney, Dennis M.
**Federal investigations of IRBs and institutions**
Human Research Report 2005 December; 20(12): 4

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 1490
Maloney, Dennis M.
**Institutional review boards (IRBs) and working with adverse event reports**

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 1491
Gunsalus, C.K.; Bruner, Edward M.; Burbules, Nicholas C.; Dash, Leon; Finkin, Matthew; Goldberg, Joseph P.; Greenough, William; Miller, Gregory A.; Pratt, Michael G.; Iriye, Masumi; Aronson, Deb
Center for Advanced Study. Center for Advanced Study Project Steering Committee
**Illinois White Paper. Improving the system for protecting human subjects: counteracting IRB "mission creep"**

Document 1492
Montori, Victor M.; Devereaux, P.J.; Adhikari, Neill K.J.; Burns, Karen E.A.; Eggert, Christoph H.; Briel, Matthias; Lacchetti, Christina; Leung, Teresa W.; Darling, Elizabeth; Bryant, Dianne M.; Bucher, Heiner C.; Schunemann, Holger J.; Meade, Maureen O.; Cook, Deborah J.; Erwin, Patricia J.; Sood, Amit; Sood, Richa; Lo, Benjamin; Thompson, Carly A.; Zhou, Qi; Mills, Edward; Guyatt, Gordon H.
**Randomized trials stopped early for benefit: a systematic review**
JAMA: The Journal of the American Medical Association 2005 November 2; 294(17): 2203-2209

**Abstract:** CONTEXT: Randomized clinical trials (RCTs) that stop earlier than planned because of apparent benefit often receive great attention and affect clinical practice. Their prevalence, the magnitude and plausibility of their treatment effects, and the extent to which they report information about how investigators decided to stop early are, however, unknown. OBJECTIVE: To evaluate the epidemiology and reporting quality of RCTs involving interventions stopped early for benefit. DATA SOURCES: Systematic review up to November 2004 of MEDLINE, EMBASE, Current Contents, and full-text journal content databases to identify RCTs stopped early for benefit. STUDY SELECTION: Randomized clinical trials of any intervention reported as having stopped early because of results favoring the intervention. There were no exclusion criteria. DATA EXTRACTION: Twelve reviewers working independently and in duplicate abstracted data on content area and type of intervention tested, reporting of funding, type of end point driving study termination, treatment effect, length of follow-up, estimated sample size and total sample studied, role of a data and safety monitoring board in stopping the study, number of interim analyses planned and conducted, and existence and type of monitoring methods, statistical boundaries, and adjustment procedures for interim analyses and early stopping. DATA SYNTHESIS: Of 143 RCTs stopped early for benefit, the majority (92) were published in 5 high-impact medical journals. Typically, these were industry-funded drug trials in cardiology, cancer, and human immunodeficiency virus/AIDS. The proportion of all RCTs published in high-impact journals that were stopped early for benefit increased from 0.5% in 1990-1994 to 1.2% in 2000-2004 (P<.001 for
trend). On average, RCTs recruited 63% (SD, 25%) of the planned sample and stopped after a median of 13 (interquartile range [IQR], 3-25) months of follow-up, 1 interim analysis, and when a median of 66 (IQR, 23-195) patients had experienced the end point driving study termination (event). The median risk ratio among truncated RCTs was 0.53 (IQR, 0.28-0.66). One hundred thirty-five (94%) of the 143 RCTs did not report at least 1 of the following: the planned sample size (n = 28), the interim analysis after which the trial was stopped (n = 45), whether a stopping rule informed the decision (n = 48), or an adjusted analysis accounting for interim monitoring and truncation (n = 129). Trials with fewer events yielded greater treatment effects (odds ratio, 28; 95% confidence interval, 11-73).

CONCLUSIONS: RCTs stopped early for benefit are becoming more common, often fail to adequately report relevant information about the decision to stop early, and show implausibly large treatment effects, particularly when the number of events is small. These findings suggest clinicians should view the results of such trials with skepticism.
Responsible conduct of radiology research. Part IV. The boundary of research and practice
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1498
Vick, Catherine C.; Finan, Kelly R.; Kiefe, Catarina; Neumayer, Leigh; Hawn, Mary T.
Variation in Institutional Review processes for a multisite observational study
American Journal of Surgery 2005 November; 190(5): 805-809
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1499
Hayward, Rodney A.; Kent, David M.; Vijan, Sandeep; Hofer, Timothy P.
Reporting clinical trial results to inform providers, payers, and consumers
Health Affairs 2005 November-December; 24(6): 1571-1581
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1500
Wilson, Mark
Vulnerable subjects and Canadian research governance
Georgetown users check Georgetown Journal Finder for access to full text

Document 1501
Maloney, Dennis M.
Required study of law's impact could affect institutional review boards (IRBs)
Georgetown users check Georgetown Journal Finder for access to full text

Document 1502
Maloney, Dennis M.
University still fails to follow regulations governing exemption from IRB review [case study]
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1503
Maloney, Dennis M.
IRBs, human subjects, and reporting adverse events
Georgetown users check Georgetown Journal Finder for access to full text
* Document 1504
Blackmer, Jeff; Haddad, Henry
The Declaration of Helsinki: an update on paragraph 30 [opinion]
CMAJ/JAMC: Canadian Medical Association Journal 2005 October 25; 173(9): 1052-1053
Georgetown users check Georgetown Journal Finder for access to full text
http://www.cmaj.ca (link may be outdated)

* Document 1505
Page-Shafer, Kimberly; Saphonn, Vonthanak; Sun, Ly Penh; Vun, Mean Chhi; Cooper, David A.; Kaldor, John M.
HIV prevention research in a resource-limited setting: the experience of planning a trial in Cambodia [opinion]
Lancet 2005 October 22-28; 366(9495): 1499-1503
Georgetown users check Georgetown Journal Finder for access to full text
http://www.thelancet.com/journal (link may be outdated)

* Document 1506
Sumathipala, Athula; Siribaddana, Sisira
Research and clinical ethics after the tsunami: Sri Lanka [opinion]
Lancet 2005 October 22-28; 366(9495): 1418-1420
Georgetown users check Georgetown Journal Finder for access to full text
http://www.thelancet.com/journal (link may be outdated)

Document 1507
Office for Research Protections [OHRP]
OHRP's Compliance Oversight Procedures for Evaluating Institutions
http://www.hhs.gov/ohrp/humansubjects/guidance/ohrpcomp101905.pdf (link may be outdated)

* Document 1508
Guidance on reporting and reviewing adverse events and unanticipated problems involving risks to subjects or others: Draft - October 11, 2005
http://www.hhs.gov/ohrp/requests/aerg.pdf [2007 March 10]
http://www.hhs.gov/ohrp/requests/aerg.pdf (link may be outdated)
**Document 1509**
Frank, Samuel; Kieburz, Karl; Holloway, Robert; Kim, Scott Y.H.
*What is the risk of sham surgery in Parkinson disease clinical trials? A review of published reports*
Neurology 2005 October 11; 65(7): 1101-1103
Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 1510**
*Part 46 - Protection of human subjects [Revised 2005 June 23; Effective 2005 June 23]*

[http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm) (link may be outdated)

**Document 1511**
United States. Department of Health and Human Services [HHS]. Office for Human Research Protections [OHRP]
*International Compilation of Human Subject Research Protections, 2nd Edition*
Call number: [electronic resource](#)

[http://www.hhs.gov/ohrp/international/HSPCompilation.pdf](http://www.hhs.gov/ohrp/international/HSPCompilation.pdf) (link may be outdated)

**Document 1512**
Brasel, Karen J.
*Research ethics primer*
Journal of Surgical Research 2005 October; 128(2): 221-225
Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 1513**
Mattingly, Cheryl
*Toward a vulnerable ethics of research practice*
Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 1514**
Whittaker, Elvi
*Adjudicating entitlements: the emerging discourses of research ethics boards*
Health (London) 2005 October; 9(4): 513-535
Georgetown users check [Georgetown Journal Finder](#) for access to full text
Goldberg, David J.  
**Dermatologic surgical research and the institutional review board**  
*Dermatologic Surgery* 2005 October; 31(10): 1317-1322  
Georgetown users check [Georgetown Journal Finder](https://library.georgetown.edu) for access to full text

Perlis, Roy H.; Perlis, Clifford S.; Wu, Yelena; Hwang, Cindy; Joseph, Megan; Nierenberg, Andrew A.  
**Industry sponsorship and financial conflict of interest in the reporting of clinical trials in psychiatry**  
Georgetown users check [Georgetown Journal Finder](https://library.georgetown.edu) for access to full text

http://ajp.psychiatryonline.org (link may be outdated)

Yim, Robyn  
**Administrative and research policies required to bring cellular therapies from the research laboratory to the patient's bedside**  
*Transfusion* 2005 October; 45(4 Supplement): 144S-158S  
Georgetown users check [Georgetown Journal Finder](https://library.georgetown.edu) for access to full text

Cooper, Jeffrey A.  
**Responsible conduct of radiology research Part III. Exemptions from regulatory requirements for human research**  
*Radiology* 2005 October; 237(1): 3-7  
Georgetown users check [Georgetown Journal Finder](https://library.georgetown.edu) for access to full text

Al-Shahi, Rustam  
**Research ethics committees in the UK – the pressure is now on research and development departments**  
*Journal of the Royal Society of Medicine* 2005 October; 98(10): 444-447  
Georgetown users check [Georgetown Journal Finder](https://library.georgetown.edu) for access to full text

Parker, Damon B.; James, Michael; Barrett, Robert J.  
**The practical logic of reasonableness: an ethnographic reconnaissance of a research ethics committee**  
Georgetown users check [Georgetown Journal Finder](https://library.georgetown.edu) for access to full text
Analysis of some Filipino perspectives on ethical issues in multi-country collaborative research: a case of deep listening
Manaloto, Renato B.; Alvarez, Allen Andrew A.; Alvarez, Mary Ann V.
Bioethics 2005 October; 19(5-6): 550-564

Abstract: The discussion on ethical issues, it is said, should not be confined to experts but should be extended to patients and local communities, because of the real need to engage stakeholders and non-stakeholders alike not only in carrying out any biomedical research project, but also in the drafting and legislation of bioethics instruments. Several local and inter-country consultations have already been conducted in furtherance of this goal, but there is much left to be desired in them. The consultations may have helped in articulating local principles, but not in making the instruments embody these principles. As such, instruments turn incompossible, i.e. the principles and actions they legitimate are not performable. In an ethnographic study conducted in the Philippines, for example, paragraphs 29 and 30 of the Declaration of Helsinki and CIOMS guidelines 8 and 15 are construed as not only contradictory to one another but also to local principles. This problem can be solved by taking deliberate steps to ensure that consultations are grounded in ethnographic data about local principles, which the instruments would embody. A steering committee can be of help in gathering ethnographic data, in conducting consultations at the local level, and in providing a venue for discourse on various bioethical issues.

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Focus groups and human subjects
Maloney, Dennis M.

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Human research accreditation group disbands joint program
Maloney, Dennis M.

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Understanding the structure and practices of research ethics committees through research and audit: a study from Mexico
Valdez-Martinez, Edith; Trumbull, Bernardo; Garduno-Espinosa, Juan; Porter, John David Henley
Health Policy 2005 September 28; 74(1): 56-68

Georgetown users check Georgetown Journal Finder for access to full text

Consensus and controversy in clinical research ethics
Brody, Baruch A.; McCullough, Laurence B.; Sharp, Richard R.

Georgetown users check Georgetown Journal Finder for access to full text

Gonzalez, Luis S. 3rd, Miller, Stephanie; Barnhart, Donna; Leifheit, Michael
Institutional review board approval of projects presented as posters at an ASHP midyear clinical meeting
American Journal of Health-System Pharmacy 2005 September 15; 62(18): 1890-1893

United States. Environmental Protection Agency [EPA]
Protections for subjects in human research; proposed rule

Taylor, G.J.; Wainwright, P.
Open label extension studies: research or marketing?
BMJ: British Medical Journal 2005 September 10; 331(7516): 572-574

Wadman, Meredith
US set to endorse human pesticide testing
Nature 2005 September 1; 437(7055): 24-25
Document 1531

Denscombe, Martyn

**Research ethics and the governance of research projects: the potential of internet home pages**

Sociological Research Online 2005 September; 10(3): U125-U140

Georgetown users check [Georgetown Journal Finder](#) for access to full text

[http://www.socresonline.org.uk/10/3/denscombe.html](http://www.socresonline.org.uk/10/3/denscombe.html) (link may be outdated)

Document 1532

Swazo, Norman K.

**Research integrity and rights of indigenous peoples: appropriating Foucault's critique of knowledge/power**

Studies in History and Philosophy of Biological and Biomedical Sciences 2005 September; 36(3): 568-584

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 1533

Jeffries, Shawn K.; Choi, Won; Butler, James; Harris, Kari Jo; Ahluwalia, Jasjit S.

**Strategies for recruiting African-American residents of public housing developments into a randomized controlled trial**

Ethnicity and Disease 2005 Autumn; 15(4): 773-778

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 1534

Caron-Flinterman, J. Francisca; Broerse, Jacqueline E.W.; Teerling, Julia; Bunders, Joske F.G.

**Patients' priorities concerning health research: the case of asthma and COPD research in the Netherlands**

Health Expectations 2005 September; 8(3): 253-263

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 1535

Jenkinson, Crispin; Burton, John S.; Cartwright, Julia; Magee, Helen; Hall, Ian; Alcock, Chris; Burge, Sherwood

**Patient attitudes to clinical trials: development of a questionnaire and results from asthma and cancer patients**

Health Expectations 2005 September; 8(3): 244-252

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 1536

Kubar, Olga

**Ethical aspects in clinical trials in the CIS, in particular the setting up of ethical committees**

Journal International de Bioéthique = International Journal of Bioethics 2005 September-December; 16(3-4): 81-87, 172-173

**Abstract:** The ethical aspects of clinical trials in the CIS are based on the development of systematic ethical review and ethical insight and responsibility on the part of researchers, sponsors, and government agencies and society.
This is the main purpose of the Forum for Ethics Committees in the Commonwealth of Independent States (FECCIS) whose establishment and activities are focused on the integration of the CIS into the world system of biomedical research with regard to safeguarding ethical standards of human rights protection and harmonization of regulative and methodological space to safeguard protection of human rights and the dignity of biomedical research participants in the CIS.

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**Document 1537**

Lichterman, Boleslav L.

**Under the shelter of ethics**

Journal International de Bioéthique = International Journal of Bioethics 2005 September-December; 16(3-4): 77-79, 172

**Abstract:** Problems of ethics committees in post-communist Russia are briefly discussed. The first ethics committees were established in 1980s upon the initiative of international pharmaceutical companies involved in clinical trials. Generally, such committees exist at hospitals conducting these trials and at research institutions dealing with human experimentation. They are bureaucratic structures heavily dependent on hospital or institution administration. Publication of research results in international periodicals is the main reason for their existence. An officially recognized National Ethics Committee is non-existent although there are several competing ethics committees at a national level (at the Ministry of Health, Academy of Sciences, Academy of Medical Sciences, Russian Medical association etc.). There is no federal legislation on the structure and status of ethics committees.

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**Document 1538**

McCoy, Clyde B.; Achi, Rosario; Wolfe, Harlan P.; Crandall, Lee A.

**The CDRC principles of international health research**

Journal of Urban Health 2005 September; 82(3 Supplement 4): iv5-iv8

Georgetown users check [Georgetown Journal Finder](http://journalfinder.georgetown.edu) for access to full text.

**Document 1539**

Giordano, James; Engebretson, Joan; Garcia, Mary K.

**Challenges to complementary and alternative medical research: focal issues influencing integration into a cancer care model**

Integrative Cancer Therapies 2005 September; 4(3): 210-218

Georgetown users check [Georgetown Journal Finder](http://journalfinder.georgetown.edu) for access to full text.

**Document 1540**

Olanow, C. Warren

**Double-blind, placebo-controlled trials for surgical interventions in Parkinson disease**

Archives of Neurology 2005 September; 62(9): 1343-1344

Georgetown users check [Georgetown Journal Finder](http://journalfinder.georgetown.edu) for access to full text.

**Document 1541**

Kim, Scott Y.H.; Frank, Samuel; Holloway, Robert; Zimmerman, Carol; Wilson, Renee; Kieburtz, Karl

*
Science and ethics of sham surgery: a survey of Parkinson disease clinical researchers
Archives of Neurology 2005 September; 62(9): 1357-1360

Georgetown users check Georgetown Journal Finder for access to full text

* Article Document 1542
Sprumont, Dominique; Gytis, Andrulionis
The importance of national laws in the implementation of European legislation of biomedical research

Georgetown users check Georgetown Journal Finder for access to full text

* Article Document 1543
Grossman, Jason; Mackenzie, Fiona J.
The randomized controlled trial: gold standard or merely standard?
Perspectives in Biology and Medicine 2005 Autumn; 48(4): 516-534

Georgetown users check Georgetown Journal Finder for access to full text

* Article Document 1544
Litton, Paul; Miller, Franklin G.
A normative justification for distinguishing the ethics of clinical research from the ethics of medical care
Journal of Law, Medicine and Ethics 2005 Fall; 33(3): 566-574

Georgetown users check Georgetown Journal Finder for access to full text

* Article Document 1545
Fitzgerald, Daniel W.; Wasunna, Angela
Away from exploitation and towards engagement: an ethical compass for medical researchers working in resource-poor countries
Journal of Law, Medicine and Ethics 2005 Fall; 33(3): 559-565

Georgetown users check Georgetown Journal Finder for access to full text

* Article Document 1546
DuVal, Gordon; Gensler, Gary; Danis, Marion
Ethical dilemmas encountered by clinical researchers
Journal of Clinical Ethics 2005 Fall; 16(3): 267-276

Georgetown users check Georgetown Journal Finder for access to full text

* Article Document 1547
Porter, Maureen; Bhattacharya, Siladitya
Investigation of staff and patients’ opinions of a proposed trial of elective single embryo transfer
Human Reproduction 2005 September; 20(9): 2523-2530
Document 1548
Schwartz, Myrna F.; Brecher, Adelyn R.; Whyte, John; Klein, Mary G.
**A patient registry for cognitive rehabilitation research: a strategy for balancing patients' privacy rights with researchers' need for access**
Archives of Physical Medicine and Rehabilitation 2005 September; 86(9): 1807-1814

Document 1549
McCullough, Laurence B.; Coverdale, John H.; Chervenak, Frank A.
**A comprehensive ethical framework for responsibly designing and conducting pharmacologic research that involves pregnant women**

Document 1550
Kilama, W.L.
**Ethical perspective on malaria research for Africa**
Acta Tropica 2005 September; 95(3): 276-284

Document 1551
Wendler, David
**Protecting subjects who cannot give consent**
Hastings Center Report 2005 September-October; 35(5): 37-43

Document 1552
Jansen, Lynn A.
**A closer look at the bad deal trial: beyond clinical equipoise**

Document 1553
Hawkins, Jennifer S.; Emanuel, Ezekiel J.
**Clarifying confusions about coercion**
* Document 1554
Maschke, Karen J.
Reconciling protection with scientific progress
Hastings Center Report 2005 September-October; 35(5): 3
Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Document 1555
Kaebnick, Gregory E.
Rethinking the ethics of research
Hastings Center Report 2005 September-October; 35(5): 2
Georgetown users check [Georgetown Journal Finder](#) for access to full text

http://www.jstor.org/action/showPublication?journalCode=hastcentrepo (link may be outdated)

* Document 1556
Currie, Peter M.
Balancing privacy protections with efficient research: institutional review boards and the use of certificates of confidentiality
IRB: Ethics and Human Research 2005 September-October; 27(5): 7-12
Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Document 1557
Saver, Richard S.
What IRBs could learn from corporate boards
IRB: Ethics and Human Research 2005 September-October; 27(5): 1-6
Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Document 1558
Cooper, Jeffrey A.
Responsible conduct of radiology research: Part II. Regulatory requirements for human research
Radiology 2005 September; 236(3): 748-752
Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Document 1559
Afshar, Kourosh; Lodha, Abhay; Costei, Adriana; Vaneyke, Nancy
Recruitment in pediatric clinical trials: an ethical perspective
Journal of Urology 2005 September; 174(3): 835-840
Georgetown users check [Georgetown Journal Finder](#) for access to full text
Maloney, Dennis M.

**Bill affecting institutional review boards (IRBs) has detailed requirements for research registry**

Human Research Report 2005 September; 20(9): 9

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---

Maloney, Dennis M.

**University still struggles to get its institutional review board (IRB) approved [case study]**

Human Research Report 2005 September; 20(9): 6-7

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---

Maloney, Dennis M.

**Who is responsible for working with the IRB?**

Human Research Report 2005 September; 20(9): 3

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Maloney, Dennis M.

**Protecting human research subjects is aim of guidance on clinical trials**


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Mann, H.

