Learning to think continentally.
Nature genetics 2011 August 29; 43(9): 817
Abstract: The US Department of Health and Human Services (DHHS) is proposing to enhance federal regulation intended to protect human research subjects, in particular to increase measures aimed at security of personal data. Since the ethical review process is partially based on respect for people and their autonomy, harmonization of these rules will be a process of convincing individuals and their states to accept uniform standards that give enough privacy but do not lock away personal data from either research participants or researchers.

Research using blogs for data: public documents or private musings?
Abstract: Nursing and other health sciences researchers increasingly find blogs to be valuable sources of information for investigating illness and other human health experiences. When researchers use blogs as their exclusive data source, they must discern the public/private aspects inherent in the nature of blogs in order to plan for appropriate protection of the bloggers’ identities. Approaches to the protection of human subjects are poorly addressed when the human subject is a blogger and the blog is used as an exclusive source of data. Researchers may be assisted to protect human subjects via a decisional framework for assessing a blog author’s intended position on the public/private continuum.

Who is the research subject in cluster randomized trials in health research?
Trials 2011 July 26; 12: 183
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, we set out six areas of inquiry that must be addressed if the CRT is to be set on a firm ethical foundation. This paper addresses the first of the questions posed, namely, who is the research subject in a CRT in health research? The identification of human research subjects is logically prior to the application of protections as set out in research ethics and regulation. Aspects of CRT design, including the fact that in a single study the units of randomization, experimentation, and observation may differ, complicate the identification of human research subjects. But the proper identification of human research subjects is important if they are to be protected from harm and exploitation, and if research ethics committees are to review CRTs efficiently. We examine the research ethics literature and international regulations to identify the core features of human research subjects, and then unify these features under a single, comprehensive definition of human research subject. We define a human research subject as any person whose interests may be compromised as a result of
interventions in a research study. Individuals are only human research subjects in CRTs if: (1) they are directly intervened upon by investigators; (2) they interact with investigators; (3) they are deliberately intervened upon via a manipulation of their environment that may compromise their interests; or (4) their identifiable private information is used to generate data. Individuals who are indirectly affected by CRT study interventions, including patients of healthcare providers participating in knowledge translation CRTs, are not human research subjects unless at least one of these conditions is met.

Mosavel, Maghboeba; Ahmed, Rashid; Daniels, Doria; Simon, Christian

**Community researchers conducting health disparities research: Ethical and other insights from fieldwork journaling.**


**Abstract:** Lay persons who are trained to conduct research in their own communities form an essential part of many research projects. However, the effects of conducting research in their own communities have not been adequately explored. This paper examines the experiences, perceptions, and challenges faced by a group of community researchers during their involvement in a research project that examined if, and how, the relationships between mothers and their adolescent daughters could be harnessed to develop a daughter-initiated cervical cancer intervention. Seven community researchers interviewed 157 mother-daughter pairs in Cape Town, South Africa. We examine the use of journaling as a tool to document the experiences of community researchers, and we consider how journaling may help the community-based researcher grapple with the research process, and, more broadly, what such journal content illustrates with respect to the nature and challenges of community-engaged health research. An analysis of the content of the journals provides a strong indication of how personal and intimate the research process can be for community researchers by virtue of the background that they bring into the process as well as the additional weight of the research process itself. The complexities of navigating dual and somewhat oppositional roles - the role of impartial scientist or researcher and the role of invested community person - has been both underestimated and insufficiently researched.

Chadwick, Ruth

**How should research in bioethics be assessed?**

Bioethics 2011 Jul; 25(6): ii

Santini, Ario; Eaton, Kenneth A

**An introduction to research for primary dental care clinicians part 4: stage 6a. Obtaining ethical approval.**

Primary dental care : journal of the Faculty of General Dental Practitioners (UK) 2011 Jul; 18(3): 127-32

Carragee, Eugene J; Ghanayem, Alexander J; Weiner, Bradley K; Rothman, David J; Bono, Christopher M

**A challenge to integrity in spine publications: years of living dangerously with the promotion of bone growth factors.**

Document 8
Spengler, Dan M
Resetting standards for sponsored research: do conflicts influence results?

Document 9
Mirza, Sohail K
Folly of FDA-approval studies for bone morphogenetic protein.