**Controversial choice of a control intervention in a trial of ventilator therapy in ARDS: standard of care arguments in a randomised controlled trial**

Journal of Medical Ethics 2005 September; 31(9): 548-553

**Abstract:** When evaluating an innovative intervention in a randomised controlled trial (RCT), choosing an appropriate control intervention is necessary for a clinically meaningful result. An RCT reported in 2000 addressed the relative merits of two tidal volume ventilatory strategies, 6 ml/kg (innovative) and 12 ml/kg (control), in patients with acute respiratory distress syndrome. Critics claim that the 12 ml/kg volume did not represent the clinical practice standard at that time, and that lower tidal volumes had been used in some patients prior to randomisation. The trialists responded that current practice involved the use of a broad range of tidal volumes, including 12 ml/kg. Appropriate control interventions for RCTs can be ensured by: a systematic review of the relevant literature; a formal survey of expert clinicians; and publication of the proposed research protocol to solicit critical appraisal. A global survey of experts during the RCT's design stage would have been of probative value in determining the appropriate control tidal volume. Hypothetical, but plausible, results of such a survey are presented and examined to demonstrate the value of this method.

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[http://www.jmedethics.com](http://www.jmedethics.com) (link may be outdated)
**Document 1565**

Markin, Karen M.

*Playing it safe with research risk: if you fail to follow the rules, you could conduct an entire project and be forbidden to publish the results*

Chronicle of Higher Education 2005 August 12; 51(49): C1, C4

Georgetown users check [Georgetown Journal Finder](http://chronicle.com) for access to full text

**Document 1566**

Duval, Gordon

*The benefits and threats of research partnerships with industry*


Georgetown users check [Georgetown Journal Finder](http://chronicle.com) for access to full text

**Document 1567**

Abadie, Eric C.; Devogeleer, Jean-Pierre; Ringe, Johann D.; Ethgen, Dominique J.; Bouvenot, Gilles M.; Kreutz, Gottfried; Laslop, Andrea; Orloff, John J.; Vanderauwera, Philippe M.; Delmas, Pierre D.; Dere, Willard H.; Branco, Jaime; Altman, Roy D.; Avouac, Bernard P.; Menkes, Charles J.; Vanhaelst, Luc; Mitlak, Bruce H.; Tsouderos, Yannis; Reginster, Jean-Yves L.

*Recommendations for the registration of agents to be used in the prevention and treatment of glucocorticoid-induced osteoporosis: updated recommendations from the group for the respect of ethics and excellence in science*

Seminars in Arthritis and Rheumatism 2005 August; 35(1): 1­4

Georgetown users check [Georgetown Journal Finder](http://chronicle.com) for access to full text

**Document 1568**

Mosconi, Paola; Poli, Paola; Giolo, Antonio; Apolone, Giovanni

*How Italian health consumers feel about clinical research: a questionnaire survey*


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**Document 1569**

Moazam, Farhat

*National Academy of Sciences guidelines for human embryonic stem cell research*

Bioethics Links 2005 August; 1(2): 2

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http://www.siut.org (link may be outdated)

**Document 1570**
Bower, Peter; King, Michael; Nazareth, Irwin; Lampe, Fiona; Sibbald, Bonnie

**Patient preferences in randomised controlled trials: conceptual framework and implications for research**
Social Science and Medicine 2005 August; 61(3): 685-695

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

Dhai, A.

**Research ethics review -- protecting participants in research**
South African Medical Journal 2005 August; 95(8): 595-597

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

**Clinical trials**

Bulletin of Medical Ethics 2005 August-September; (210): 2

Georgetown users check [Georgetown Journal Finder](#) for access to full text

[http://www.bullmedeth.info/](http://www.bullmedeth.info/) (link may be outdated)

---


**Recommended guidelines for studies of human subjects with spinal cord injury**

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

Newgard, Craig D.; Hui, Sai-Hung Joshua; Stamps-White, Patrick; Lewis, Roger J.

**Institutional variability in a minimal risk, population-based study: recognizing policy barriers to health services research**
Health Services Research 2005 August; 40(4): 1247-1258

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

Maloney, Dennis M.

**Companion bill contains requirements for institutional review boards (IRBs)**

Georgetown users check [Georgetown Journal Finder](#) for access to full text
Maloney, Dennis M.
University struggles to get its institutional review board (IRB) approved again [case study]
Georgetown users check Georgetown Journal Finder for access to full text

Maloney, Dennis M.
Updated Q&As on protecting human research subjects
Georgetown users check Georgetown Journal Finder for access to full text

Horton, Richard
Expression of concern: Indo-Mediterranean diet heart study
Lancet 2005 July 30-August 5; 366(9483): 354-356
Georgetown users check Georgetown Journal Finder for access to full text
http://www.thelancet.com/journal (link may be outdated)

Mann, Jim
The Indo-Mediterranean diet revisited
Lancet 2005 July 30-August 5; 366(9483): 353-354
Georgetown users check Georgetown Journal Finder for access to full text
http://www.thelancet.com/journal (link may be outdated)

Grimes, David A.; Hubacher, David; Nanda, Kavita; Schulz, Kenneth F.; Moher, David; Altman, Douglas G.
The Good Clinical Practice guideline: a bronze standard for clinical research [opinion]
Georgetown users check Georgetown Journal Finder for access to full text
http://www.thelancet.com/journal (link may be outdated)

Ethgen, Morgane; Boutron, Isabelle; Baron, Gabriel; Giraud, Bruno; Sibilia, Jean; Ravaud, Philippe
Reporting of harm in randomized, controlled trials of nonpharmacologic treatment for rheumatic disease
Document 1582
Decullier, Evelyne; Lheritier, Veronique; Chapuis, Francois
Fate of biomedical research protocols and publication bias in France: retrospective cohort study
BMJ: British Medical Journal 2005 July 2; 331(7507): 19-22

Abstract: OBJECTIVES: To describe the fate of protocols approved by the French research ethics committees, a national system created by the French 1988 Huriet-Serusclat Act; to assess publication bias at a national level. DESIGN: Retrospective cohort study. SETTING: Representative sample of 25/48 French research ethics committees in 1994. PROTOCOLS: 649 research protocols approved by committees, with follow-up information. MAIN OUTCOME MEASURES: Protocols' initial characteristics (design, study size, investigator) abstracted from committees' archives; follow-up information (rates of initiation, completion, and publication) obtained from mailed questionnaire to principal investigators. RESULTS: Completed questionnaires were available for 649/976 (69%) protocols. Of these, 581 (90%) studies were initiated, 501/581 (86%) were completed, and 190/501 (38%) were published. Studies with confirmatory results were more likely to be published as scientific papers than were studies with inconclusive results (adjusted odds ratio 4.59, 95% confidence interval 2.21 to 9.54). Moreover, studies with confirmatory results were published more quickly than studies with inconclusive results (hazard ratio 2.48, 1.36 to 4.55). CONCLUSION: At a national level, too many research studies are not completed, and among those completed too many are not published. We suggest capitalising on research ethics committees to register and follow all authorised research on human participants on a systematic and prospective basis.
* Document 1586

Lynn, Mary R.; Nelson, Daniel K.

**Common (mis)perceptions about IRB review of human subjects research**

Nursing Science Quarterly 2005 July; 16(3): 264-270

Georgetown users check [Georgetown Journal Finder](http://www.georgetown.edu) for access to full text

* Document 1587

Brion, Nathalie; Demarez, Jean-Paul.; Belorgey, Chantal

**Committee for the protection of persons**

Therapie 2005 July-August; 60(4): 319-328, 329-337

Georgetown users check [Georgetown Journal Finder](http://www.georgetown.edu) for access to full text

* Document 1588

Garrard, Eve; Dawson, A.

**What is the role of the research ethics committee? Paternalism, inducements, and harm in research ethics**

Journal of Medical Ethics 2005 July; 31(7): 419-423

**Abstract:** In a recent paper Edwards, Kirchin, and Huxtable have argued that research ethics committees (RECs) are often wrongfully paternalistic in their approach to medical research. They argue that it should be left to competent potential research subjects to make judgments about the acceptability of harms and benefits relating to research, and that this is not a legitimate role for any REC. They allow an exception to their overall antipaternalism, however, in that they think RECs should have the power to prohibit the use of financial inducements to recruit research subjects into trials. In this paper it is argued that these claims are unjustified and implausible. A sketch is provided of an alternative model of the role of the REC as an expert body making judgments about the acceptability of research proposals through a consensual weighing of different moral considerations.

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[http://www.jmedethics.com](http://www.jmedethics.com) (link may be outdated)

* Document 1589

Iltis, A.S.

**Stopping trials early for commercial reasons: the risk-benefit relationship as a moral compass**

Journal of Medical Ethics 2005 July; 31(7): 410-414

**Abstract:** Decisions by industry sponsors to end clinical trials early for commercial reasons have been the subject of controversy. I argue that the principal consideration in assessing these decisions ought to be the way in which the termination would affect the trial's risk-benefit relationship. If there is not yet sufficient benefit to be gained from the study to offset the risks to which participants were exposed and it is expected that important scientific information would be obtained if the trial were continued, early termination constitutes an unethical alteration of the risk-benefit relationship. This violates the grounds on which permission is given to conduct human research, patients consent to participate, and investigators agree to conduct studies. These knowable and avoidable changes in risk-benefit relationship should generally be seen as impermissible.

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[http://www.jmedethics.com](http://www.jmedethics.com) (link may be outdated)
**Heckerling, Paul S.**

*The ethics of single blind trials*


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---

**Jansen, Lynn A.**

*Local IRBs, multicenter trials, and the ethics of internal amendments*


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---

**Kimmelman, Jonathan**

*Medical research, risk, and bystanders*


Georgetown users check [Georgetown Journal Finder](http://www.journalfinder.georgetown.edu) for access to full text

---

**Dickert, Neal; Sugarman, Jeremy**

*Ethical goals of community consultation in research*

American Journal of Public Health 2005 July; 95(7): 1123-1127

**Abstract:** In response to the traditional emphasis on the rights, interests, and well-being of individual research subjects, there has been growing attention focused on the importance of involving communities in research development and approval. Community consultation is a particularly common method of involving communities. However, the fundamental ethical goals of community consultation have not been delineated, which makes it difficult for investigators, sponsors, and institutional review boards to design and evaluate consultation efforts. Community consultation must be tailored to the communities in which it is conducted, but the purposes of consultation—the ethical goals it is designed to achieve—should be universal. We propose 4 ethical goals that give investigators, sponsors, institutional review boards, and communities a framework for evaluating community consultation processes.

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[http://www.ajph.org](http://www.ajph.org) (link may be outdated)

---

**Williams, Erin D.**

*Federal protection for human research subjects: an analysis of the common rule and its interactions with FDA regulations and the HIPAA privacy rule*


[http://www.fas.org/sgp/crs/misc/RL32909.pdf](http://www.fas.org/sgp/crs/misc/RL32909.pdf) (link may be outdated)

---

**Perlis, Clifford S.; Harwood, Michael; Perlis, Roy H.**

*Document 1599*
Extent and impact of industry sponsorship conflicts of interest in dermatology research

Georgetown users check Georgetown Journal Finder for access to full text

* Document 1602
Boshier, A.; Shakir, S.A.W.; Telfer, P.; Behr, E.; Pakrashi, T.; Camm, A.J.
The negative effect of red tape on research
Pharmacoepidemiology and Drug Safety 2005 June; 14(6): 373-376

Georgetown users check Georgetown Journal Finder for access to full text

* Document 1603
Onder, Robert F.
The ethics of placebo-controlled trials: the case of asthma
Journal of Allergy and Clinical Immunology 2005 June; 115(6): 1228-1234

Georgetown users check Georgetown Journal Finder for access to full text

* Document 1604
Aita, Marilyn; Richer, Marie-Claire
Essentials of research ethics for healthcare professionals
Nursing and Health Sciences 2005 June; 7(2): 119-125

Georgetown users check Georgetown Journal Finder for access to full text

* Document 1605
Marron, Jonathan M.; Siegler, Mark
Ethical issues in innovative colorectal surgery
Diseases of the Colon and Rectum 2005 June; 48(6): 1109-1113

Georgetown users check Georgetown Journal Finder for access to full text

* Document 1606
Research ethics committees; Good Clinical Practice; advance directives [policy statements]
Bulletin of Medical Ethics 2005 June-July; (209): 8-11

Georgetown users check Georgetown Journal Finder for access to full text

http://www.bullmedeth.info/ (link may be outdated)

* Document 1607
Harrison, Jayne E.
Orthodontic clinical trials III: reporting of ethical issues associated with clinical trials published in three orthodontic journals between 1989 and 1998
Document 1608
Fergusson, Dean; Glass, Kathleen Cranley; Hutton, Brian; Shapiro, Stan
Randomized controlled trials of aprotinin in cardiac surgery: could clinical equipoise have stopped the bleeding?
Clinical Trials 2005 June; 2(3): 218-232
Georgetown users check Georgetown Journal Finder for access to full text

Document 1609
Gilbert, Donald L.; Buncher, C. Ralph
Assessment of scientific and ethical issues in two randomized clinical trial designs for patients with Tourette's syndrome: a model for studies of multiple neuropsychiatric diagnoses
Journal of Neuropsychiatry and Clinical Neurosciences 2005 Summer; 17(3): 324-332
Georgetown users check Georgetown Journal Finder for access to full text

Document 1610
Dinnett, Eleanor M.; Mungall, Moira M.B.; Kent, Jane A.; Ronald, Elizabeth S.; McIntyre, Karen E.; Anderson, Elizabeth; Gaw, Allan
Unblinding of trial participants to their treatment allocation: lessons from the Prospective Study of Pravastatin in the Elderly at Risk (PROSPER)
Clinical Trials 2005 June; 2(3): 254-259
Georgetown users check Georgetown Journal Finder for access to full text

Document 1611
Heilig, Charles M.; Weijer, Charles
A critical history of individual and collective ethics in the lineage of Lellouch and Schwartz
Clinical Trials 2005 June; 2(3): 244-253
Georgetown users check Georgetown Journal Finder for access to full text

Document 1612
Mann, Howard; London, Alex John; Mann, Jeffrey
Equipoise in the Enhanced Suppression of the Platelet IIb/IIIa Receptor with Integrilin Trial (ESPRIT): a critical appraisal
Clinical Trials 2005 June; 2(3): 233-243
Georgetown users check Georgetown Journal Finder for access to full text

Document 1613
Ashby, Deborah; Tan, Say-Beng
Where's the utility in Bayesian data-monitoring of clinical trials?
* Document 1614
Beran, Roy G.
*Ethical considerations within clinical research with special focus upon clinical drug trials*
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1615
Blader, Joseph C.
*Can keeping clinical trial participants blind to their study treatment adversely affect subsequent care?*
Contemporary Clinical Trials 2005 June; 26(3): 290-299
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1616
Ross, Lainie Friedman
*Lessons to be learned from the 407 process*
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1617
Hohmann, Elizabeth; Woodson, Jonathan
"Inefficient, arbitrary, inconsistent": a frank look at how some investigators view IRBs and a few suggestions for improvement [discussion]
Protecting Human Subjects 2005 Summer; (12): 12-14
Georgetown users check Georgetown Journal Finder for access to full text

Document 1618
Maloney, Dennis M.
*Agency says institutional review board (IRB) members must receive "ongoing" education [case study]*
Georgetown users check Georgetown Journal Finder for access to full text

Document 1619
Armstrong, Karen
*Reducing a review burden for IRBs [review of the Evolution -- Creation Struggle, by Michael Ruse]*
Georgetown users check Georgetown Journal Finder for access to full text
Medical Research Council [MRC] (Great Britain)

Medical Research Council position statement on research regulation and ethics

http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002462 (link may be outdated)

Hewitt, Catherine; Hahn, Seokyung; Torgerson, David J.; Watson, Judith; Bland, J. Martin

Adequacy and reporting of allocation concealment: review of recent trials published in four general medical journals
BMJ: British Medical Journal 2005 May 7; 330(7499): 1057-1058

Georgetown users check Georgetown Journal Finder for access to full text

http://www.bmj.com (link may be outdated)

Altman, Douglas G.

Endorsement of the CONSORT statement by high impact medical journals: survey of instructions for authors
BMJ: British Medical Journal 2005 May 7; 330(7499): 1056-1057

Georgetown users check Georgetown Journal Finder for access to full text

http://www.bmj.com (link may be outdated)

Pildal, Julie; Chan, An-Wen; Hrobjartsson, Asbjom; Forfang, Elisabeth; Altman, Douglas G.; Gotzsche, Peter C.

Comparison of descriptions of allocation concealment in trial protocols and the published reports: cohort study
BMJ: British Medical Journal 2005 May 7; 330(7499): 1049-1052

Georgetown users check Georgetown Journal Finder for access to full text

http://www.bmj.com (link may be outdated)

Walsh, Michael K.; McNeil, John J.; Breen, Kerry J.

Improving the governance of health research
Medical Journal of Australia 2005 May 2; 182(9): 468-471

Georgetown users check Georgetown Journal Finder for access to full text

http://www.bmj.com (link may be outdated)

Kojima, Somei; Waikagul, Jitra; Rojekittikhun, Wichit; Keicho, Naoto

The current situation regarding the establishment of national ethical guidelines for biomedical research in
EthxWeb Search Results

Search Detail:
Result=(("18.2".PC.) AND (@YD => "20040000")) NOT (EDITORIAL OR LETTER OR NEWS)
2=1:
Documents: 1626 - 1950 of 2150

Document 1626
Ashcroft, Richard
After the trial is over: what are the sponsor's obligations?

http://www.scidev.net/dossiers/index.cfm?fuseaction=policybrief&dossier=5&policy=63 (link may be outdated)

Document 1627
Schwetz, Bernard A.; Lehman-McKeeman, Lois; Birnbaum, Linda S.
Toxicological research involving humans: ethical and regulatory considerations
Toxicological Sciences 2005 May; 85(1): 419-421
Georgetown users check Georgetown Journal Finder for access to full text

Document 1628
Wolf, Leslie E.; Walden, Janice Ferrara; Lo, Bernard
Human subjects issues and IRB review in practice-based research
Georgetown users check Georgetown Journal Finder for access to full text

Document 1629
Lehmann, Harold P.
Are we ready for patient-based effect sizes in clinical-trials research?
Medical Decision Making 2005 May-June; 25(3): 248-249
Georgetown users check Georgetown Journal Finder for access to full text

Document 1630
Barrett, Bruce; Brown, David; Mundt, Marlon; Brown, Roger
Sufficiently important difference: expanding the framework of clinical significance
Medical Decision Making 2005 May-June; 25(3): 250-261
Georgetown users check Georgetown Journal Finder for access to full text
Document 1631
Mann, Howard

American Journal of Bioethics 2005 May-June; 5(3): 72-74

Georgetown users check Georgetown Journal Finder for access to full text

http://bioethics.net (link may be outdated)

Document 1632
Samanta, Ash; Samanta, Jo

Research governance: panacea or problem?
Clinical Medicine 2005 May-June; 5(3): 235-239

Georgetown users check Georgetown Journal Finder for access to full text

Document 1633
Parnis, Deborah; Du Mont, Janice; Gombay, Brydon

Cooperation or co-optation?: assessing the methodological benefits and barriers involved in conducting qualitative research through medical institutional settings
Qualitative Health Research 2005 May; 15(5): 686-697

Georgetown users check Georgetown Journal Finder for access to full text

Document 1634
March, John S.; Silva, Susan G.; Compton, Scott; Shapiro, Mark; Califf, Robert; Krishnan, Ranga

The case for practical clinical trials in psychiatry
American Journal of Psychiatry 2005 May; 162(5): 836-846

Georgetown users check Georgetown Journal Finder for access to full text

http://ajp.psychiatryonline.org (link may be outdated)

Document 1635
Sheppard, Vanessa B.; Cox, Lisa Sanderson; Kanamori, Mariano J.; Canar, Janet; Rodriguez, Yosselyn; Goodman, Michelle; Pomeroy, Jyl; Mandelblatt, Jeanne; Huerta, Elmer E.

Latin American Cancer Research Coalition [LACRC]
Brief report: if you build it, they will come: methods for recruiting Latinos into cancer research

Georgetown users check Georgetown Journal Finder for access to full text

http://www.pubmedcentral.nih.gov (link may be outdated)

Document 1636
Napoles-Springer, Anna M.; Santoyo, Jasmine; Stewart, Anita L.

**Recruiting ethnically diverse general internal medicine patients for a telephone survey on physician-patient communication**

Georgetown users check [Georgetown Journal Finder](http://www.pubmedcentral.nih.gov) for access to full text

**http://www.pubmedcentral.nih.gov** (link may be outdated)

---

**Document 1637**

Maloney, Dennis M.

**Change proposed for regulations that affect institutional review boards (IRBs)**

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---

**Document 1638**

Maloney, Dennis M.

**Institutional review board (IRB) members must receive continuing education [case study]**

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---

**Document 1639**

Maloney, Dennis M.

**Reducing risks for human subjects**

Georgetown users check [Georgetown Journal Finder](http://www.pubmedcentral.nih.gov) for access to full text

---

**Document 1640**

Maloney, Dennis M.

**Comments sought on record keeping for protection rules**

Georgetown users check [Georgetown Journal Finder](http://www.pubmedcentral.nih.gov) for access to full text

---

**Document 1641**

Tuech, J.J.; Pessaux, P.; Moutel, G.; Thoma, V.; Schraub, S.; Herve, C.

**Methodological quality and reporting of ethical requirements in phase III cancer trials**
Journal of Medical Ethics 2005 May; 31(5): 251-255

**Abstract:** BACKGROUND: The approval of a research ethics committee (REC) and obtaining informed consent from patients (ICP) could be considered the main issues in the ethics of research with human beings. The aim of this study was to assess both methodological quality and ethical quality, and also to assess the relationship between these two qualities in randomised phase III cancer trials. METHOD: Methodological quality (Jadad score) and ethical quality (Berdeu score) were assessed for all randomised controlled trials (RCTs) published in 10 international journals between 1999 and 2001 (n = 231). RESULTS: The mean Jadad score was 9.86 +/- 1.17. The methodological quality was poor in 75 RCTs (Jadad score <9). The mean Berdeu score was 0.42 +/- 0.133. The mean ethical quality score...
for poor methodological quality RCTs (n = 75) was 0.39 +/- 0.133; it was 0.43 +/- 0.133 for good (n = 156) methodological quality RCTs (p = 0.07). There was improvement in ethical quality according to the year of commencement of the trials (p < 0.001). There was no correlation between methodological quality and the number of participating patients (R2 = 0.003, p = 0.78), between ethical quality and the number of participating patients (R2 = 0.003, p = 0.78), or between ethical quality and methodological quality (R2 = 0.012, p = 0.1). ICP and REC approval were not obtained for 21 and 77 trials respectively. CONCLUSION: The association between methodological quality and the reporting of ethical requirements probably reflects the respect shown for patients during the whole research process. These results suggest that closer attention to the conduct of clinical research, as well as the reporting of its ethical aspects, is needed.

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http://www.jmedethics.com (link may be outdated)
* Article Document 1647
Krleza-Jeric, Karmela; Chan, An-Wen; Dickersin, Kay; Sim, Ida; Grimshaw, Jeremy; Gluud, Christian
Canadian Institutes of Health Research. Ottawa Group
Principles for international registration of protocol information and results from human trials of health related interventions: Ottawa statement (part 1)
Georgetown users check Georgetown Journal Finder for access to full text

http://www.bmj.com (link may be outdated)

* Article Document 1648
Small, Meredith F.
My body on the line
Washington Post 2005 April 19; p. F1, F6

http://www.washingtonpost.com (link may be outdated)

* Article Document 1649
Aronson, Jeffrey K.
Commentary: open access publishing: too much oxygen?
BMJ: British Medical Journal 2005 April 2; 330(7494): 759
Georgetown users check Georgetown Journal Finder for access to full text

http://www.bmj.com (link may be outdated)

* Article Document 1650
Chan, An-Wen; Altman, Douglas G.
Identifying outcome reporting bias in randomised trials on PubMed: review of publications and survey of authors
BMJ: British Medical Journal 2005 April 2; 330(7494): 753-759
Georgetown users check Georgetown Journal Finder for access to full text

http://www.bmj.com (link may be outdated)

* Article Document 1651
Fox, R.M.
Debate: should Australia move towards a centralized ethics committees system? The case for
Internal Medicine Journal 2005 April; 35(4): 247-248
Georgetown users check Georgetown Journal Finder for access to full text

http://www.bmj.com (link may be outdated)
Document 1652
Dixon, Roz
**Ethical research with participants who are deaf**
Bulletin of Medical Ethics 2005 April; (207): 13-19
Georgetown users check [Georgetown Journal Finder](http://www.bullmedeth.info/) for access to full text

Document 1653
Fisher, Celia B.
**Commentary: SES, ethnicity and goodness-of-fit in clinician-parent communication during pediatric cancer trials**
Journal of Pediatric Psychology 2005 April-May; 30(3): 231-234
Georgetown users check [Georgetown Journal Finder](http://www.bullmedeth.info/) for access to full text

Document 1654
Shaul, Randi Zlotnik
**Potato, potato, proxy consent, permission -- just don't call the a whole thing off [opinion]**
Critical Care 2005 April; 9(2): 123-124
Georgetown users check [Georgetown Journal Finder](http://www.bullmedeth.info/) for access to full text

Document 1655
Burke, Georgine S.
**Looking into the institutional review board: observations from both sides of the table**
Journal of Nutrition 2005 April; 135(4): 921-924
Georgetown users check [Georgetown Journal Finder](http://www.bullmedeth.info/) for access to full text

Document 1656
Kiskaddon, Sarah H.
**Balancing access to participation in research and protection from risks: applying the principle of justice**
Journal of Nutrition 2005 April; 135(4): 929-932
Georgetown users check [Georgetown Journal Finder](http://www.bullmedeth.info/) for access to full text

Document 1657
Weijer, Charles
**Is clinical research and ethics a zero-sum game?**
Critical Care Medicine 2005 April; 33(4): 912-913
Georgetown users check [Georgetown Journal Finder](http://www.bullmedeth.info/) for access to full text
Document 1658
Bromberg, Jonathan S.; Silverstein, Jeffrey H.; Kirk, Allan D.
Proposal for the American Journal of Transplantation policy for review of ethical standards of clinical research involving live human subjects

Georgetown users check Georgetown Journal Finder for access to full text

Document 1659
Storosum, Jitschak G.; Wohlfarth, Tamar; Gispen-de Wied, Christine C.; Linszen, Don H.; Gersons, Berthold P.R.; van Zwieten, Barbara J.; van den Brink, Wim
Suicide risk in placebo-controlled trials of treatment for acute manic episode and prevention of manic-depressive episode
American Journal of Psychiatry 2005 April; 162(4): 799-802

Georgetown users check Georgetown Journal Finder for access to full text

http://ajp.psychiatryonline.org (link may be outdated)

Document 1660
Maloney, Dennis M.
University ordered to halt human research [case study]

Georgetown users check Georgetown Journal Finder for access to full text

Document 1661
Maloney, Dennis M.
Additional provisions for protecting human subjects

Georgetown users check Georgetown Journal Finder for access to full text

Document 1662
Maloney, Dennis M.
Update on procedures for protecting human subjects

Georgetown users check Georgetown Journal Finder for access to full text

Document 1663
United States. Food and Drug Administration
Draft guidance for industry on using a centralized institutional review boards process in multicenter clinical trials; availability
* Document 1664
Lurie, Peter; Greco, Dirceu B.
**US exceptionalism comes to research ethics**
Lancet 2005 March 26-April 1; 365(9465): 1117-1119
Georgetown users check Georgetown Journal Finder for access to full text
http://www.thelancet.com/journal (link may be outdated)

* Document 1665
United States. Department of Health and Human Services. Office of the Secretary
**Protection of Human Subjects, Proposed Criteria for Determinations of Equivalent Protection. Notice**
Federal Register 2005 March 25; 70(57): 15322-15327
Georgetown users check Georgetown Journal Finder for access to full text
http://www.gpoaccess.gov/fr/index.html (link may be outdated)

* Document 1666
Partridge, Ann H.; Wong, Julia S.; Knudsen, Katherine; Gelman, Rebecca; Sampson, Ebonie; Gadd, Michele; Bishop, Karyn L.; Harris, Jay R.; Winer, Eric P.
**Offering participants results of a clinical trial: sharing results of a negative study**
Lancet 2005 March 12-18; 365(9463): 963-964
*Abstract*: In general, patients are not given information about the results of trials in which they have participated. We aimed to assess the process and effect of providing clinical trial participants with results of a negative study. We offered results to 135 participants in a phase II trial of breast excision alone for women with ductal carcinoma in situ, which was stopped early because of an early high rate of local recurrence. 85 (90%) of 94 respondents chose to receive results; these women were more educated (57 [67%] of 85 college graduates) than those who chose not to (two [22%] of nine, p=0.006). Most participants reported positive feelings about being offered results and about clinical trials in general. These preliminary findings from sharing clinical trial results are encouraging.
Georgetown users check Georgetown Journal Finder for access to full text
http://www.thelancet.com/journal (link may be outdated)

* Document 1667
**Issues in Data Monitoring and Interim Analysis of Trials**
HEALTH TECHNOLOGY ASSESSMENT 2005 March; 9(7): iii-223
Call number: Special Issue shelf

* Document 1668
Pandya, Dipak P.; Dave, Jay
Protection of human subjects in clinical research: the pitfalls in clinical research
Comprehensive Therapy 2005 Spring; 31(1): 72-77
Georgetown users check Georgetown Journal Finder for access to full text

Document 1669
Kaufert, Joseph M.; Glass, Kathleen Cranley; Freeman, William L.
Background paper on issues of group, community or first nation consent in health research
NCEHR Communique CNERH 2005 Spring; 13(1): 19-20
Georgetown users check Georgetown Journal Finder for access to full text
http://www.ncehr.medical.org (link may be outdated)

Document 1670
Hinberg, Irwin
Investigational testing of medical devices in Canada--presented at NCEHR national conference, 06 March 2005
NCEHR Communique CNERH 2005 Spring; 13(1): 19
Georgetown users check Georgetown Journal Finder for access to full text
http://www.ncehr.medical.org (link may be outdated)

Document 1671
Quest, Dale
Case vignette 3: a multi-centered trial to compare TCT vs Clozapine for treatment-resistant schizophrenia
NCEHR Communique CNERH 2005 Spring; 13(1): 11-12
Georgetown users check Georgetown Journal Finder for access to full text
http://www.ncehr.medical.org (link may be outdated)

Document 1672
Quest, Dale
Case vignette 2: a phase 2, randomized, double-blind, placebo-controlled study of DPE6591A in rheumatoid arthritis patients
NCEHR Communique CNERH 2005 Spring; 13(1): 9-10
Georgetown users check Georgetown Journal Finder for access to full text
http://www.ncehr.medical.org (link may be outdated)

Document 1673
Quest, Dale
Case vignette 1: a randomized double-blind double-dummy cross-over study of oral hexylinsulin monoconjugate 2 [PEGinsulin] versus insulin lispro for postprandial glycaemic control in adult patients with Type 2 diabetes mellitus
Document 1674

Poff, Deborah


Georgetown users check Georgetown Journal Finder for access to full text

[http://www.ncehr.medical.org](http://www.ncehr.medical.org) (link may be outdated)

Document 1675

Coleman, Carl H.

*Duties to subjects in clinical research*


Georgetown users check Georgetown Journal Finder for access to full text

Document 1676

Sraer, Jean-Daniel; Hauw, Jean-Jacques; Ardaillou, Raymond; Bach, Jean-François

*Recommandations de l'Académie nationale de médecine dans le domaine de la recherche biomédicale / Recommendations in the National Academy of Medicine in the field of biomedical research*

Bulletin de l'Academie Nationale de Medecine 2005 March; 189(3): 555-563

Georgetown users check Georgetown Journal Finder for access to full text

Document 1677

Bennett, Jill A.

*The consolidated standards of reporting trials (CONSORT) guidelines for reporting randomized trials*

Nursing Research 2005 March-April; 54(2): 128-132

Georgetown users check Georgetown Journal Finder for access to full text

Document 1678

Truog, Robert D.

*Will ethical requirements bring critical care research to a halt?*

Intensive Care Medicine 2005 March; 31(3): 338-344

Georgetown users check Georgetown Journal Finder for access to full text

Document 1679
Dreyfuss, Didier
Is it better to consent to an RCT or to care? Muetaeltaepsilonnualpha"nothing in excess"
Intensive Care Medicine 2005 March; 31(3): 345-355

Fielder, John H.
The Vioxx debacle

Shaver, Frances M.
Sex work research: methodological and ethical challenges
Journal of Interpersonal Violence 2005 March; 20(3): 296-319

Terry, Robert
Funding the way to open access

Glasa, Jozef
Training and dissemination of good practices for research ethics committees: standardization, harmonization and collaboration
Medical Ethics and Bioethics / Medicinska Etika & Bioetika 2005 Spring-Summer; 12(1): 7-8

Hodge, James G., Jr.
An enhanced approach to distinguishing public health practice and human subjects research

Miser, William F.
Educational research – to IRB, or not to IRB?
Georgetown users check Georgetown Journal Finder for access to full text

Weiss, Barry D.; Smith, Mindy A.; Magill, Michael K.
Journal policy statement – IRB approval for educational research [policy statement]
Family Medicine 2005 March; 37(3): 219-220
Georgetown users check Georgetown Journal Finder for access to full text

Margolin, Gayla; Chien, Deborah; Duman, Sarah E.; Fauchier, Angele; Gordis, Elana B.; Oliver, Pamella H.; Ramos, Michelle C.; Vickerman, Katrina A.
Ethical issues in couple and family research
Georgetown users check Georgetown Journal Finder for access to full text

Jenkins, Gwynne L.; Sugarman, Jeremy
The importance of cultural considerations in the promotion of ethical research with human biologic material
Journal of Laboratory Clinical Medicine 2005 March; 145(3): 118-124
Georgetown users check Georgetown Journal Finder for access to full text

Hammerschmidt, Dale E.
Kibuka's umbilical cord
Georgetown users check Georgetown Journal Finder for access to full text

Olde Rikkert, Marcel G.M.; Lauque, S.; Frolich, L.; Vellas, B.; Dekkers, W.
The practice of obtaining approval from medical research ethics committees: a comparison within 12 European countries for a descriptive study on acetylcholinesterase inhibitors in Alzheimer's dementia
Georgetown users check Georgetown Journal Finder for access to full text

Slovenko, Ralph
The evolution of standards for experimental treatment or research
Sham surgery controls are mitigated trolleys
Albin, R.L.
Journal of Medical Ethics 2005 March; 31(3): 149-152
Abstract: Debate continues about the ethics of sham surgery controls. The most powerful argument for sham surgery controls is that rigorous experiments are needed to demonstrate safety and efficacy of surgical procedures. Without such experiments, there is danger of adopting worthless procedures in clinical practice. Opponents of sham surgery controls argue that sham surgery constitutes unacceptable violation of the rights of research subjects. Recent philosophical discussion has used two thought experiments-the transplant case and the trolley problem-to explore the circumstances under which individuals may be harmed to benefit a larger group. The transplant case is felt to exemplify circumstances that forbid harming some to benefit a larger group while the trolley problem exemplifies circumstances that permit harming some to benefit others. I argue that sham surgery controls satisfy criteria derived from the trolley problem and are morally permissible.

Guidance for industry. Using a centralized IRB review process in multicenter clinical trials. Draft guidance
United States. Food and Drug Administration [FDA]; Good Clinical Practice Program, Office of the Commissioner [OC]; Center for Drug Evaluation and Research [CDER]; Center for Biologics Evaluation and Research [CBER]; Office of Regulatory Affairs [ORA]

Determining the level of statistician participation on Canadian-based research ethics boards
Thabane, Lehana; Childs, Aaron; Lafontaine, Amanda
IRB: Ethics and Human Research 2005 March-April; 27(2): 11-14

Just-in-time IRB review: capitalizing on scientific merit review to improve human subjects research compliance
Kelly, P. Adam; Johnson, Michael L.
IRB: Ethics and Human Research 2005 March-April; 27(2): 6-10
Dhai, Ames
**Module five: implementation of ethics review**
Developing World Bioethics 2005 March; 5(1): 73-91

**Abstract:** The objective of this module is to inform you on issues of concern for Research Ethics Committee members and investigators during the review process. The many guidelines on research ethics, including those from the South African Department of Health and the World Health Organisation, will be referred to extensively to educate you on the requirements of Research Ethics Committees. The evolution of the review process in South Africa will be detailed.

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---

Document 1697

Maloney, Dennis M.
**Investigator agreements for protecting human subjects**
Human Research Report 2005 March; 20(3): 4

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

Document 1698

Maloney, Dennis M.
**Institutional review boards (IRBs) and the review of adverse events**

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

Document 1699

Carlson, Robert
**How then should we do medical research?**
Ethics and Medicine 2005 Spring; 21(1): 59-61

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

Document 1700

McMillan, John; Sheehan, Mark
**Commentary: ethical review and ethical behaviour**

Georgetown users check [Georgetown Journal Finder](#) for access to full text

[http://www.bmj.com](http://www.bmj.com) (link may be outdated)

---

Document 1701

Alexander, John
**Commentary: research ethics committees deserve support**

Georgetown users check [Georgetown Journal Finder](#) for access to full text
**Document 1702**

Wade, Derick T.

*Ethics, audit, and research: all shades of grey*


Georgetown users check [Georgetown Journal Finder](http://www.bmj.com) for access to full text

**Document 1703**


*The impact of privacy protections on recruitment in a multicenter stroke genetics study*

Neurology 2005 February 22; 64(4): 721-724

Georgetown users check [Georgetown Journal Finder](http://www.bmj.com) for access to full text

**Document 1704**

Jenkins, V.; Fallowfield, L.; Solis-Trapala, I.; Langridge, C.; Farewell, V.

*Discussing randomised clinical trials of cancer therapy: evaluation of a cancer research UK training programme*

BMJ: British Medical Journal 2005 February 19; 330(7488): 400-403

Georgetown users check [Georgetown Journal Finder](http://www.bmj.com) for access to full text

**Document 1705**


*A proposed charter for clinical trial data monitoring committees: helping them to do their job well*


**Abstract:** Formal monitoring of data from randomised controlled trials (RCTs) is becoming more common. Wide variation exists in the structure and organisation of data monitoring committees (DMCs), with little guidance on how they should operate. We used various strategies to consider the behavioural, procedural, and organisational aspects of data monitoring in RCTs: systematic reviews of DMCs and small group processes in decision making; surveys of reports of RCTs, recently completed and ongoing RCTs, and the policies of major organisations connected with RCTs; detailed case studies of four DMCs that faced difficult decisions; and interviews with experienced DMC members. The findings aided the development of a template for a charter for DMCs. We summarise the findings and outline the key considerations at every stage of the data monitoring process. Widespread use of a charter for the structure and organisation of DMCs would promote a systematic and transparent approach, and enable them to operate more effectively and efficiently.

Georgetown users check [Georgetown Journal Finder](http://www.bmj.com) for access to full text

**Document 1706**


United States. Food and Drug Administration [FDA]
Reporting of Adverse Events to Institutional Review Boards; Public Hearing
Federal Register 2005 February 8; 70(25): 6693-6696

http://www.fda.gov/OHRMS/DOCKETS/98fr/05-2300.pdf (link may be outdated)

Document 1707
Schoenfeld, David A.
Pro/con clinical debate: It is acceptable to stop large multicentre randomized controlled trials at interim analysis for futility. Pro: Futility stopping can speed up the development of effective treatments
Critical Care 2005 February; 9(1): 34-36
Georgetown users check Georgetown Journal Finder for access to full text

Document 1708
Meade, Maureen O.
Pro/con clinical debate: It is acceptable to stop large multicentre randomized controlled trials at interim analysis for futility. Con: the hazards of stopping for futility
Critical Care 2005 February; 9(1): 34-36
Georgetown users check Georgetown Journal Finder for access to full text

Document 1709
Santarlasci, Benedetta; Messori, Andrea; Pelagotti, Filippo; Trippoli, Sabrina; Vaiani, Monica
Heterogeneity in the evaluation of observational studies by Italian ethics committees
Pharmacy World and Science 2005 February; 27(1): 2-3
Georgetown users check Georgetown Journal Finder for access to full text

Document 1710
Manasco, Penelope K.
Ethical and legal aspects of applied genomic technologies: practical solutions
Georgetown users check Georgetown Journal Finder for access to full text

Document 1711
Mavroforou, Anna; Giannoukas, Athanasios D.; Mavrophoros, Dimitrios; Michalodimitrakis, Emmanuel
Confidentiality governing surgical research practice
Georgetown users check Georgetown Journal Finder for access to full text

Document 1712
Dominguez, Roberto A.; Feaster, Daniel J.; Twiggs, Leo B.; Altman, Norman H.
Searching for an efficient institutional review board review model: interrelationship of trainee-investigators, funding, and initial approval
Journal of Laboratory and Clinical Medicine 2005 February; 145(2): 65-71

Georgetown users check Georgetown Journal Finder for access to full text

Dziak, Kathleen; Anderson, Roger; Sevick, Mary Ann; Weisman, Carol S.; Levine, Douglas W.; Scholle, Sarah Hudson
Variations among institutional review board reviews in a multisite health services research study
Health Services Research 2005 February; 40(1): 279-290

Georgetown users check Georgetown Journal Finder for access to full text

Gold, Jennifer L.; Dewa, Carolyn S.
Institutional review boards and multisite studies in health services research: is there a better way?