Document 10
Phillips, Trisha B
A living wage for research subjects.
Abstract: Offering cash payments to research subjects is a common recruiting method, but this practice continues to be controversial because of its potential to compromise the protection of human subjects. Federal regulations and guidelines currently allow researchers to pay subjects for participation, but they say very little about how much researchers can pay their subjects. This paper argues that the federal regulations and guidelines should implement a standard payment formula. It argues for a wage payment model, and critically examines three candidates for a base wage: the nonfarm production wage, the FLSA minimum wage, and a living wage. After showing that the nonfarm production wage is too high to satisfy ethical criteria, and the minimum wage is too low, this paper concludes that the wage payment model with a base wage equivalent to a living wage is the best candidate for a standard payment formula in human subjects research.

Document 11
Kenyon, Gillian M; Mendelow, Alexander David; Gregson, Barbara A; Rowan, Elise
Obtaining regulatory approval for multicentre randomised controlled trials: experiences in the STICH II trial.
Abstract: Centres wishing to participate in international multicentre randomised controlled surgical trials such as STICH II (Surgical Trial in Lobar Intracerebral Haemorrhage) have to go through a number of regulatory hurdles. These depend on the nature of the study. In surgical studies, there is a need to obtain ethical approval and individual hospital approval including fully executing contracts between the host organisation and each institution. Firsthand experience has been gained in STICH II by guiding over 80 hospitals through this process in over 20 different countries worldwide.
Wasserman, David
**Challenges in a divided assessment of the social benefits and risks of research.**
The American journal of bioethics : AJOB 2011 May; 11(5): 12-3

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

---

Lunstroth, John
**The role of controversial research in the IRB's risk/benefit analysis.**
The American journal of bioethics : AJOB 2011 May; 11(5): 14-6

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

---

Foulkes, Mary
**Social contexts, social media, and human subjects research.**
The American journal of bioethics : AJOB 2011 May; 11(5): 35-6

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

---

Kutty, V Raman
**The draft National Health Research Policy**
Indian Journal of Medical Ethics 2011 April-June; 8(2): 93-94

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

---

Sundararaman, T.
**Comments on the National Health Research Policy**
Indian Journal of Medical Ethics 2011 April-June; 8(2): 90-92

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

---

Butterworth, John F 4th.
**Ethics and human experimentation.**
Anesthesiology 2011 Apr; 114(4): 1001-2; author reply 1002-3

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

---

Takahashi, Marystella Tomoe; Ramos, Henrique Faria; Pinheiro-Neto, Carlos Diógenes; Miziara, Ivan Dieb; Oliveira, Reynaldo Ayer de
**Current outlook of ethics in research with human subjects.**
Brazilian journal of otorhinolaryngology 2011 Mar-Apr; 77(2): 263-6
Abstract: In the last decades, medical care has been increasingly permeated by the concept of evidence-based-medicine, in which clinical research plays a crucial role in establishing diagnostic and treatment. Following the improvements in clinical research, we have a growing concern and understanding that some ethical issues must be respected when the subjects are human beings. Research with human subjects relies on the principles of autonomy, beneficence, no maleficence and justice. Ordinance 196/96 from the National Health Board adds to the Brazilian legislation such renowned bioethical principles.

Georgetown users check Georgetown Journal Finder for access to full text

---

Document 19

Hyman, Mark

Dangerous spin doctors: seven steps to protect yourself from deception in medical research.


Georgetown users check Georgetown Journal Finder for access to full text

---

Document 20

Asher, Shellie L; Schears, Raquel M; Miller, Chadwick D

Conflicts of interest in human subjects research: special considerations for academic emergency physicians.


Abstract: Trust in the doctor-patient or investigator-subject relationship is vital to the practice of medicine and advancement through biomedical research. Individual and environmental factors can make this trust more difficult to establish in the emergency department (ED). To perform research ethically and maintain this trust, it is important to minimize and manage conflicts of interest in human subjects research. While principle-based ethics are an important starting point, the virtue of the individual investigator is required to assure that the interests and safety of research participants are prioritized over the interests of the investigator or the medical community at large. SAEM Ethics Committee 2009-2010 Objective 4: "Based on the results of the didactic session presented at the annual meeting, develop a guide to assist SAEM members in the recognition of potential conflicts of interest in the practice of academic emergency medicine".

Georgetown users check Georgetown Journal Finder for access to full text

---

Document 21

'Abd al-Rahim, Mar'i Mansur

Al-Jawanib al-jina'iyah lil-tajarib al-'ilmiyah 'ala jism al-insan = Criminal aspects of scientific experiments on the human body


---

Document 22

Lenk, Christian; Hoppe, Nils; Beier, Katharina; and Wiesemann, Claudia, eds.