Georgetown users check Georgetown Journal Finder for access to full text

Paasche-Orlow, Michael K.; Brancati, Frederick L.
Assessment of medical school institutional review board policies regarding compensation of subjects for research-related injury
American Journal of Medicine 2005 February; 118(2): 175-180

Georgetown users check Georgetown Journal Finder for access to full text

Walker, Gay; de Valois, Beverley; Davies, Raten; Young, Teresa; Maher, Jane
Opinions of research participants about study paperwork [review]
Bulletin of Medical Ethics 2005 February; (205): 21-24

Georgetown users check Georgetown Journal Finder for access to full text

http://www.bullmedeth.info/ (link may be outdated)

Maloney, Dennis M.
Official says his own agency failed to protect research subjects and patients

Georgetown users check Georgetown Journal Finder for access to full text
Maloney, Dennis M.

**Institutional review boards must conduct safety review**


Georgetown users check [Georgetown Journal Finder](http://www.georgetownjournalfinder.com) for access to full text

---

* Article Document 1719

Maloney, Dennis M.

**Protection of human subjects and coded private information**


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---

* Article Document 1720

Bacchetti, Peter; Wolf, Leslie E.; Segal, Mark R.; McCulloch, Charles E.

**Ethics and sample size**

American Journal of Epidemiology 2005 January 15; 161(2): 105-110

Georgetown users check [Georgetown Journal Finder](http://www.georgetownjournalfinder.com) for access to full text

---

* Article Document 1721

Prentice, Ross

**Invited commentary: ethics and sample size -- another view**


Georgetown users check [Georgetown Journal Finder](http://www.georgetownjournalfinder.com) for access to full text

---

Article Document 1722

Devereaux, P.J.; Bhandari, Mohit; Clarke, Mike; Montori, Victor M.; Cook, Deborah J.; Yusuf, Salim; Sackett, David L.; Cina, Claudio S.; Walter, S.D.; Haynes, Brian; Schunemann, Holger J.; Norman, Geoffrey R.; Guyatt, Gordon H.

**Need for expertise based randomised controlled trials**

BMJ: British Medical Journal 2005 January 8; 330(7482): 88-91

Georgetown users check [Georgetown Journal Finder](http://www.georgetownjournalfinder.com) for access to full text

[http://www.bmj.com](http://www.bmj.com) (link may be outdated)

---

* Article Document 1723

Rothwell, Peter M.

**External validity of randomised controlled trials: "to whom do the results of this trial apply?"**

Lancet 2005 January 1-7; 365(9453): 82-93

Georgetown users check [Georgetown Journal Finder](http://www.georgetownjournalfinder.com) for access to full text

[http://www.thelancet.com/journal](http://www.thelancet.com/journal) (link may be outdated)
* Document 1724
Hoffman, Sharona; Berg, Jessica Wilen
**The suitability of IRB liability.**
Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Document 1725
Pelias, Mary Kay
**Research in human genetics: the tension between doing no harm and personal autonomy**
Clinical Genetics 2005 January; 67(1): 1-5
Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Document 1726
O'Sullivan, Amy K.; Thompson, David; Drummond, Michael F.
**Collection of health-economic data alongside clinical trials: is there a future for piggyback evaluations?**
Value in Health 2005 January-February; 8(1): 67-79
Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Document 1727
Frank, John W.
**Setting research priorities for arthritis: the environmental perspective**
Journal of Rheumatology 2005 January; 32(Supplement 72): 58-61
Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Document 1728
DeAngelis, Catherine D.; Drazen, Jeffrey M.; Frizelle, Frank A.; Haug, Charlotte; Hoey, John; Horton, Richard; Kotzin, Sheldon; Laine, Christine; Marusic, Ana; Overbeke, A. John P.M.; Schroeder, Torben V.; Sox, Hal C.; Van Der Weyden, Martin B.
**Clinical trial registration -- a statement from the International Committee of Medical Journal Editors**
Archives of Dermatology 2005 January; 141(1): 76-77
Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Document 1729
Callen, Jeffrey P.; Robinson, June
**Clinical trial registration -- a step forward in providing transparency for the positive and negative results of clinical trials**
Archives of Dermatology 2005 January; 141(1): 75
Georgetown users check [Georgetown Journal Finder](#) for access to full text
Document 1730
International Association of Cancer Registries
Guidelines on confidentiality for population-based cancer registration
Georgetown users check Georgetown Journal Finder for access to full text

Document 1731
Trachtman, Howard
Does Uncle Sam really want you?: a response to "Rethinking Research Ethics" by Rosamond Rhodes (AJOB 5:1)
Georgetown users check Georgetown Journal Finder for access to full text
http://bioethics.net (link may be outdated)

Document 1732
McGuire, Amy L.; McCullough, Laurence B.
Respect as an organizing normative category for research ethics
Georgetown users check Georgetown Journal Finder for access to full text
http://bioethics.net (link may be outdated)

Document 1733
Justo, Luis
Trust, understanding and utopia in the research setting
Georgetown users check Georgetown Journal Finder for access to full text
http://bioethics.net (link may be outdated)

Document 1734
List, Justin M.
Histories of mistrust and protectionism: disadvantaged minority groups and human-subject research policies
Georgetown users check Georgetown Journal Finder for access to full text
http://bioethics.net (link may be outdated)

Document 1735
Spike, Jeffrey

**Putting the "ethics" into "research ethics"**

*Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text*

**http://bioethics.net** (link may be outdated)

---

* Article  Document 1736

Allhoff, Fritz

**Free-riding and research ethics**

*Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text*

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---

* Document 1737

Wachbroit, Robert; Wasserman, David

**Research participation: are we subject to a duty?**

*Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text*

**http://bioethics.net** (link may be outdated)

---

* Document 1738

Simmerling, Mary; Schwegler, Brian

**Beginning anew: same principles, different direction for research ethics**

*Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text*

**http://bioethics.net** (link may be outdated)

---

* Document 1739

Morreim, Haavi

**Research versus innovation: real differences**

*Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text*

**http://bioethics.net** (link may be outdated)

---

* Document 1740

Sharp, Richard R.; Yarborough, Mark

**Additional thoughts on rethinking research ethics**

*Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text*

**http://bioethics.net** (link may be outdated)
* Document 1741

London, Alex John

**Does research ethics rest on a mistake? The common good, reasonable risk and social justice**


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http://bioethics.net (link may be outdated)

* Document 1742

Hougham, Gavin W.

**Waste not, want not: cognitive impairment should not preclude research participation**


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http://bioethics.net (link may be outdated)

* Document 1743

Miller, Franklin G.

**Does research ethics rest on a mistake?**


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http://bioethics.net (link may be outdated)

* Document 1744

Beauchamp, Tom L.

**How not to rethink research ethics**


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http://bioethics.net (link may be outdated)

* Document 1745

Macklin, Ruth

**Some questionable premises about research ethics**


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http://bioethics.net (link may be outdated)
Rethinking research ethics

Abstract: Contemporary research ethics policies started with reflection on the atrocities perpetrated upon concentration camp inmates by Nazi doctors. Apparently, as a consequence of that experience, the policies that now guide human subject research focus on the protection of human subjects by making informed consent the centerpiece of regulatory attention. I take the choice of context for policy design, the initial prioritization of informed consent, and several associated conceptual missteps, to have set research ethics off in the wrong direction. The aim of this paper is to sort out these confusions and their implications and to offer instead a straightforward framework for considering the ethical conduct of human subject research. In the course of this discussion I clarify different senses of autonomy that have been confounded and present more intelligible justifications for informed consent. I also take issue with several of the now accepted dogmas that govern research ethics. These include: the primacy of informed consent, the protection of the vulnerable, the substitution of beneficence for research's social purpose, and the introduction of an untenable distinction between innovation and research.

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**Document 1751**
Zlotnik Shaul, Randi; Reid, Lynette; Essue, Beverley; Gibson, Julie; Marzinotto, Velma; Daneman, Denis
Dissemination to research subjects: operationalizing investigator accountability
Accountability in Research 2005 January-March; 12(1): 1-16
Abstract: Recent articles have argued from principles of bioethics for the right of research subjects to receive the results of the studies in which they have participated. We argue that accountability is a powerful tool of meso-level analysis appropriate to reasoning about answerability in research ethics, and that it captures the responsibility of researchers to disseminate study results to research subjects. We offer the following features of the research situation as relevant to the manner of dissemination to study subject, in addition to factors already proposed in the literature (risk and impact on health outcome): (a) features of the research subject in relation to identity, personal investment, disease, and community; (b) characteristics of the research study and field of inquiry in relation to certainty and significance; and (c) relationships among the research subjects and the healthcare workers involved in their care and in the research.

**Document 1752**
Benedek, Thomas G.
Gonorrhea and the beginnings of clinical research ethics
Perspectives in Biology and Medicine 2005 Winter; 48(1): 54-73

**Document 1753**
Resnik, D.B.
Eliminating the daily life risks standard from the definition of minimal risk
Journal of Medical Ethics 2005 January; 31(1): 35-38

**Document 1754**
Wilkinson, Martin
Payments to research subjects
Monash Bioethics Review 2005 January; 24(1): 70-74

**Document 1755**
Abbott, Lura Jeanne
FACTORS ASSOCIATED WITH THE EFFICIENCY OF THE CLINICAL RESEARCH REVIEW PROCESS IN THE INTRAMURAL PROGRAM OF THE NATIONAL INSTITUTES OF HEALTH
Call number: R852.5.A22 2005a
Document 1756
Beyleveld, D.; Townend, D.; and Wright, J., eds.
RESEARCH ETHICS COMMITTEES, DATA PROTECTION AND MEDICAL RESEARCH IN EUROPEAN COUNTRIES
Call number: KJE6229 .R43 R474 2005

Document 1757
Derenzo, Evan G. and Moss, Joel
WRITING CLINICAL RESEARCH PROTOCOLS: ETHICAL CONSIDERATIONS
Call number: R853 .P75 D47 2006

Document 1758
Schuster, Daniel P. and Powers, William J., eds.
TRANSLATIONAL AND EXPERIMENTAL CLINICAL RESEARCH
Call number: R850 .T73 2005

Document 1759
Hajitarkhani, Amir Hossein
Ethics in medical research: review of international and national rights

Document 1760
Pahari, Sachey Kumar; Adhikari, Ramesh Kant; Singh, Shanker Pratap; Kumar, Rajendra; Banmali, Pearl; Rathour, Shaleen Singh
Nepal Health Research Council [NHRC]
National Guidelines on Clinical Trials with the Use of Pharmaceutical Products

Document 1761
Plomer, Aurora
Rights, principles and political values in medical research: the Achre Report and the Council of Europe's Convention on Human Rights and Biomedicine
Call number: BJ21 .E845 2005
**Document 172**

Borgerson, Janet

*Preparation of ethics for the future: addressing the "global basic structure" in the ethics of international biomedical research involving human subjects*


Call number: BJ21 .E845 2005

**Document 173**

Fovargue, Sara

*A leap of faith? Sanctioning xenotransplant clinical trials*


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**Document 174**

Gunsalus, C. Kristina

*Human subject protections: some thoughts on costs and benefits in the humanistic disciplines*


Call number: QH332 .E96 2005

**Document 175**

Romeo-Casabona, Carlos; Nicolas, Pilar

*Research ethics committees in Spain*


Call number: KJE6229 .R43 R474 2005

**Document 176**

Baker, Stephen; Beyleved, Deryck; Wallace, Susan; Wright, Jessica

*Research ethics committees and the law in the UK.*


Call number: KJE6229 .R43 R474 2005

**Document 177**

Rynning, Elisabeth

*The Swedish system for ethics review of biomedical research and processing of sensitive personal data.*


Call number: KJE6229 .R43 R474 2005

**Document 178**

Trontelj, Joze

*Research ethics committees in Slovenia.*
Call number: KJE6229 .R43 R474 2005

Document 1769
Glasa, Jozef; Miller, Jane
Research ethics committees in Slovakia.
Call number: KJE6229 .R43 R474 2005

Document 1770
Doaga, Octavian
Bioethical review in Romania.
Call number: KJE6229 .R43 R474 2005

Document 1771
Moniz, Helena; Figalgo, Sónia; Vale e Reis, Rafael; Almeida, Rosalvo
The constitution and operation of health ethics committees in Portugal: rights of patients to personal data protection.
Call number: KJE6229 .R43 R474 2005

Document 1772
Bong-Polec, Patrycja; Luków, Pawel
Research ethics committees and personal data protection in Poland.
Call number: KJE6229 .R43 R474 2005

Document 1773
Kvalheim, Vigdis
The Norwegian model for ethical review of medical research.
Call number: KJE6229 .R43 R474 2005

Document 1774
Wright, Jessica; Gordijn, Bert
Medical research on human subjects and RECs in the Netherlands.
Call number: KJE6229 .R43 R474 2005
Document 1775

Mallia, Pierre

Research ethics committees in Malta.
Call number: KJE6229 .R43 R474 2005

Document 1776

Cekanauskaite, Asta; Gefenas, Eugenijus

Research ethics committees in Lithuania.
Call number: KJE6229 .R43 R474 2005

Document 1777

Rudze, Laima

Research ethics committees in Latvia.
Call number: KJE6229 .R43 R474 2005

Document 1778

Lattanzi, Roberto

Research ethics committees in Italy's legal system.
Call number: KJE6229 .R43 R474 2005

Document 1779

Madden, Deirdre; McDonagh, Maeve

Research ethics committees in Ireland.
Call number: KJE6229 .R43 R474 2005

Document 1780

Sándor, Judit

Research ethics committees in Hungary
Call number: KJE6229 .R43 R474 2005

Document 1781

Garanis-Papadatos, Tina; Boukis, Dimitris

Research ethics committees in Greece.
In: Beyleveld, D.; Townend, D.; Wright, J., eds. Research Ethics Committees, Data Protection and Medical
Document 1782

Kettner, Matthias

**Research ethics committees in Germany.**


Call number: KJE6229 .R43 R474 2005

Document 1783

Feuillet, Brigitte

**The role of ethics committees in relation to French biomedical research: protection of the person and personal data.**


Call number: KJE6229 .R43 R474 2005

Document 1784

Lehtonen, Lasse A.; Halila, Ritva

**The general legal responsibility of research ethics committees in Finland.**


Call number: KJE6229 .R43 R474 2005

Document 1785

Veidebaum, Toomas

**Research ethics in Estonia.**


Call number: KJE6229 .R43 R474 2005

Document 1786

Rosenzweig, Mary; Knudsen, Lisbeth

**Research ethics committees in Denmark.**


Call number: KJE6229 .R43 R474 2005

Document 1787

Prudil, Lukáš; Kure, Josef

**Research ethics committees in the Czech Republic.**


Call number: KJE6229 .R43 R474 2005
* Document 1788
Tomova, Sylvia

**Research ethics committees in Bulgaria.**
Call number: KJE6229 .R43 R474 2005

* Document 1789
Lebeer, Guy; De Boeck, Geneviève

**Belgian ethics committees and the protection of personal data.**
Call number: KJE6229 .R43 R474 2005

* Document 1790
Rehak, Peter

**Research ethics committees in Austria.**
Call number: KJE6229 .R43 R474 2005

* Document 1791
Lillehammer, Hallvard

**Benefit, disability and the non-identity problem.**
Call number: R725.5 .P48 2005

* Document 1792
Ludbrook, Philip A.; Clemens, Diane K.; Munson, Ronald; Scannell, Patricia M.

**Responsible conduct of research.**
Call number: R850 .T73 2005

* Document 1793
ter Meulen, Ruud

**Ethical issues of evidence-based medicine**
Call number: BJ1581.2 .E85 2005 v.1

* Document 1794
Lötjönen, Salla

**Research on human subjects**
Anscombe, G.E.M.

Sins of omission? The non-treatment of controls in clinical trials
Call number: BJ1011.A57.2005

Briggle, Adam

Institutional review boards
Call number: Q175.35.E53.2005 v.2

Weijer, Charles

Clinical trials
Call number: Q175.35.E53.2005 v.1

World Health Organization [WHO]. Special Programme for Research and Training in Tropical Disease (TDR)
Operational guidelines for the establishment and functioning of data and safety monitoring boards

http://www.who.int/tdr/publications/publications/pdf/operat_guidelines.pdf (link may be outdated)

Kubiak, Cinead R.

Conflicting interests and conflicting laws: re-aligning the purpose and practice of research ethics committees
Georgetown users check Georgetown Journal Finder for access to full text

Churchill, Larry R.

Towards a more robust autonomy: revisiting the Belmont Report.
Call number: R853.H8.B45.2005
Ranking, balancing, or simultaneity: resolving conflicts among the Belmont principles.
Call number: R853 .H8 B45 2005

Sherwin, Susan
Belmont revisited through a feminist lens.
Call number: R853 .H8 B45 2005

King, Patricia A.
Justice beyond Belmont.
Call number: R853 .H8 B45 2005

Levine, Robert J.
The National Commission's ethical principles with special attention to beneficence.
Call number: R853 .H8 B45 2005

Shapiro, Harold T.; Meslin, Eric M.
Call number: R853 .H8 B45 2005

Capron, Alexander M.
The dog in the night-time: or, the curious relationship of the Belmont Report and the President's Commission.
Call number: R853 .H8 B45 2005

Beauchamp, Tom L.
The origins and evolution of the Belmont Report.
Call number: R853 .H8 B45 2005
* Chapter Document 1808
Jonsen, Albert R.
**On the origins and future of the Belmont Report.**
Call number: R853 .H8 B45 2005

* Chapter Document 1809
Jonsen, Albert R.
**Research with humans: experimentation, autonomy, and benefits to others.**
Call number: R724 .J655 2005

* Article Document 1810
Wilkes, Lesley; Cert, Renal; Beale, Barbara
**Role conflict: appropriateness of a nurse researcher's actions in the clinical field**
Nurse Researcher 2005; 12(4): 57-70
Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Article Document 1811
Daneshgari, Firouz
**IRB approval: needed but insufficient**
Neurology and Urodynamics 2005; 24(2): 151
Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Article Document 1812
Clemens, Felicity; Elbourne, Diana; Darbyshire, Janet; Pocock, Stuart
**Data monitoring in randomized controlled trials: surveys of recent practice and policies**
Clinical Trials 2005; 2(1): 22-33
Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Article Document 1813
Mitchell, Rick; Shah, Maitri; Ahmad, Sushma; Rogers, Audrey Smith; Ellenberg, Jonas H.
**A unified web-based query and notification system (QNS) for subject management, adverse events, regulatory, and IRB components of clinical trials**
Clinical Trials 2005; 2(1): 61-71
Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Article Document 1814
Langston, Anne L.; McCallum, Marilyn; Campbell, Marion K.; Robertson, Clare; Ralston, Stuart H.  
An integrated approach to consumer representation and involvement in a multicentre randomized controlled trial  
Clinical Trials 2005; 2(1): 80-87  
Georgetown users check Georgetown Journal Finder for access to full text

* Article  
Document 1815  
Markman, Maurie  
Reflections on ethical concerns arising from the incorporation of results of randomized trials of antineoplastic therapy into routine clinical practice  
Cancer Investigation 2005; 23(8): 735-740  
Georgetown users check Georgetown Journal Finder for access to full text

* Article  
Document 1816  
Geller, Alisa L.  
Regulations limiting medical research in prisons remains necessary  
Georgetown users check Georgetown Journal Finder for access to full text

* Article  
Document 1817  
Luu, Arlene D.  
The impact of the HIPAA Privacy Rule on research participation  
Georgetown users check Georgetown Journal Finder for access to full text

* Article  
Document 1818  
Keith-Spiegel, Patricia; Koocher, Gerald P.  
The IRB paradox: could the protectors also encourage deceit?  
Abstract: The efforts of some institutional review boards (IRBs) to exercise what is viewed as appropriate oversight may contribute to deceit on the part of investigators who feel unjustly treated. An organizational justice paradigm provides a useful context for exploring why certain IRB behaviors may lead investigators to believe that they have not received fair treatment. These feelings may, in turn, lead to intentional deception by investigators that IRBs will rarely detect. Paradoxically, excessive protective zeal by IRBs may actually encourage misconduct by some investigators. The authors contend that, by fostering a climate in which investigators perceive that they receive fair and unbiased treatment, IRBs optimize the likelihood of collegial compliance with appropriate participant protections.  
Georgetown users check Georgetown Journal Finder for access to full text

* File  
Document 1819  
United Kingdom. Department of Health  
Report of the ad hoc advisory group on the operation of NHS research ethics committees  
Document 1820
Matala, Erik
**Publishing all clinical trial results may become standard policy**

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

Document 1821
Fisher, Celia B.
**Deception research involving children: ethical practices and paradoxes**

Abstract: This commentary draws on the thoughtful contemplation and innovative procedures described in the special section articles as well as current professional codes and federal regulations to highlight ethical practices and paradoxes of deception research involving children. The discussion is organized around 4 key decision points for the conduct of responsible deception research involving children: (a) evaluating the scientific validity and social value of deception research within the context of alternative methodologies, (b) avoiding and minimizing experimental risk, (c) the use of child assent procedures as questionable ethical safeguards, and (d) debriefing as both remedy and risk.

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---

Document 1822
Weijer, Charles
**Meaningful work as due inducement**

Abstract: James A. Anderson and Charles Weijer take the wage payment model proposed by Neil Dickert and Christine Grady and extend the analogy of research participation to unskilled wage labor to include just working conditions. Although noble in its intentions, this moral extension generates unsavory outcomes. Most notably, Anderson and Weijer distinguish between two types of research subjects: occasional and professional. The latter, in this case, receives benefits beyond the moral minima in the form of "the right to meaningful work." The problem is that meaningful work can itself be a form of inducement, and consequently, may in fact increase the incidence of inducement contrary to the intentions of the wage payment model.

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---

Document 1823
McEachern, Terrence P.
**The inducement of meaningful work: a response to Anderson and Weijer**

Abstract: James A. Anderson and Charles Weijer take the wage payment model proposed by Neil Dickert and Christine Grady and extend the analogy of research participation to unskilled wage labor to include just working conditions. Although noble in its intentions, this moral extension generates unsavory outcomes. Most notably, Anderson and Weijer distinguish between two types of research subjects: occasional and professional. The latter, in this case, receives benefits beyond the moral minima in the form of "the right to meaningful work." The problem is that meaningful work can itself be a form of inducement, and consequently, may in fact increase the incidence of inducement contrary to the intentions of the wage payment model.

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---

Document 1824
Canada. Canadian Institutes of Health Research; Natural Sciences and Engineering Research Council of Canada;
Social Sciences and Humanities Research Council of Canada

**Tri-Council policy statement: ethical conduct for research involving humans**


http://www.pre.ethics.gc.ca/policy-politique/tcps-epct/docs/TCPS%2020October%202005_E.pdf (link may be outdated)

---

* Document 1825
Lavery, James V.; McDonald, Michael; Meslin, Eric M.
**Research ethics across the 49th parallel: the potential value of pilot testing "equivalent protections" in Canadian research institutions**

Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Document 1826
Dinsdale, Henry
**Professional responsibility and the protection of human subjects of research in Canada**

Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Document 1827
Pullman, Daryl
**Research governance, bio-politics and political will: recent lessons from Newfoundland and Labrador**

Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Document 1828
Brunger, Fern; Burgess, Michael
**A cultural understanding of research ethics governance**

Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Document 1829
Beagan, Brenda; McDonald, Michael
**Evidence-based practice of research ethics review?**

Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Document 1830
Enzle, Michael E.; Schmaltz, Rodney
*Ethics review of multi-centre clinical trials in Canada*
Georgetown users check [Georgetown Journal Finder](http://www.georgetownjournalfinder.org) for access to full text

Lemmens, Trudo
*Federal regulation of REB review of clinical trials: a modest but easy step towards an accountable REB review structure in Canada*
Georgetown users check [Georgetown Journal Finder](http://www.georgetownjournalfinder.org) for access to full text

Hadskis, Michael; Carver, Peter
*The long arm of administrative law: applying administrative law principles to research ethics boards*
Georgetown users check [Georgetown Journal Finder](http://www.georgetownjournalfinder.org) for access to full text

Zimmerman, Susan V.
*Translating ethics into law: duties of care in health research involving humans*
Georgetown users check [Georgetown Journal Finder](http://www.georgetownjournalfinder.org) for access to full text

Gandhi, Rupali
*Research involving children: regulations, review boards and reform*
Georgetown users check [Georgetown Journal Finder](http://www.georgetownjournalfinder.org) for access to full text

Kirigia, Joses M.; Wambebe, Charles; Baba-Moussa, Amido
*Status of national research bioethics committees in the WHO African region*
Georgetown users check [Georgetown Journal Finder](http://www.georgetownjournalfinder.org) for access to full text

http://www.biomedcentral.com/bmcmedethics/ (link may be outdated)
Decullier, Evelyne; Lheritier, Veronique; Chapuis, Francois
The activity of French Research Ethics Committees and characteristics of biomedical research protocols involving humans: a retrospective cohort study

Bouvier, Paul
Good epidemiological practice: ethical review is essential [opinion]

Shaul, Randi Zlotnik; Birenbaum, Shelley; Evans, Megan
Legal liabilities in research: early lessons from North America

Abstract: The legal risks associated with health research involving human subjects have been highlighted recently by a number of lawsuits launched against those involved in conducting and evaluating the research. Some of these cases have been fully addressed by the legal system, resulting in judgments that provide some guidance. The vast majority of cases have either settled before going to trial, or have not yet been addressed by the courts, leaving us to wonder what might have been and what guidance future cases may bring. What is striking about the lawsuits that have been commenced is the broad range of individuals/institutions that are named as defendants and the broad range of allegations that are made. The research community should take this early experience as a warning and should reflect carefully on practices where research involving human subjects is concerned.

Wieand, Samuel; Murphy, Kate
A commentary on treatment at random: the ultimate science or the betrayal of Hippocrates?
Journal of Clinical Oncology 2004 December 15; 22(24): 5009- 5011

Georgetown users check Georgetown Journal Finder for access to full text
Retsas, Spyros
*Treatment at random: the ultimate science or the betrayal of Hippocrates?
Journal of Clinical Oncology 2004 December 15; 22(24): 5005-5008

Georgetown users check Georgetown Journal Finder for access to full text

Fadel, Hossam E.
The Islamic viewpoint on the international ethical guidelines for biomedical research involving human subjects

http://www.emro.who.int/ahsn/Presentations/Day2/Dr-HossamFadel.pdf (link may be outdated)

Dal-Re, Rafael; Morejon, Elena; Ortega, Rafael
*Nature and extent of changes in the patient's information sheets of international multicentre clinical trials as requested by Spanish Research Ethics Committees
Medicina Clinica 2004 December 4; 123(20): 770-774

Georgetown users check Georgetown Journal Finder for access to full text

Wei, S.J.; Metz, J.M.; Coyle, C.; Hampshire, M.; Jones, H.A.; Markowitz, S.; Rustgi, A.K.
Recruitment of patients into an internet-based clinical trials database: the experience of OncoLink and the National Colorectal Cancer Research Alliance
Journal of Clinical Oncology 2004 December 1; 22(23): 4678-4736

Georgetown users check Georgetown Journal Finder for access to full text

Sansone, Randy A.; McDonald, Stephen
Quality improvement within institutional review boards.

Georgetown users check Georgetown Journal Finder for access to full text

Mielke, J.; Ndebele, P.
Making research ethics review work in Zimbabwe -- the case for investment in local capacity
Central African Journal of Medicine 2004 November-December; 50(11-12): 115-119

Georgetown users check Georgetown Journal Finder for access to full text
Document 1847
Bubien, Rosemary S.
**Practice or research — patient or participant: is there a difference?**
Heart Rhythm 2004 December; 1(6): 757-759

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 1848
Silverman, Henry J.
**The Acute Respiratory Distress Syndrome Network controversy: lessons and legacy**
Current Opinion in Critical Care 2004 December; 10(6): 560-564

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 1849
Lemaire, François
**Patient care versus research: does clinical research provide individual benefit to patients enrolled in trials?**
Current Opinion in Critical Care 2004 December; 10(6): 565-569

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 1850
Dreyfuss, Didier
**Beyond randomized, controlled trials**
Current Opinion in Critical Care 2004 December; 10(6): 574-578

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 1851
Barie, Philip S.
**Oh Lord! I've got those clinical research blues**
Surgical Infections 2004 Winter; 5(4): 327-342

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 1852
Kopelman, Loretta M.
**What conditions justify risky nontherapeutic or “no benefit” pediatric studies: a sliding scale analysis**

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 1853
Document 1860
Dyer, Sarah
Rationalising public participation in the health service: the case of research ethics committees
Health and Place 2004 December; 10(4): 339-348
Georgetown users check Georgetown Journal Finder for access to full text

Document 1861
Wood, Anne; Grady, Christine; Emanuel, Ezekiel J.
Regional ethics organizations for protection of human research participants [opinion]
Nature Medicine 2004 December; 10(12): 1283-1288
Georgetown users check Georgetown Journal Finder for access to full text

Document 1862
Kimmelman, Jonathan
Valuing risk: the ethical review of clinical trial safety
Kennedy Institute of Ethics Journal 2004 December; 14(4): 369-393
Georgetown users check Georgetown Journal Finder for access to full text

Document 1863
Maloney, Dennis M.
Angry father accuses researcher of violating his family's privacy
Human Research Report 2004 December; 19(12): 6-7
Georgetown users check Georgetown Journal Finder for access to full text

Document 1864
Maloney, Dennis M.
IRBs, radioactive drugs, and vulnerable research subjects
Georgetown users check Georgetown Journal Finder for access to full text

Document 1865
Bernard, Jeffrey
When is research really research? Academic physicians push to keep oversight of most quality-improvement projects away from institutional review boards
Chronicle of Higher Education 2004 November 26; LI(14): 21
Georgetown users check Georgetown Journal Finder for access to full text

http://chronicle.com (link may be outdated)
Document 1866
From the ministerial summit on health research: Mexico City, November 16-20, 2004
The Mexico statement on health research: knowledge for better health: strengthening health systems.
From the ministerial summit on health research 2004: 4p. [Online]. Accessed:

Georgetown users check Georgetown Journal Finder for access to full text

http://www.who.int/rpc/summit/agenda/en/mexico_statement_on_health_research.pdf (link may be outdated)

Document 1867
Ioannidis, John P.A.; Evans, Stephen J.W.; Gotzsche, Peter C.; O'Neill, Robert T.; Altman, Douglas G.; Schulz, Kenneth; Moher, David
Better reporting of harms in randomized trials: an extension of the CONSORT statement
Annals of Internal Medicine 2004 November 16; 141(10): 781-788

Georgetown users check Georgetown Journal Finder for access to full text

http://www.annals.org (link may be outdated)

Document 1868
Petereit, Daniel G.; Rogers, Deborah; Govern, Frank; Coleman, Norman; Osburn, Christen H.; Howard, Steve P.; Kaur, Judith; Burhansstipanov, Linda; Fowler, Jack F.; Chappell, Richard; Mehta, Minesh P.
Increasing access to clinical cancer trials and emerging technologies for minority populations: the Native American Project
Journal of Clinical Oncology 2004 November 15; 22(22): 4452- 4455

Georgetown users check Georgetown Journal Finder for access to full text

Document 1869
Saver, Richard S.
Medical research oversight from the corporate governance perspective: comparing institutional review boards and corporate boards
William and Mary Law Review 2004 November; 46(2): 619-730

Georgetown users check Georgetown Journal Finder for access to full text

* Document 1870
Gilles, Kathy
Uncovering the relationship between IRBs and the HIPAA privacy rule
Journal of AHIMA 2004 November-December; 75(10): 48-49, 52, 55-56

Georgetown users check Georgetown Journal Finder for access to full text

Document 1871
Pirotta, Marie; Chondros, Patty
Data monitoring (and safety) committees -- what are they and why do we need them?

Australian Family Physician 2004 November; 33(11): 950-952

Document 1872

Callery, Peter

Running the ethics race [opinion]

Paediatric Nursing 2004 November; 16(9): 13

Document 1873

Artinian, Nancy T.; Froelicher, Erika Sivarajan; Vander Wal, Jillon S.

Data and safety monitoring during randomized controlled trials of nursing interventions

Nursing Research 2004 November-December; 53(6): 414-418

Document 1874

Sarson-Lawrence, M.; Alt, C.; Mok, M.T.; Dodds, M.; Rosenthal, M.A.

Trust and confidence: towards mutual acceptance of ethics committee approval of multicentre studies

Internal Medicine Journal 2004 November; 34(11): 598-603

Document 1875

Tamakoshi, Akiko

Informed consent in epidemiologic research before the implementation of ethical guidelines

Journal of Epidemiology 2004 November; 14(6): 177-181

Document 1876

Doyal, Len

The ethical governance and regulation of student projects: a draft proposal

Bulletin of Medical Ethics 2004 November; (203): 8-11

Document 1877

Tinker, Anthea; Coomber, V.

University research ethics committees: their role, remit and conduct

http://www.bullmedeth.info/ (link may be outdated)
Lockwood, Alan H.

**Human testing pesticides: ethical and scientific considerations**

**Abstract:** I reviewed ethical and scientific aspects of 6 human pesticide-dosing studies submitted to the Environmental Protection Agency (EPA) for consideration during the pesticide reregistration process. All had serious ethical or scientific deficiencies—or both—including unacceptable informed consent procedures, unmanaged financial conflicts of interest, inadequate statistical power, inappropriate test methods and endpoints, and distorted results. Given today's knowledge of the effects of pesticides, there is no assurance that any such study can be completely free of short-term risks, long-term risks, or both. Therefore, there is no basis for allowing pesticide studies to continue or for using them during the pesticide reregistration process. An EPA committee that is free from political and financial conflicts of interest should review this practice.

Maloney, Dennis M.

**Institution tells researcher that he must follow special procedures for the future**

Maloney, Dennis M.

**IRBs and radioactive drugs for certain research uses**

Maloney, Dennis M.

**Subscriber spotlight: you too can make a difference**
Human Research Report 2004 November; 19(11): 4

Maloney, Dennis M.

**Institutional review boards and clinical trials registry**
*  Document 1883
Clayton, Ellen Wright
**So what are we going to do about research using clinical information and samples?**

*  Document 1884
Ilits, Ana S.
**Costs to subjects for research participation and the informed consent process: regulatory and ethical considerations**

*  Document 1885
Morreim, E. Haavi
**By any other name: the many iterations of "patient advocate" in clinical research**

*  Document 1886
Alpert, Joseph S.; Shine, Kenneth I.; Adams, Robert J.; Antman, Elliott M.; Kavey, Rae Ellen W.; Friedman, Lawrence; Frye, Robert L.; Harrington, Robert A.; Kom, David; Merz, Jon F.; Ofili, Elizabeth
**Task force 1: the ACCF and AHA codes of conduct in human subjects research**
Journal of the American College of Cardiology 2004 October 19; 44(8): 1724-1728

*  Document 1887
Califf, Robert M.; Nissen, Steven E.; DeMaria, Anthony N.; Ohman, Erik Magnus; Pitt, Bertram; Willerson, James T.; Bilheimer, David W.; Cohn, Jay N.; Feigal, David W., Jr.; Hampson, Lindsay; Lorell, Beverly H.; Pepine, Carl J.; Popp, Richard L.
**Task force 2: investigator participation in clinical research**
Journal of the American College of Cardiology 2004 October 19; 44(8): 1729-1736

*  Document 1888
Popp, Richard J.; Smith, Sidney C., Jr.; Adams, Robert J.; Antman, Elliott M.; Kavey, Rae Ellen W.; DeMaria, Anthony N.; Ohman, Erik Magnus; Pitt, Bertram; Willerson, James T.; Bellande, Bruce J.; Fonarow, Gregg C.; Nishimura, Rick A.; Shah, Pravin M.; Hirshfeld, John W., Jr.; Messer, Joseph V.; Peterson, Eric D.; Prystowsky,
Eric N.; Anderson, Jeffrey L.; Cheitlin, Melvin D.; Goldstein, Larry B.; Grant, Augustus O.; Beller, George A.; Hines, Edward F., Jr.; Livingston, David W.; McEntee, Christine W.
American College of Cardiology Foundation; American Heart Association
**ACCF/AHA consensus conference report on professionalism and ethics**
Circulation 2004 October 19; 110(16): 2506-2549

Georgetown users check [Georgetown Journal Finder](http://findinlibrary.georgetown.edu) for access to full text

---

**Document 1889**
Loff, Bebe; Black, Jim

**Research ethics committees: what is their contribution? [opinion]**
Medical Journal of Australia 2004 October 18; 181(8): 440-441

Georgetown users check [Georgetown Journal Finder](http://findinlibrary.georgetown.edu) for access to full text

---

**Document 1890**
Tan, Siao Pei

**My disappointment with an ethics committee [opinion]**
BMJ: British Medical Journal 2004 October 2; 329(7469): 807

Georgetown users check [Georgetown Journal Finder](http://findinlibrary.georgetown.edu) for access to full text

[http://www.bmj.com](http://www.bmj.com) (link may be outdated)

---

**Document 1891**
Alcolado, John C.

**Commentary: funding will make you free**
BMJ: British Medical Journal 2004 October 2; 329(7469): 797

Georgetown users check [Georgetown Journal Finder](http://findinlibrary.georgetown.edu) for access to full text

[http://www.bmj.com](http://www.bmj.com) (link may be outdated)

---

**Document 1892**
Levenson, Deborah

**Major medical journals will require registration of clinical trials for publication**

Georgetown users check [Georgetown Journal Finder](http://findinlibrary.georgetown.edu) for access to full text

---

**Document 1893**
Tumber, M.B.; Dickersin, K.

**Publication of clinical trials: accountability and accessibility**
Journal of Internal Medicine 2004 October; 256(4): 271-283

Georgetown users check [Georgetown Journal Finder](http://findinlibrary.georgetown.edu) for access to full text
Role des groupes cooperateurs dans la qualite ethique et methodologique des essais de phase III en cancerologie / Methodological and ethical quality in phase III cancer trials: role of the cooperative group

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---

International co­ordination of clinical research

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---

Role of ethics committees in medical research

[http://www.issuesinmedicalethics.org](http://www.issuesinmedicalethics.org) (link may be outdated)

---

Concerns about ethical review of health research in India

[http://www.issuesinmedicalethics.org](http://www.issuesinmedicalethics.org) (link may be outdated)

---

Clinical research 2: legal and ethical issues in research

Georgetown users check [Georgetown Journal Finder](#) for access to full text.

---

The interface between the practice of medical genetics and human genetic research: what every genetic counselor needs to know

Georgetown users check [Georgetown Journal Finder](#) for access to full text.
Document 1900
Maloney, Dennis M.
Releasing even negative results of drug experiments

Document 1901
Maloney, Dennis M.
Court agrees with arguments on behalf of Institutional Review Board (IRB)
Human Research Report 2004 October; 19(10): 8

Document 1902
Maloney, Dennis M.
Institutional Review Board (IRB) did not have enough information to approve protocol

Document 1903
United States. Department of Health and Human Services [DHHS]. Office for Human Subjects Protections [OHRP]
Human Subject Regulations Decision Charts

Document 1904
Singh, Jerome A.
Standards of care in the antiretroviral rollout world
Lancet 2004 September 11-17; 364(9438): 920-922

Document 1905
Vedantam, Shankar
Journals insist drug manufacturers register all trials: editors say that, otherwise, studies will not be published; goal is to ferret out suppressed data
Washington Post 2004 September 9; p. A2
Document 1906
Council of Europe
Additional protocol to the convention on human rights and biomedicine concerning biomedical research, Council of Europe, 2004.
European Journal of Health Law 2004 September; 11(3): 293-307
Georgetown users check Georgetown Journal Finder for access to full text

Document 1907
DeMarco, Joseph P.; Markman, Maurie
The research misconception
Georgetown users check Georgetown Journal Finder for access to full text

Document 1908
Bryan, Wilson W.
Regulatory issues in ALS clinical trials
Amyotrophic Lateral Sclerosis and Other Motor Neuron Disorders 2004 September; 5(Supplement 1): 36-41
Georgetown users check Georgetown Journal Finder for access to full text

Document 1909
Im, Eun-Ok; Chee, Wonshik
Recruitment of research participants through the Internet
CIN: Computers, Informatics, Nursing 2004 September-October; 22(5): 289-297
Georgetown users check Georgetown Journal Finder for access to full text

Document 1910
Moler, Frank W.
Resuscitation research and the final rule: is there an impasse? [opinion]
Pediatrics 2004 September; 114(3): 859-861
Georgetown users check Georgetown Journal Finder for access to full text

Document 1911
International Committee of Medical Journal Editors
Clinical trial registration
Medical Ethics and Bioethics / Medicinska Etika & Bioetika 2004 Autumn-Winter; 11(3-4): 10-11
Georgetown users check Georgetown Journal Finder for access to full text
Document 1912
Mazumdar, Madhu

Group sequential design for comparative diagnostic accuracy studies: implications and guidelines for practitioners
Medical Decision Making 2004 September-October; 24(5): 525-533

Georgetown users check Georgetown Journal Finder for access to full text

Document 1913
Sorenson, J.R.; Lakon, C.; Spinney, T.; Jennings-Grant, T.

Assessment of a decision aid to assist genetic testing research participants in the informed consent process
Genetic Testing 2004 Fall; 8(3): 336-346

Georgetown users check Georgetown Journal Finder for access to full text

Document 1914
Coleman, Carl H.

Why have IRBs at all? A reply to Noah
Journal of Legal Medicine 2004 September; 25(3): 295-301

Georgetown users check Georgetown Journal Finder for access to full text

Document 1915
Noah, Lars

Deputizing institutional review boards to police (audit?) biomedical research

Georgetown users check Georgetown Journal Finder for access to full text

Document 1916

Research ethics committees
Bulletin of Medical Ethics 2004 September; (201): 2

Georgetown users check Georgetown Journal Finder for access to full text

http://www.bullmedeth.info/ (link may be outdated)

Document 1917
Maloney, Dennis M.

Immunity of researchers from liability due to their status as state employees
Human Research Report 2004 September; 19(9): 8

Georgetown users check Georgetown Journal Finder for access to full text
Maloney, Dennis M.

**More failures of Institutional Review Boards (IRBs) cited by federal office**

Human Research Report 2004 September; 19(9): 6-7

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

Maloney, Dennis M.

**Enforcement of HIPAA privacy rule provisions**

Human Research Report 2004 September; 19(9): 5

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

Maloney, Dennis M.

**Radioactive drugs and human subjects' safety**

Human Research Report 2004 September; 19(9): 5

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

Maloney, Dennis M.

**IRBs and the time needed for their record keeping**

Human Research Report 2004 September; 19(9): 4

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

Maloney, Dennis M.

**Institutional Review Boards (IRBs) and risk considerations for children**


Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

Hamilton, Michael

**Some precision would be helpful**

IRB: Ethics and Human Research 2004 September-October; 26(5): 19

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

Appelbaum, Paul S.; Lidz, Charles W.; Grisso, Thomas
Correction and clarification
IRB: Ethics and Human Research 2004 September-October; 26(5): 18

Georgetown users check Georgetown Journal Finder for access to full text

*  Article  Document 1925
Pentz, Rebecca D.; Khayat, Anita F.
The poster child for the need for central review of research protocols: the Children's Oncology Group

Georgetown users check Georgetown Journal Finder for access to full text

*  Article  Document 1926
Edwards, Sarah J.L.; Ashcroft, Richard; Kirchin, Simon
Research ethics committees: differences and moral judgement
Bioethics 2004 September; 18(5): 408-427
Abstract: Many people argue that disagreements and inconsistencies between Research Ethics Committees are morally problematic and there has been much effort to 'harmonise' their judgements. Some inconsistencies are bad because they are due to irrationality, or carelessness, or the operation of conflicting interests, and so should be reduced or removed. Other inconsistencies, we argue, are not bad and should be left or even encouraged. In this paper we examine three arguments to reject the view that we should strive for complete consistency between committees. The first argument is that differences in judgement are not necessarily incompatible with ideas of justice for patients who are potential participants of research reviewed by different committees. We call this 'the justice argument.' The second argument is that such committees do not have access to a single moral truth, to which their judgement is supposed to correspond. We call this the 'moral pluralism argument.' The third argument is that the process of ethics committee review is also morally relevant and not solely the outcome. We call this the 'due process argument.' While we fall short of establishing exactly how much variation and on what substantive issues would ethical permissible, we show that it is largely inevitable and that a certain amount of variation could be seen as a desirable part of the institution of medical research.

Georgetown users check Georgetown Journal Finder for access to full text

Document 1927
Rees, Jonathan
The fundamentals of clinical discovery
Perspectives in Biology and Medicine 2004 Autumn; 47(4): 597- 607

Georgetown users check Georgetown Journal Finder for access to full text

Document 1928
Swazey, Judith P.; Fox, Renee C.
Remembering the "golden years" of patient-oriented clinical research: a collective conversation
Perspectives in Biology and Medicine 2004 Autumn; 47(4): 487- 504

Georgetown users check Georgetown Journal Finder for access to full text

Document 1929
Schechter, Alan N.; Perlman, Robert L.; Rettig, Richard A.
Editors' introduction: why is revitalizing clinical research [sic; research] so important, yet so difficult?
Perspectives in Biology and Medicine 2004 Autumn; 47(4): 476-486

Georgetown users check Georgetown Journal Finder for access to full text

---

* Document 1930
Yasko, Laurel L.; Wicclair, Mark; DeVita, Michael A.
Committee for Oversight of Research Involving the Dead (CORID): insights from the first year
CQ: Cambridge Quarterly of Healthcare Ethics 2004 Fall; 13(4): 327-337

Georgetown users check Georgetown Journal Finder for access to full text

---

Document 1931
Moher, David; Altman, Douglas G.; Schulz, Kenneth F.; Elbourne, Diana R.
Opportunities and challenges for improving the quality of reporting clinical research: CONSORT and beyond

Georgetown users check Georgetown Journal Finder for access to full text

http://www.cmaj.ca (link may be outdated)

---

Document 1932
United States. Department of Health and Human Services [DHHS]. Office for Human Research Protections [OHRP]
Guidance on Research Involving Coded Private Information or Biological Specimens
Rockville, MD: Office for Human Research Protections [OHRP], 2004 August 10; 7 p. [Online]. Available:
http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf [2004 August 23]

http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf (link may be outdated)

---

Document 1933
Epstein, Andrew E.
Jumping in before the water is hot: the need to support randomized controlled clinical trials
Journal of Cardiovascular Electrophysiology 2004 August; 15(8): 867-869

Georgetown users check Georgetown Journal Finder for access to full text

---

* Document 1934
Malfroy, Moira; Llewelyn, C.A.; Johnson, T.; Williamson, L.M.
Using patient-identifiable data for epidemiological research
Transfusion Medicine 2004 August; 14(4): 275-279

Georgetown users check Georgetown Journal Finder for access to full text

---

* Document 1935
Wagner, Todd H.; Cruz, Anne Marie; Chadwick, Gary L.
Economies of scale in institutional review boards
Medical Care 2004 August; 42(8): 817-823
Georgetown users check Georgetown Journal Finder for access to full text

Document 1936
Maloney, Dennis M.
**Funding for Institutional Review Boards (IRBs)**
Georgetown users check Georgetown Journal Finder for access to full text

Document 1937
Maloney, Dennis M.
**Defense says researchers cannot be blamed for defective product**
Human Research Report 2004 August; 19(8): 8
Georgetown users check Georgetown Journal Finder for access to full text

Document 1938
Maloney, Dennis M.
**Federal agency places numerous restrictions on research institutions [case study]**
Human Research Report 2004 August; 19(8): 6-7
Georgetown users check Georgetown Journal Finder for access to full text

Document 1939
Maloney, Dennis M.
**Future training requirements for IRB members and IRB staff**
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1940
Parker, M.; Ashcroft, R.; Wilkie, A.O.M.; Kent, A.
**Ethical review of research into rare genetic disorders**
BMJ: British Medical Journal 2004 July 31; 329(7460): 288-289
Georgetown users check Georgetown Journal Finder for access to full text

[http://www.bmj.com](http://www.bmj.com) (link may be outdated)

* Document 1941
Jamrozik, Konrad
**Research ethics paperwork: what is the plot we seem to have lost?**
BMJ: British Medical Journal 2004 July 31; 329(7460): 286-287
* Document 1942
Wald, David S.

Bureaucracy of ethics applications
BMJ: British Medical Journal 2004 July 31; 329(7460): 282-284

Georgetown users check Georgetown Journal Finder for access to full text

http://www.bmj.com (link may be outdated)

* Document 1943
Ward, Hester J.T.; Cousens, Simon N.; Smith-Bathgate, Blaire; Leitch, Margaret; Everington, Dawn

Obstacles to conducting epidemiological research in the UK general population

Georgetown users check Georgetown Journal Finder for access to full text

http://www.bmj.com (link may be outdated)

* Document 1944
United States. Food and Drug Administration [FDA]

Institutional Review Boards; Registration Requirements [proposed rule]
Federal Register 2004 July 6; 69(128): 40555-40562

http://www.gpoaccess.gov/fr (link may be outdated)

* Document 1945
Ananworanich, Jintanat; Cheunyam, Theshinee; Teeratakulpisam, Somsong; Boyd, Mark A.; Ruxrungthan, Kiat; Lange, Joe; Cooper, David; Phanuphak, Praphan

Creation of a drug fund for post-clinical trial access to antiretrovirals
Lancet 2004 July 3-9; 364(9428): 101-102

Georgetown users check Georgetown Journal Finder for access to full text

http://www.thelancet.com/journal (link may be outdated)

* Document 1946
Pahl, Jan

Ethics Review of Social Care Research: Options Appraisal and Guidelines.
Document 1947
Holkup, Patricia A.; Tripp-Reiner, Toni; Salois, Emily Matt; Weinert, Clarann
**Community-based participatory research: an approach to intervention research with a Native American community**
Advances in Nursing Science 2004 July-September; 27(3): 162-175
Georgetown users check [Georgetown Journal Finder](http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_4100253) for access to full text

Document 1948
Kim, Scott Y.H.
**Evidence-based ethics for neurology and psychiatry research**
NeuroRx 2004 July; 1(3): 372-377
Georgetown users check [Georgetown Journal Finder](http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_4100253) for access to full text

Document 1949
Tolmie, Elizabeth P.; Mungall, Moira M.B.; Louden, Greig; Lindsay, Grace M.; Gaw, Allan
**Understanding why older people participate in clinical trials: the experience of the Scottish PROSPER participants**
Age and Ageing 2004 July; 33(4): 374-378
Georgetown users check [Georgetown Journal Finder](http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_4100253) for access to full text

Document 1950
**Additional protocol to the convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine, on biomedical research**
Revista de Derecho y Genoma-Humano / Law and the Human Genome Review 2004 July-December; (21): 201-214
Georgetown users check [Georgetown Journal Finder](http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_4100253) for access to full text

EthxWeb Search Results

Search Detail:
Result=(("18.2".PC.) AND (@YD >= "20040000")) NOT (EDITORIAL OR LETTER OR NEWS)
2=1 : "
Documents: 1951 - 2150 of 2150

* Document 1951
Glanville, Julie
Ethics of health care and research
Journal of Health Services Research and Policy 2004 July; 9(3): 189-190
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1952
Itani, Kamal M.F.; McCullough, Laurence B.
Randomized clinical surgical trials: are they really necessary?
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1953
Mamdani, Bashir
The Helsinki Declaration, 2000, and ethics of human research in developing countries
Indian Journal of Medical Ethics 2004 July-September; 1(3): 94-95
Georgetown users check Georgetown Journal Finder for access to full text
http://www/issuesinmedicalethics.org (link may be outdated)

* Document 1954
Sharp, S. Michael; Pentz, Rebecca D.
Issues, both ethical and practical, in the development and conduct of chemoprevention trials
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1955
Valdez-Martinez, E.; Garduno-Espinosa, J.; Martinez-Salgado, H.; Porter, J.D.H.
Local research ethics committees of the Mexican Institute of Social Security: results of a national survey
Public Health 2004 July; 118(5): 329-336
Georgetown users check Georgetown Journal Finder for access to full text
Document 1956
Gillam, Lynn
Expertise in research ethics: is there any such thing?
Monash Bioethics Review 2004 July; 23(3): 58-64
Georgetown users check Georgetown Journal Finder for access to full text

Document 1957
Cribb, Robert
Ethical regulation and humanities research in Australia: problems and consequences
Georgetown users check Georgetown Journal Finder for access to full text

Document 1958
Hull, Sara Chandros; Glanz, Karen; Steffen, Alana; Wilfond, Benjamin S.
Recruitment approaches for family studies: attitudes of index patients and their relatives
Georgetown users check Georgetown Journal Finder for access to full text

Document 1959
Maloney, Dennis M.
Institution says it does not have to present protocol reviews individually at IRB meetings [case study]
Human Research Report 2004 July; 19(7): 6-7
Georgetown users check Georgetown Journal Finder for access to full text

Document 1960
Maloney, Dennis M.
Enhanced protections for human research subjects
Georgetown users check Georgetown Journal Finder for access to full text

Document 1961
Maloney, Dennis M.
Safety of human subjects and easier medical research
Human Research Report 2004 July; 19(7): 4
Georgetown users check Georgetown Journal Finder for access to full text
IRBs and financial conflict of interest

Maloney, Dennis M.

Human Research Report 2004 July; 19(7): 4

Georgetown users check Georgetown Journal Finder for access to full text

Untapped potential: IRB guidance for the ethical research use of stored biological materials

Wolf, Leslie E.; Lo, Bernard


Georgetown users check Georgetown Journal Finder for access to full text

Medical researchers' ancillary clinical care responsibilities

Belsky, Leah; Richardson, Henry S.

BMJ: British Medical Journal 2004 June 19; 328(7454): 1494-1496

Georgetown users check Georgetown Journal Finder for access to full text

http://www.bmj.com (link may be outdated)

Satisfaction of the uncertainty principle in cancer clinical trials: retrospective cohort analysis

Joffe, Steven; Harrington, David P.; George, Stephen L.; Emanuel, Ezekiel J.; Budzinski, Lindsay A.; Weeks, Jane C.

BMJ: British Medical Journal 2004 June 19; 328(7454): 1463-1466

Abstract: OBJECTIVE: To assess whether publicly funded adult cancer trials satisfy the uncertainty principle, which states that physicians should enroll a patient in a trial only if they are substantially uncertain which of the treatments in the trial is most appropriate for the patient. This principle is violated if trials systematically favour either the experimental or the standard treatment. DESIGN: Retrospective cohort study of completed cancer trials, with randomisation as the unit of analysis. SETTING: Two cooperative research groups in the United States. STUDIES INCLUDED: 93 phase III randomised trials (103 randomisations) that completed recruitment of patients between 1981 and 1995. MAIN OUTCOME MEASURES: Whether the randomisation favoured the experimental treatment, the standard treatment, or neither treatment; effect size (outcome of the experimental treatment compared with outcome of the standard treatment) for each randomisation. RESULTS: Three randomisations (3%) favoured the standard treatment, 70 (68%) found no significant difference between treatments, and 30 (29%) favoured the experimental treatment. The average effect size was 1.20 (95% confidence interval 1.13 to 1.28), reflecting a slight advantage for the experimental treatment. CONCLUSIONS: In cooperative group trials in adults with cancer, there is a measurable average improvement in disease control associated with assignment to the experimental rather than the standard arm. However, the heterogeneity of outcomes and the small magnitude of the advantage suggest that, as a group, these trials satisfy the uncertainty principle.

Georgetown users check Georgetown Journal Finder for access to full text

http://www.bmj.com (link may be outdated)

Reaching beyond the white middle classes

Boynton, Petra M.; Wood, Gary W.; Greenhalgh, Trisha

BMJ: British Medical Journal 2004 June 12; 328(7453): 1433-1436
**Document 1967**

Daugherty, Christopher K.

**Ethical issues in phase I clinical trials**
Clinical Advances in Hematology and Oncology 2004 June; 2(6): 358-360

Georgetown users check [Georgetown Journal Finder](http://www.bmj.com) for access to full text

**Document 1968**

Lavery, James

**The challenge of regulating international research with human subjects**

**Document 1969**

Eckstein, Sue

**Efforts to build capacity in research ethics: an overview**

**Document 1970**

Bhutta, Zulfiqar A.

**Building capacity for ethical review in developing countries**

**Document 1971**

Laupland, Kevin B.; Boucher, Paul; Rotstein, Coleman; Cook, Deborah J.; Doig, Christopher J.

**Intravenous immunoglobulin for severe infections: a survey of Canadian specialists**
Journal of Critical Care 2004 June; 19(2): 75-81

Georgetown users check [Georgetown Journal Finder](http://www.bmj.com) for access to full text

**Document 1972**

Davis, Wendy N.

**When clinical trials fail**
ABA Journal 2004 June; 90: 20

Georgetown users check [Georgetown Journal Finder](http://www.bmj.com) for access to full text
* Article  Document 1973
Lavery, James V.
**Putting international research ethics guidelines to work for the benefit of developing countries**
Yale Journal of Health Policy, Law, and Ethics 2004 Summer; 4(2): 319-336
Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Article  Document 1974
EU clinical trials directive: 0% inspiration, 100% perspiration?
Lancet Neurology 2004 June; 3(6): 321
Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Article  Document 1975
Rahman, Mahbubur; Morita, Satoshi; Fukui, Tsuguya; Sakamoto, Junichi
**Physicians' reasons for not entering their patients in a randomized controlled trial in Japan**
Tohoku Journal of Experimental Medicine 2004 June; 203(2): 105-109
Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Article  Document 1976
Clark, Chalmers C.
**Design and direction in research ethics: a question of direction**
American Journal of Bioethics 2004 Summer; 4(3): 78-80
Georgetown users check [Georgetown Journal Finder](#) for access to full text

**http://bioethics.net** (link may be outdated)

* Article  Document 1977
Vawter, Dorothy E.; Gervais, Karen G.; Freeman, Thomas B.
**Strategies for achieving high-quality IRB review**
American Journal of Bioethics 2004 Summer; 4(3): 74-76
Georgetown users check [Georgetown Journal Finder](#) for access to full text

**http://bioethics.net** (link may be outdated)

* Article  Document 1978
Grinnell, Frederick
**Subject vulnerability: the precautionary principle of human research**
American Journal of Bioethics 2004 Summer; 4(3): 72-74
Georgetown users check [Georgetown Journal Finder](#) for access to full text
Document 1979
Silvers, Anita
**Historical vulnerability and special scrutiny: precautions against discrimination in medical research**
American Journal of Bioethics 2004 Summer; 4(3): 56-57
Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text

Document 1980
Marshall, Mary Faith
**Vulnerable subjects and civic professionalism: would six-sigma research and research ethics consultation solve the vulnerability problem?**
American Journal of Bioethics 2004 Summer; 4(3): 54-55
Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text

Document 1981
Maschke, Karen J.; Trump, Eric
**Facial transplantation research: a need for additional deliberation**
Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text

**Document 1982**
Kopelman, Loretta M.
**Minimal risk as an international ethical standard in research**
Journal of Medicine and Philosophy 2004 June; 29(3): 351-378
*Abstract:* Classifying research proposals by risk of harm is fundamental to the approval process and the most pivotal risk category in most regulations is that of "minimal risk." If studies have no more than a minimal risk, for example, a nearly worldwide consensus exists that review boards may sometimes: (1) expedite review, (2) waive or modify some or all elements of informed consent, or (3) enroll vulnerable subjects including healthy children, incapacitated persons and prisoners even if studies do not hold out direct benefits to them. The moral and social purposes behind this threshold are discussed along with relevant views from the National Commission, NBAC, NHRPAC, Grimes v. Kennedy Krieger Institute, The Nuremberg Code, and The WMA's Declaration of Helsinki. Representative policies from Australia, Canada, South Africa, the U.S., and CIOMS are reviewed revealing different understandings of this sorting threshold. Six of nine frequently cited interpretations of "minimal risk" are untenable. The "absolute" interpretation of the "routine examination" standard is defended as best.
Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text

Document 1983
**Community members: "more training"**
Protecting Human Subjects 2004 Summer; (10): 15

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

Document 1984
Gunsalus, C. Kristina
*Who are we protecting, and why?*
Protecting Human Subjects 2004 Summer; (10): 14

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

Document 1985
Schwetz, Bernard
*Focus on public trust*
Protecting Human Subjects 2004 Summer; (10): 10-11

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

Document 1986
Childress, James; Sugarman, Jeremy; Joffe, Steven
*Belmont and respect for persons: panelists discuss informed consent, dignity, and respect*
Protecting Human Subjects 2004 Summer; (10): 9, 16

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

Document 1987
Capron, Alexander Morgan
*More issues than ever*
Protecting Human Subjects 2004 Summer; (10): 6-8

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

* Document 1988
Beauchamp, Tom L.
*The legacy and the future: 30 years after the Belmont Report, Beauchamp sets the record straight*
Protecting Human Subjects 2004 Summer; (10): 1-3

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

* Document 1989
Carlson, Robert V.; Boyd, Kenneth M.; Webb, David J.
*The revision of the Declaration of Helsinki: past, present and future*
British Journal of Clinical Pharmacology 2004 June; 57(6): 695-713

Georgetown users check [Georgetown Journal Finder](#) for access to full text
* Document 1990
Coffey, M. Justin; Ross, Lainie Friedman
Human subject protections in genetic research
Genetic Testing 2004 Summer; 8(2): 209-213
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1991
Resnik, David B.
Liability for institutional review boards; from regulation to litigation
Journal of Legal Medicine 2004 June; 25(2): 131-184
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1992
Maloney, Dennis M.
Institution announces that only one healthy human subject died in research [case study]
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1993
Weijer, Charles
The quest for legitimacy: comment on Cox Macpherson's `to strengthen consensus, consult the stakeholders'
Bioethics 2004 June; 18(3): 293-300
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1994
Cooper, Zachary N.; Nelson, Robert M.; Ross, Lainie Friedman
Certificates of confidentiality in research: rationale and usage
Genetic Testing 2004 Summer; 8(2): 214-220
Georgetown users check Georgetown Journal Finder for access to full text

* Document 1995
Slingsby, Brian T.; Nagao, Noriko; Akabayashi, Akira
Administrative legislation in Japan: guidelines on scientific and ethical standards
CQ: Cambridge Quarterly of Healthcare Ethics 2004 Summer; 13(3): 245-253
Georgetown users check Georgetown Journal Finder for access to full text
Document 1996

Caulfield, Timothy; Lemmens, Trudo; Kinsella, Douglas; McDonald, Michael

Research ethics and the role of the professional bodies: a view from Canada

Georgetown users check Georgetown Journal Finder for access to full text

Document 1997

Rajczi, Alex

Making risk-benefit assessments of medical research protocols

Georgetown users check Georgetown Journal Finder for access to full text

Document 1998

Wainwright, P.; Saunders, J.

What are local issues? The problem of the local review of research
Journal of Medical Ethics 2004 June; 30(3): 313-317

Abstract: Local review of research by ethics committees in the UK has long been held to be an important right of the local research ethics committee and, even with the introduction of the European Clinical Trials Directive, the governance arrangements for research ethics committees continue to allow for local review of multicentre studies. There is no requirement for local review in either the European Union directive or in the guidelines on good clinical practice, and there is little evidence of it anywhere else in Europe. The idea that there can be "local", as opposed to "central" ethical issues in research is an interesting one, which raises important issues about the nature of research ethics and ethical review. The aim of this paper is to argue that there are no such things as local issues in research ethics, and suggest that those questions currently addressed as local issues properly belong within the research governance framework.

Georgetown users check Georgetown Journal Finder for access to full text

http://www.jmedethics.com (link may be outdated)

Document 1999

Sansone, R.A.; McDonald, S.; Hanley, P.; Sellbom, M.; Gaither, G.A.

The stipulations of one institutional review board: a five year review
Journal of Medical Ethics 2004 June; 30(3): 308-310

Abstract: OBJECTIVES: This study was designed to explore the prevalence and types of stipulations (such as clarifications or changes) required of investigators by the institutional review board (IRB) of one institution over a five year period. DESIGN: Stipulations to research proposals (n = 124) were documented from the minutes of the IRB meetings. SETTING: Community hospital. PARTICIPANTS: IRB submissions. Main measurements: Number and type of IRB stipulations. RESULTS: Nineteen research submissions (15.3%) were approved without any stipulations. For the remainder, the majority of stipulations related to consent forms (74.2%). CONCLUSIONS: Consent forms appear to be at highest risk for IRB stipulations. Being aware of high risk areas before submission of research proposals may reduce the frequency of stipulations required of investigators.

Georgetown users check Georgetown Journal Finder for access to full text

http://www.jmedethics.com (link may be outdated)
Defendant says violating regulations is not a legal basis for a lawsuit [Robertson et al. v. McGee et al. (Part VII)]

Minimizing the risks for research subjects

Easier global monitoring of randomized clinical trials


A major trial needs three statisticians: why, how and who?

The role of the unblinded sponsor statistician
Document 2006
Siegel, Jay P.; O'Neill, Robert; Temple, Robert; Campbell, Gregory; Foulkes, Mary A.
Independence of the statistician who analyses unblinded data
Statistics in Medicine 2004 May 30; 23(10): 1527-1529
Georgetown users check Georgetown Journal Finder for access to full text

Document 2007
Wittes, Janet
Playing safe and preserving integrity: making the FDA model work
Statistics in Medicine 2004 May 30; 23(10): 1523-1525
Georgetown users check Georgetown Journal Finder for access to full text

Document 2008
Lachin, John M.
Conflicts of interest in data monitoring of industry versus publicly financed clinical trials
Statistics in Medicine 2004 May 30; 23(10): 1519-1521
Georgetown users check Georgetown Journal Finder for access to full text

Document 2009
DeMets, David L.; Fleming, Thomas R.
The independent statistician for data monitoring committees
Statistics in Medicine 2004 May 30; 23(10): 1513-1517
Georgetown users check Georgetown Journal Finder for access to full text

Document 2010
Bryant, John
What is the appropriate role of the trial statistician in preparing and presenting interim findings to an independent data monitoring committee in the U.S. Cancer Cooperative Group setting?
Statistics in Medicine 2004 May 30; 23(10): 1507-1511
Georgetown users check Georgetown Journal Finder for access to full text

Document 2011
Ellenberg, Susan S.; George, Stephen L.
Should statisticians reporting to data monitoring committees be independent of the trial sponsor and leadership?
Statistics in Medicine 2004 May 30; 23(10): 1503-1505
Georgetown users check Georgetown Journal Finder for access to full text
**Document 2012**

Hodge, James G., Jr.; Gostin, Lawrence O.
Council of State and Territorial Epidemiologists. Advisory Committee

**Public practice vs. research: a report for public health practitioners including cases and guidance for making distinctions**


Georgetown users check [Georgetown Journal Finder](http://www.ihs.gov) for access to full text

[http://www.ihs.gov](http://www.ihs.gov) (link may be outdated)

---

**Document 2013**


**Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection [Notice]**

Federal Register 2004 May 12; 69(92): 26393-26397

Georgetown users check [Georgetown Journal Finder](http://www.gpoaccess.gov/fr/) for access to full text

[http://www.gpoaccess.gov/fr/](http://www.gpoaccess.gov/fr/) (link may be outdated)

---

**Document 2014**

Couzin, Jennifer

**Unorthodox clinical trials held science and care**

Science 2004 May 7; 304(5672): 816-817

Georgetown users check [Georgetown Journal Finder](http://www.sciencemag.org) for access to full text

[http://www.sciencemag.org](http://www.sciencemag.org) (link may be outdated)

---

**Document 2015**

Buchbinder, Susan P.; Metch, Barbara; Holte, Sarah E.; Scheer, Susan; Coletti, Anne; Vittinghoff, Eric

**Determinants of enrollment in a preventive HIV vaccine trial: hypothetical versus actual willingness and barriers to participation**

Journal of Acquired Immune Deficiency Syndrome 2004 May 1; 36(1): 604-612

Georgetown users check [Georgetown Journal Finder](http://www.sciencemag.org) for access to full text

---

**Document 2016**

Bélorgey, Chantan; Plétan, Yannick; Goehrs, Jean-Marie

**Transposition de la directive essais cliniques: recommandations sur le contenu d'un dossier de demande d'autorisation pour les premiers essais chez l'homme = Adaptation of the clinical trials directive: recommendations on the contents of a dossier for the request for authorisation of the first trials in human subjects**

Therapie 2004 May-June; 59(3): 329-336

Georgetown users check [Georgetown Journal Finder](http://www.sciencemag.org) for access to full text
Document 2017
Nõmper, Ants
Research ethics committees in Estonia
EACME Newsletter 2004 May (10): 4-6

Georgetown users check Georgetown Journal Finder for access to full text

Document 2018
Medicines for human use (clinical trials) regulations 2004
Bulletin of Medical Ethics 2004 May; (198): 2

Georgetown users check Georgetown Journal Finder for access to full text

Document 2019
Deschenes, Mylene
Continuing review of genetics research
Nature Reviews Genetics 2004 May; 5(5): 332

Georgetown users check Georgetown Journal Finder for access to full text

* Document 2020
Grady, Christine
Ethics of vaccine research
Nature Immunology 2004 May; 5(5): 465-468

Georgetown users check Georgetown Journal Finder for access to full text

* Document 2021
Fitzsimons, Donna; McAloon, Toni
The ethics of non-intervention in a study of patients awaiting coronary artery bypass surgery
Journal of Advanced Nursing 2004 May; 46(4): 395-402

Georgetown users check Georgetown Journal Finder for access to full text

Document 2022
Maloney, Dennis M.
Plaintiffs seek extra punitive damages against university and Institutional Review Board (IRB)
Human Research Report 2004 May; 19(5): 8
Document 2023
Maloney, Dennis M.
**Institutional Review Board (IRB) did not burden itself by taking minutes of meetings**

Georgetown users check [Georgetown Journal Finder](http://georgetownjournalfinder.georgetown.edu) for access to full text

Document 2024
Maloney, Dennis M.
**Federal agency seeks input on existing IRB requirements**

Georgetown users check [Georgetown Journal Finder](http://georgetownjournalfinder.georgetown.edu) for access to full text

Document 2025
Maloney, Dennis M.
**Institutional Review Boards (IRBs) and research involving children as subjects**

Georgetown users check [Georgetown Journal Finder](http://georgetownjournalfinder.georgetown.edu) for access to full text

Document 2026
Rosoff, Philip M.
**Can underpowered clinical trials be justified?**

Georgetown users check [Georgetown Journal Finder](http://georgetownjournalfinder.georgetown.edu) for access to full text

Document 2027
Markman, Maurie
**What must research subjects be told regarding the results of completed randomized trials?**
IRB: Ethics and Human Research 2004 May-June; 26(3): 8-10

Georgetown users check [Georgetown Journal Finder](http://georgetownjournalfinder.georgetown.edu) for access to full text

Document 2028
Weingarten, Michael A.; Paul, Mical; Leibovici, Leonard
**Assessing ethics of trials in systematic reviews**
BMJ: British Medical Journal 2004 April 24; 328(7446): 1013-1014

Georgetown users check [Georgetown Journal Finder](http://georgetownjournalfinder.georgetown.edu) for access to full text

http://www.bmj.com (link may be outdated)
Document 2029
Thomas, James; Harden, Angela; Oakley, Ann; Oliver, Sandy; Sutcliffe, Katy; Rees, Rebecca; Brunton, Ginny; Kavanagh, Josephine
**Integrating qualitative research with trials in systematic reviews**
BMJ: British Medical Journal 2004 April 24; 328(7446): 1010-1012
Georgetown users check [Georgetown Journal Finder](http://www.bmj.com) for access to full text

Document 2030
Smith, Alexandra G.; Fear, Nicola T.; Law, Graham R.; Roman, Eve
**Representativeness of samples from general practice lists in epidemiological studies: case-control study**
BMJ: British Medical Journal 2004 April 17; 328(7445): 932
Georgetown users check [Georgetown Journal Finder](http://www.bmj.com) for access to full text

Document 2031
Halpern, Scott D.; Karlawish, Jason H.; Casarett, David; Berlin, Jesse A.; Asch, David A.
**Empirical assessment of whether moderate payments are undue or unjust inducements for participation in clinical trials**
Archives of Internal Medicine 2004 April 12; 164(7): 801-803
Georgetown users check [Georgetown Journal Finder](http://archinte.ama-assn.org) for access to full text

Document 2032
Sanci, Lena A.; Sawyer, Susan M.; Weller, Penny J.; Bond, Lyndal M.; Patton, George C.
**Youth health research ethics: time for a mature-minor clause?**
Medical Journal of Australia 2004 April 5; 180(7): 336-338
Georgetown users check [Georgetown Journal Finder](http://www.bmj.com) for access to full text

Document 2033
Califf, Robert M.
**Watching the WATCH trial: the role of sponsors and data monitoring committees**
Journal of Cardiac Failure 2004 April; 10(2): 113-114
Georgetown users check [Georgetown Journal Finder](http://archinte.ama-assn.org) for access to full text

Document 2034
Weijer, Charles
**The ethical analysis of risk in intensive care unit research**
* Article  

**Document 2035**

Smith, M.; Doyle, F.; McGee, H.M.; De La Harpe, D.

**Ethical approval for national studies in Ireland: an illustration of current challenges**

Irish Journal of Medical Science 2004 April-June; 173(2): 72-74

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

* Article  

**Document 2036**

Fitzgerald, Maureen H.; Yule, Elisa

**Open and closed committees**

Monash Bioethics Review 2004 April; 23(2): S35-S49

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

* Article  

**Document 2037**

Liberati, Alessandro

**Research Ethics Committees: can they contribute to the improvement of clinical research in Europe?**

Journal of Ambulatory Care Management 2004 April-June; 27(2): 154-165

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

* Article  

**Document 2038**

Maloney, Dennis M.

**Complaint against IRB alleges numerous violations of federal research regulations [Robertson et al. v. McGee et al. (Part V)]**

Human Research Report 2004 April; 19(4): 8

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

* Article  

**Document 2039**

Maloney, Dennis M.

**Institution says shutdown of all of their federally-funded research was "outrageous"**

Human Research Report 2004 April; 19(4): 6-7

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

* Article  

**Document 2040**

McMillan, J.R.; Conlon, C.

**The ethics of research related to health care in developing countries**

Journal of Medical Ethics 2004 April; 30(2): 204-206

Georgetown users check [Georgetown Journal Finder](#) for access to full text
Schulkenk, U.  
*Document 2041*

**The standard of care debate: against the myth of an "international consensus opinion"**

**Abstract:** It is argued by Lie et al in the current issue of the Journal of Medical Ethics that an international consensus opinion has formed on the issue of standards of care in clinical trials undertaken in developing countries. This opinion, so they argue, rejects the Declaration of Helsinki's traditional view on this matter. They propose furthermore that the Declaration of Helsinki has lost its moral authority in the controversy in research ethics. Although the latter conclusion is supported by this author, it will be demonstrated in this paper that there is not such a thing as an international consensus opinion, and that the authorities used by Lie et al as evidence in support of their claim should not be relied upon as authorities or final arbiters in this debate. Furthermore, it will be shown that arguments advanced substantively to show that lower standards of care are ethically acceptable in the developing world, conflate scientific with economic reasons, and ultimately fail to bolster the case they are designed to support.

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---

Lie, R.K.; Emanuel, E.; Grady, C.; Wendler, D.  
*Document 2042*

**The standard of care debate: the Declaration of Helsinki versus the international consensus opinion**

**Abstract:** The World Medical Association's revised Declaration of Helsinki endorses the view that all trial participants in every country are entitled to the worldwide best standard of care. In this paper the authors show that this requirement has been rejected by every national and international committee that has examined this issue. They argue that the consensus view now holds that it is ethically permissible, in some circumstances, to provide research participants less than the worldwide best care. Finally, the authors show that there is also consensus regarding the broad conditions under which this is acceptable.

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---

Vineis, P.  
*Document 2043*

**Evidence-based medicine and ethics: a practical approach**

**Abstract:** The clinical decision is supposed to be based on evidence. In fact, what counts as evidence is far from being established. Some definition of "proof" is needed to distinguish between scientific medicine and charlatanism. My thesis is that unfortunately a clear-cut boundary between evidence and lack of evidence cannot be found, for several reasons that I summarise in the paper. Evidence in medicine very often has fuzzy boundaries, and dichotomising fuzziness and uncertainty can have serious consequences. Physicians and patients should accept the irreducible fuzziness of many of the concepts they use when dealing with health and disease.

Georgetown users check [Georgetown Journal Finder](http://www.jmedethics.com) for access to full text
Research ethics and evidence based medicine
Journal of Medical Ethics 2004 April; 30(2): 122-125

Abstract: In this paper, the author argues that the requirement to conduct randomised clinical trials to inform policy in cases where one wants to identify a cheaper alternative to known effective but expensive interventions raises an important ethical issue. This situation will eventually arise whenever there are resource constraints, and a policy decision has been made not to fund an intervention on cost effectiveness grounds. It has been thought that this is an issue only in extremely resource poor settings. This paper gives an example from the United Kingdom illustrating that this is also a problem faced by richer countries.

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http://www.jmedethics.com (link may be outdated)

Deception in the pursuit of science [opinion]
Archives of Internal Medicine 2004 March 22; 164(6): 597-600

Georgetown users check Georgetown Journal Finder for access to full text

http://archinte.ama-assn.org (link may be outdated)

Effects of training on quality of peer review: randomised controlled trial
BMJ: British Medical Journal 2004 March 20; 328(7441): 673-675

Georgetown users check Georgetown Journal Finder for access to full text

http://www.bmj.com (link may be outdated)

The ethical relevance of the standard of care in the design of clinical trials
American Journal of Respiratory and Critical Care Medicine 2004 March 1; 169(5): 562-564

Georgetown users check Georgetown Journal Finder for access to full text

Please, sir, I want some more: Congress' carrot-and-stick approach to pediatric testing leaves therapeutic orphans needing more protection

Georgetown users check Georgetown Journal Finder for access to full text
Document 2049

**Fundamental ethical principles and clinical trials in developing countries**

Medical Ethics and Bioethics / Medicinska Etika & Bioetika 2004 Spring-Summer; 11(1-2): 1

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 2050

**Bergkamp, Lucas**

**Medical research involving human beings: some reflections on the main principles of the international regulatory instruments**

European Journal of Health Law 2004 March; 11(1): 61-69

Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 2051

**World Medical Association**

**World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects**


Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 2052

**Council of Europe. Steering Committee on Bioethics (CDBI)**

**Draft additional protocol to the Convention on Human Rights and Biomedicine, on Biomedical Research**


Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 2053

**Rosenau, Henning; Magnin, Cedric**

**Les conditions legales prealables requises pour les essais cliniques d'apres la Declaration d'Helsinki revisee et la Convention Europeenne sur les Droits de l'Homme et la Biomedicine / Legal prerequisites for clinical trials under the revised Declaration of Helsinki and the European Convention on Human Rights and Biomedicine**


Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 2054

**Sharp, Helen M.; Orr, Robert D.**

**When "minimal risk" research yields clinically-significant data, maybe the risks aren't so minimal**


Georgetown users check [Georgetown Journal Finder](#) for access to full text
* Article  Document 2055
Wang, Hong; Erickson, J. David; Li, Zhu; Berry, Robert J.
**Evaluation of the informed consent process in a randomized controlled trial in China: the Sino-U.S. NTD Project**
Journal of Clinical Ethics 2004 Spring; 15(1): 61-75
Georgetown users check **Georgetown Journal Finder** for access to full text

* Article  Document 2056
Lo, Bernard
**Research with vulnerable participants**
Georgetown users check **Georgetown Journal Finder** for access to full text

* Article  Document 2057
Xie, Zhufan
**Clinical trials in traditional Chinese medicine**
Georgetown users check **Georgetown Journal Finder** for access to full text

* Article  Document 2058
Yuan, Lu
**Clinical trials in China: protection of subjects' rights and interests**
Journal of Clinical Ethics 2004 Spring; 15(1): 30-34
Georgetown users check **Georgetown Journal Finder** for access to full text

* Article  Document 2059
Silverman, Henry J.; Miller, Franklin G.
**Control group selection in critical care randomized controlled trials evaluating interventional strategies: an ethical assessment**
Critical Care Medicine 2004 March; 32(3): 852-857
Georgetown users check **Georgetown Journal Finder** for access to full text

* Article  Document 2060
Burck, Russell
**Challenges of treating on the basis of knowledge: the ARDS Network trials and the ensuing controversy**
Critical Care Medicine 2004 March; 32(3): 904-905
Georgetown users check **Georgetown Journal Finder** for access to full text
Document 2061
Bourgeois, Warren

*Consent from competent minors and the TCPS guidelines*

Georgetown users check [Georgetown Journal Finder](http://www.ncehr-cnerh.org) for access to full text

Document 2062
Nelson, Connie H.; McPherson, Dennis H.

*The task for ethics review: should research ethics boards address an approach or a paradigm?*
NCEHR Communique CNERH 2004 Spring; 12(2): 11-22

Georgetown users check [Georgetown Journal Finder](http://www.ncehr-cnerh.org) for access to full text

Document 2063
Maloney, Dennis M.

*The basic right of human research subjects to be treated with dignity*

Georgetown users check [Georgetown Journal Finder](http://www.ncehr-cnerh.org) for access to full text

Document 2064
Maloney, Dennis M.

*Exemption for some studies from research regulations*

Georgetown users check [Georgetown Journal Finder](http://www.ncehr-cnerh.org) for access to full text

Document 2065
Maloney, Dennis M.

*First accreditation by rival human subjects organization*

Georgetown users check [Georgetown Journal Finder](http://www.ncehr-cnerh.org) for access to full text

Document 2066
Maloney, Dennis M.

*IRB approval not needed for clinical trials data bank*

Georgetown users check [Georgetown Journal Finder](http://www.ncehr-cnerh.org) for access to full text
Easter, Michelle M.; Davis, Arlene M.; Henderson, Gail E.
Confidentiality: more than a linkage file and a locked drawer
Supported by: R01-HG02087, 1999-2003
Georgetown users check Georgetown Journal Finder for access to full text

Miller, Franklin G.; Wendler, David
Assessing the ethics of ethics research: a case study
Georgetown users check Georgetown Journal Finder for access to full text

Appelbaum, Paul S.; Lidz, Charles W.; Grisso, Thomas
Therapeutic misconception in clinical research: frequency and risk factors
Georgetown users check Georgetown Journal Finder for access to full text

Fergusson, Dean; Glass, Kathleen Cranley; Waring, Duff; Shapiro, Stan
Turning a blind eye: the success of blinding reported in a random sample of randomised, placebo controlled trials
http://www.bmj.com (link may be outdated)

Hirsch, Laurence
Randomized clinical trials: what gets published, and when? [comment]
http://www.cmaj.ca (link may be outdated)

Bhandari, Mohit; Busse, Jason W.; Jackowski, Dianne; Montori, Victor M.; Schunemann, Holger; Sprague, Sheila; Mears, Derek; Schemitsch, Emil H.; Heels-anksdell, Dianne; Devereaux, P.J.
Association between industry funding and statistically significant pro-industry findings in medical and surgical randomized trials
Adams-Campbell, Lucile L.; Ahaghotu, Chiledum; Gaskins, Melvin; Dawkins, Fitzroy W.; Smoot, Duane; Polk, Octavius D.; Gooding, Robert; Dewitty, Robert L.

**Enrollment of African Americans onto clinical treatment trials: study design barriers**

Journal of Clinical Oncology 2004 February 15; 22(4): 730-734

Sydes, Matthew R.; Spiegelhalter, David J.; Altman, Douglas G.; Babiker, Abdel B.; Parmar, Mahesh K.B.

**Systematic qualitative review of the literature on data monitoring committees for randomized controlled trials**

Clinical Trials 2004 February; 1(1): 60-79

Sydes, Matthew R.; Altman, Douglas G.; Babiker, Abdel B.; Parmar, Mahesh K.B.; Spiegelhalter, David J.

**Reported use of data monitoring committees in the main published reports of randomized controlled trials: a cross-sectional study**

Clinical Trials 2004 February; 1(1): 48-59

Kiri, Antariksha; Tonascia, Susan; Meinert, Curtis L.

**Treatment effects monitoring committees and early stopping in large clinical trials**

Clinical Trials 2004 February; 1(1): 40-47

Ellenberg, Susan S.

**Monitoring data on data monitoring**

Clinical Trials 2004 February; 1(1): 6-8

Aagaard-Hansen, Jens; Johansen, Maria Vang.; Riis, Pols
Research ethical challenges in cross-disciplinary and cross-cultural health research: the diversity of codes
Danish Medical Bulletin 2004 February; 51(1): 117-120

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

Document 2079

Siegal, Gil

Western bio-ethics -- Israel between North America and Europe
Harefuah 2004 February; 143(2): 142-146, 165

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

* Document 2080

Sleight, Peter

Where are clinical trials going? Society and clinical trials
Journal of Internal Medicine 2004 February; 255(2): 151-158

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

* Document 2081

Byers, Jacqueline Fowler

Protecting patients during clinical research
Critical Care Nurse 2004 February; 24(1): 53-59

Georgetown users check [Georgetown Journal Finder](#) for access to full text

---

Document 2082

Maloney, Dennis M.

Independent audits agree that institutional review board (IRB) failed in its duties

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---

Document 2083

Maloney, Dennis M.

University must provide federal agency with a large amount of information [case study]

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---

* Document 2084

Hope, Tony; McMillan, J.

Challenge studies of human volunteers: ethical issues

Georgetown users check [Georgetown Journal Finder](#) for access to full text
Proceeding with clinical trials of animal to human organ transplantation: a way out of the dilemma

Abstract: The transplantation of porcine organs to humans could in the future be a solution to the worldwide organ shortage, but is to date still highly experimental. Further research on the potential effects of crossing the species barrier is essential before clinical application is acceptable. However, many crucial questions on efficacy and safety will ultimately only be answered by well designed and controlled solid organ xenotransplantation trials on humans. This paper is concerned with the question under which conditions, given the risks involved and the ethical issues raised, such clinical trials should be resumed. An alternative means of overcoming the safety and ethical issues is suggested: willed body donation for scientific research in the case of permanent vegetative status. This paper argues that conducting trials on such bodies with prior consent is preferable to the use of human subjects without lack of brain function.

Research ethics committees and paternalism

Abstract: In this paper the authors argue that research ethics committees (RECs) should not be paternalistic by rejecting research that poses risk to people competent to decide for themselves. However it is important they help to ensure valid consent is sought from potential recruits and protect vulnerable people who cannot look after their own best interests. The authors first describe the tragic deaths of Jesse Gelsinger and Ellen Roche. They then discuss the following claims to support their case: (1) competent individuals are epistemologically and ethically in the best position to say which risks are reasonable for them, so RECs should be no more restrictive than the "normal" constraints on people taking risks with themselves; (2) RECs do not judge individual competence (that is for researchers and psychiatrists); (3) individual liberty is mostly limited by what serves the public interest, and RECs do not determine public interest; (4) RECs may have a paternalistic role in preventing exploitation of competent people vulnerable to the use of incentives, and in protecting the interests of incompetent people; however, (5) the moral and political authority of RECs has not been established in this respect.

Non-therapeutic research with minors: how do chairpersons of German research ethics committees decide?

Abstract: OBJECTIVES: Clinical trials in humans in Germany—as in many other countries—must be approved by local research ethics committees (RECs). The current study has been designed to document and evaluate decisions of chairpersons of RECs in the problematic field of non-therapeutic research with minors. The authors’ purpose was to examine whether non-therapeutic research was acceptable for chairpersons at all, and whether there was certainty on how to decide in research trials involving more than minimal risk. DESIGN: In a questionnaire, REC chairpersons had to evaluate five different scenarios with (in parts) non-therapeutic research. The scenarios described realistic potential research projects with minors, involving increasing levels of risk for the research participants. The chairpersons had to decide whether the respective projects should be approved. METHODS: A total of 49 German REC chairpersons were sent questionnaires; 29 questionnaires were returned. The main measurements were approval or rejection of research scenarios. RESULTS: Chairpersons of German RECs generally tend to accept non-therapeutic research with minors if the apparent risk for the participating children is low. If the risk is clearly higher than "minimal", the chairpersons’ decisions differ widely. CONCLUSION: The fact that there seem to be different attitudes of chairpersons to non-therapeutic research with minors is problematic from an ethical point of view. It suggests a general uncertainty about the standards of protection for minor research participants in Germany. Therefore, further ethical and legal regulation of non-therapeutic research with minors in Germany seems necessary.
Tangwa, G.B.  
**Between universalism and relativism: a conceptual exploration of problems in formulating and applying international biomedical ethical guidelines**  
Journal of Medical Ethics 2004 February; 30(1): 63-67  
*Abstract:* In this paper, the author attempts to explore some of the problems connected with the formulation and application of international biomedical ethical guidelines, with particular reference to Africa. Recent attempts at revising and updating some international medical ethical guidelines have been bedeviled by intractable controversies and wrangling regarding both the content and formulation. From the vantage position of relative familiarity with both African and Western contexts, and the privilege of having been involved in the revision and updating of one of the international ethical guidelines, the author reflects broadly on these issues and attempts prescribing an approach from both the theoretical and practical angles liable to mitigate, if not completely eliminate, some of the problems and difficulties.

Woods, Kent  
**Implementing the European clinical trials directive -- discussions continue in the European Commission and the United Kingdom**  
BMJ: British Medical Journal 2004 January 31; 328(7434): 240-241  

Shah, Seema; Whittle, Amy; Wilfond, Benjamin; Gensler, Gary; Wendler, David  
**How do institutional review boards apply the federal risk and benefit standards for pediatric research?**  
*Abstract:* CONTEXT: Federal regulations allow children in the United States to be enrolled in clinical research only when the institutional review board (IRB) determines that the risks are minimal or a minor increase over minimal, or that the research offers a prospect of direct benefit. Despite this reliance on IRBs, no data exist on how IRBs apply the risk and benefit categories for pediatric research. OBJECTIVE: To determine how IRB chairpersons apply the federal risk and benefit categories for pediatric research. DESIGN, SETTING, AND PARTICIPANTS: Telephone survey, conducted between May and August 2002 of 188 randomly selected chairpersons of IRBs in the United States. The survey consisted of 21 questions to assess the application of federal risk standards to research procedures, whether certain interventions offer a prospect of direct benefit to participating children, and the extent to which IRBs use the federal definition of minimal risk when categorizing the risks of research procedures in children. MAIN OUTCOME MEASURES: Responses regarding categorization of the risk level and direct benefits of pediatric research procedures. RESULTS: A single blood draw was the only procedure categorized as minimal risk by a majority (152 or 81%) of the 188 respondents. An electromyogram was categorized as minimal risk by 100 (53%) and as more than a minor increase over minimal risk by 77 (41%). Allergy skin testing was categorized as minimal risk by 43 IRB chairpersons (23%), a minor increase over minimal risk by 81 (43%), and more than a minor increase over minimal risk by 51 (27%). Regarding benefits, 113 chairpersons (60%) considered added psychological counseling to be a direct benefit, while participant payment was considered a direct benefit by 10% (n = 19). CONCLUSIONS: Application of the federal risk and benefit categories for pediatric research by IRB chairpersons is variable and sometimes contradicted by the available data on risks and the regulations themselves. To protect children from excessive risks while allowing appropriate research, IRB chairpersons need guidance on applying the federal risk and benefit categories and also need data on the risks children face in daily life.
and during routine physical or psychological tests.

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http://jama.ama-assn.org (link may be outdated)

---

* **Document 2091**

Kondro, Wayne

**Canadian researchers testing SARS vaccine in China**
CMAJ/JAMC: Canadian Medical Association Journal 2004 January 20; 170(2): 183

Georgetown users check [Georgetown Journal Finder](http://www.cmaj.ca) for access to full text

http://www.cmaj.ca (link may be outdated)

---

* **Document 2092**

Van Essen, Gabrielle L.; Story, David A.; Poustie, Stephanie J.; Griffiths, Max M.J.; Marwood, Cynthia L.

**Natural justice and human research ethics committees: an Australia-wide survey**
Medical Journal of Australia 2004 January 19; 180(2): 63-66

Georgetown users check [Georgetown Journal Finder](http://www.cmaj.ca) for access to full text

---

* **Document 2093**

Brown, David

**U.S.-backed AIDS vaccine trial in Thailand is questioned**
Washington Post 2004 January 19; p. A2

http://www.nytimes.com (link may be outdated)

---

* **Document 2094**

Heamshaw, Hilary

**Comparison of requirements of research ethics committees in 11 European countries for a non-invasive interventional study**
BMJ: British Medical Journal 2004 January 17; 328(7432): 140-141

Georgetown users check [Georgetown Journal Finder](http://www.cmaj.ca) for access to full text

http://www.cmaj.ca (link may be outdated)

---

* **Document 2095**

Burton, Dennis R.; Desrosiers, Ronald C.; Doms, Robert W.; Feinberg, Mark B.; Gallo, Robert C.; Hahn, Beatrice; Hoxie, James A.; Hunter, Eric; Korber, Bette; Landay, Alan; Lederman, Michael M.; Lieberman, Judy; McCune, Joseph M.; Moore, John P.; Nathanson, Neal; Picker, Louis; Richman, Douglas; Rinaldo, Charles; Stevenson, Mario; Watkins, David I.; Wolinsky, Steven M.; Zack, Jerome A.

**A sound rationale needed for phase III HIV-1 vaccine trials**
Science 2004 January 16; 303(5656): 316
* Article  Document 2096
Silversides, Ann
**The tribulations of community-based trials**

* Article  Document 2097
Turner, Leigh
**Ethics board review of biomedical research: improving the process**
Drug Discovery Today 2004 January 1; 9(1): 8-12

* Article  Document 2098
Castellano, Marlene Brant
**Ethics of Aboriginal research**

* Article  Document 2099
Calder, N.; Boyce, M.; Posner, J.; Sciberras, D.
**Clinical pharmacology studies in UK Phase 1 units: an AHPPI survey 1999-2000**
British Journal of Clinical Pharmacology 2004 January; 57(1): 76-79

* Article  Document 2100
Mulder, Gerit
**Recommendations for designing and implementing protocols for advanced technology clinical trials**

* Article  Document 2101
Anderson, Rob W.
E-review versus pre-review: an integrated approach to electronic protocol review
Contemporary Topics in Laboratory Animal Science 2004 January; 43(1): 82-83

Georgetown users check Georgetown Journal Finder for access to full text

Document 2102
Torgerson, David
The use of Zelen's design in randomised trials [opinion]

Georgetown users check Georgetown Journal Finder for access to full text

Document 2103
Touitou, Yvan; Portaluppi, Francesco; Smolensky, Michael H.; Rensing, Ludger
Ethical principles and standards for the conduct of human and animal biological rhythm research
Chronobiology International 2004 January; 21(1): 161-170

Georgetown users check Georgetown Journal Finder for access to full text

Document 2104
Miksanek, Tony
Long for this world, by Michael Byers [book review]
Medical Ethics Newsletter [Lahey Clinic] 2004 Winter; 11(1): 9

Georgetown users check Georgetown Journal Finder for access to full text
http://www.lahey.org/Ethics/ (link may be outdated)

Document 2105
Brody, Howard
Should a clinical trial coordinator blow the whistle?

Georgetown users check Georgetown Journal Finder for access to full text
http://www.lahey.org/Ethics/ (link may be outdated)

Document 2106
Miller, Franklin G.
Sham surgery: an ethical analysis

Georgetown users check Georgetown Journal Finder for access to full text

Document 2107
Ways to improve genetic trials informed consent: be sensitive to disclosure risks
* Document 2108
Brown, Morton B.
Control groups appropriate for surgical interventions: ethical and practical issues
Gastroenterology 2004 January; 126(1, Supplement 1): S164-S168
Georgetown users check Georgetown Journal Finder for access to full text

* Document 2109
Motil, Kathleen J.; Allen, Janet; Taylor, Addison
When a research subject calls with a complaint, what will the institutional review board do?
Georgetown users check Georgetown Journal Finder for access to full text

* Document 2110
Maloney, Dennis M.
Bill forbids mandatory accreditation of Institutional Review Boards (IRBs)
Georgetown users check Georgetown Journal Finder for access to full text

* Document 2111
Maloney, Dennis M.
Institutional Review Board (IRB) is accused of serious non-compliance
Georgetown users check Georgetown Journal Finder for access to full text

* Document 2112
Maloney, Dennis M.
Death of a research subject and a halt to all federally-funded research [case study]
Georgetown users check Georgetown Journal Finder for access to full text

* Document 2113
Maloney, Dennis M.
Human subject safety and integrity of data
Georgetown users check Georgetown Journal Finder for access to full text
Faulkner, Alison
THE ETHICS OF SURVIVOR RESEARCH: GUIDELINES FOR THE ETHICAL CONDUCT OF RESEARCH CARRIED OUT BY MENTAL HEALTH SERVICE USERS AND SURVIVORS
Call number: RA790.5 .F38 2004

Singapore. Bioethics Advisory Committee
RESEARCH INVOLVING HUMAN SUBJECTS: GUIDELINES FOR IRBS
Call number: R853 .H8 R456 2004
http://www.bioethics-singapore.org/ (link may be outdated)

Spiegelhalter, David J.; Abrams, Keith R.; and Myles, Jonathan P.
BAYESIAN APPROACHES TO CLINICAL TRIALS AND HEALTH-CARE EVALUATION
Call number: R853 .S7 S66 2004

National Research Council (United States). Committee on the Use of Third Party Toxicity Research with Human Research Participants [and] National Research Council (United States). Science, Technology, and Law Program
INTENTIONAL HUMAN DOSING STUDIES FOR EPA REGULATORY PURPOSES: SCIENTIFIC AND ETHICAL ISSUES
Call number: R853 .H8 I574 2004
http://www.nap.edu (link may be outdated)

Cong, Yali
Development of research ethics in China = Çin'de Arastirma Etiginin Gelisimi

Georgetown users check Georgetown Journal Finder for access to full text

Canada. Interagency Advisory Panel and Secretariat on Research Ethics Social Sciences and Humanities Research Ethics Special Working Committee to the Interagency Advisory Panel on Research Ethics; Indigenous Peoples' Health Research Centre (IPHRC)
Cultivating a Culture of Research Ethics Packet; Tri-Council Policy Statement: Ethical Conduct for Research

Ottawa, Ontario, Canada: Interagency Advisory Panel on Research Ethics and Secretariat on Research Ethics, [2004-2006]: multiple pages

http://www.pre.ethics.gc.ca/eng/resources-ressources/reports-rapports/reports-rapports/ (link may be outdated)

* Document 2120
Dickersin, Kay; Davis, Barry R.; Dixon, Dennis O.; George, Stephen L.; Hawkins, Barbara S.; Lachin, John; Peduzzi, Peter; Pocock, Stuart
Society for Clinical Trials
The Society for Clinical Trials supports United States legislation mandating trials registration. Position paper

Georgetown users check Georgetown Journal Finder for access to full text

* Document 2121
Stone, Tracey J.
Making the decision about enrolment in a randomised controlled trial.
Call number: Q180.55 .M67 R492 2004

* Document 2122
DeMets, David; Califf, Robert; Dixon, Dennis; Ellenberg, Susan; Fleming, Thomas; Held, Peter; Julian, Desmond; Kaplan, Richard; Levine, Robert; Neaton, James; Packer, Milton; Pocock, Stuart; Rockhold, Frank; Seto, Belinda; Siegel, Jay; Snapinn, Steve; Stump, David; Temple, Robert; Whitley, Richard
Issues in regulatory guidelines for data monitoring committees
Clinical Trials 2004; 1(2): 162-169

Georgetown users check Georgetown Journal Finder for access to full text

* Document 2123
Garcia, Jo; Elbourne, Diana; Snowdon, Claire
Equipoise: a case study of the views of clinicians involved in two neonatal trials
Clinical Trials 2004; 1(2): 170-188

Georgetown users check Georgetown Journal Finder for access to full text
Has CONSORT improved the reporting of randomized controlled trials in the palliative care literature? A systematic review
Georgetown users check Georgetown Journal Finder for access to full text

Breast cancer research and the European Union Clinical Trials Directive
Georgetown users check Georgetown Journal Finder for access to full text

Reflections: guidelines for the inclusion of women and minorities in clinical studies.
Call number: JC312 .R33 2004

Research without borders: the origins of the Declaration of Helsinki.
Call number: R853 .H8 T93 2004

Liability issues for data monitoring committee members
Clinical Trials 2004; 1(6): 525-531
Georgetown users check Georgetown Journal Finder for access to full text

Ethics of randomised controlled trials--not yet time to give up on equipoise
Arthritis Research and Therapy 2004; 6(6): 237-239
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Downie, Jocelyn; McDonald, Fiona
Revisioning the oversight of research involving humans in Canada
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Beyleveld, Deryck; Townend, David M.R.
When is personal data rendered anonymous? Interpreting Recital 26 of Directive 95/46/EC
Medical Law International 2004; 6(2): 73-86
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Olsen, Jorn; Mulvad, Gert; Pedersen, Mille Sovndah; Christiansen, Thue; Sorensen, Paul Henrik
An ethics committee for medical research in Greenland: history and challenges
International Journal of Circumpolar Health 2004; 63(Supplement 2): 144-146
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Overview of research design in epidemiology
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Working with human research protections
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Larson, Elaine; Bratts, Tiffany; Zwanziger, Jack; Stone, Patricia
A survey of IRB process in 68 U.S. hospitals
Journal of Nursing Scholarship 2004; 36(3): 260-264
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Coleman, Carl H.
Rationalizing risk assessment in human subject research
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A ‘parallel process’? Beginning a constructive conversation about a Maori methodology

Abstract: This paper documents the beginning of a conversation about what it means to be Maori within a larger, mainstream research project. This larger project was conceived by a team of researchers that included a Maori principal investigator, and funding was gained from a funding agency that has established criteria for Maori responsiveness. The Maori component of the project was, however, not initially conceived of as separate from the non-Maori component. Discussions about this were initiated approximately one year into the project in response to Maori team members' desires to undertake Kaupapa Maori research. This effectively means that the Maori team collects and analyses the Maori research data prior to re-engaging with the full research team. While there is a level of uncertainty about how this process will play itself out, there is a commitment to continue a constructive conversation within the team and to journey together in good faith and trust.
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Sieber, Joan E.

**Using our best judgment in conducting human research**

*Ethics and Behavior* 2004; 14(4): 297-304

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Grienenberger, Aurelie

**Establishing pan-European clinical trials: regulatory compliance and other practical considerations**


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Irish Council for Bioethics

**Operational Procedures for Research Ethics Committees: Guidance 2004**


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de Bijl, Nicole P.Y.M.

**The legal protection of test subjects in clinical trials of medicinal products for human use in the European Union**


Abstract: On the international as well as on the level of the European Union a legal framework has been developed on the protection of test subjects. In 2000, the Declaration of Helsinki, issued by the World Medical Association, was revised and the previous distinction between therapeutic and non-therapeutic trial situations has been eliminated. Non-therapeutic trials that only aim at the progress of scientific knowledge and do not benefit the patient are now admissible. This is not to the benefit of the position of the test subject and most certainly not when the test subject should be given special protection. The question arises what this recent revision means for the group of incompetent adult patients in clinical trials on medicinal products (hereinafter called drugs) in the European Union (EU). This group needs special protection. Also relevant are national and international legal frameworks and the protection offered by informed consent procedures and screening by ethics committees and member states’ competent authorities.

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Yan, Eric G.; Munir, Kerim M.

**Regulatory and ethical principles in research involving children and individuals with developmental disabilities**

*Ethics and Behavior* 2004; 14(1): 31-49

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Noah, Barbara A.
**Bioethical malpractice: risk and responsibility in human research**

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**Regulatory perspectives on data safety monitoring boards: protecting the integrity of data**
Drug Safety 2004; 27(1): 1-6

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Horton, Linda R.; Tomhave, Jaime A.; Mailly, Jacqueline
**Major EU pharmaceutical regulatory changes effective May 1, 2004**

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Valdes, Sonia; McGuire, Penny
**Contract research organizations (CROs) may be the next trend in clinical trials liability**
Journal of Biolaw and Business 2004; 7(3): 11-15

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