HUMAN TISSUE RESEARCH: A EUROPEAN PERSPECTIVE ON THE ETHICAL AND LEGAL CHALLENGES


Call number: R857 .T55 H86 2011

---

Document 23

Wertheimer, Alan

RETHINKING THE ETHICS OF CLINICAL RESEARCH: WIDENING THE LENS
**Document 24**  
Tagliani-Ribeiro, Alice; Oliveira, Mariana; Sassi, Adriana K; Rodrigues, Maira R; Zagonel-Oliveira, Marcelo; Steinman, Gary; Matte, Ursula; Fagundes, Nelson J R; Schuler-Faccini, Lavinia  
**Twin Town in South Brazil: a Nazi’s experiment or a genetic founder effect?**  
PloS one 2011; 6(6): e20328  
**Abstract:** Cândido Godói (CG) is a small municipality in South Brazil with approximately 6,000 inhabitants. It is known as the "Twins' Town" due to its high rate of twin births. Recently it was claimed that such high frequency of twinning would be connected to experiments performed by the German Nazi doctor Joseph Mengele. It is known, however, that this town was founded by a small number of families and therefore a genetic founder effect may represent an alternatively explanation for the high twinning prevalence in CG. In this study, we tested specific predictions of the "Nazi's experiment" and of the "founder effect" hypotheses. We surveyed a total of 6,262 baptism records from 1959-2008 in CG catholic churches, and identified 91 twin pairs and one triplet. Contrary to the "Nazi's experiment hypothesis", there is no spurt in twinning between the years (1964-1968) when Mengele allegedly was in CG (P = 0.482). Moreover, there is no temporal trend for a declining rate of twinning since the 1960s (P = 0.351), and no difference in twinning among CG districts considering two different periods: 1927-1958 and 1959-2008 (P = 0.638). On the other hand, the "founder effect hypothesis" is supported by an isonymy analysis that shows that women who gave birth to twins have a higher inbreeding coefficient when compared to women who never had twins (0.0148, 0.0081, respectively, P = 0.019). In summary, our results show no evidence for the "Nazi's experiment hypothesis" and strongly suggest that the "founder effect hypothesis" is a much more likely alternative for explaining the high prevalence of twinning in CG. If this hypothesis is correct, then this community represents a valuable population where genetic factors linked to twinning may be identified.

**Document 25**  
Annas, George J  
**Self experimentation and the Nuremberg Code.**  
BMJ (Clinical research ed.) 2010 December 15; 341: c7103

**Document 26**  
Nau, Jean-Yves  
[From Black Venus and Georges Cuvier (3)]. = De la Vénus noire et du grand Georges Cuvier (3).  
Revue médicale suisse 2010 Dec 8; 6(274): 2382-3

**Document 27**  
Oh, Il-Hoan  
**Law, ethics, religion, and clinical translation in the 21st century--a conversation with Il-Hoan Oh. Interview by Majlinda Lako, Alan Trounson and Susan Daher.**  
Stem cells (Dayton, Ohio) 2010 Dec; 28(12): 2121-3
**Document 28**
Dehaene, Stanislas; Brannon, Elizabeth M

**Space, time, and number: a Kantian research program.**
Trends in cognitive sciences 2010 Dec; 14(12): 517-9

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

---

**Document 29**
Schaefer, G Owen; Wertheimer, Alan

**The right to withdraw from research.**
Kennedy Institute of Ethics journal 2010 Dec; 20(4): 329-52

**Abstract:** The right to withdraw from participation in research is recognized in virtually all national and international guidelines for research on human subjects. It is therefore surprising that there has been little justification for that right in the literature. We argue that the right to withdraw should protect research participants from information imbalance, inability to hedge, inherent uncertainty, and untoward bodily invasion, and it serves to bolster public trust in the research enterprise. Although this argument is not radical, it provides a useful way to determine how the right should be applied in various cases.

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

---

**Document 30**
Wendler, David; Abdoler, Emily

**Does it matter whether investigators intend to benefit research subjects?**
Kennedy Institute of Ethics journal 2010 Dec; 20(4): 353-70

**Abstract:** There has been long-standing, albeit largely implicit, debate over whether investigator intentions are relevant to the ethical appropriateness of clinical research. Some commentators argue that whether investigators intend to collect generalizable knowledge or to benefit subjects is central to the ethics of clinical research. Others do not even mention investigator intentions when evaluating what makes clinical research ethical. To shed light on this debate, the present paper considers the reasons why investigator intentions might be ethically relevant. This analysis reveals that investigator intentions are related to, but distinct from three ethical requirements: whether subjects understand that they are contributing to a project to help others, whether the included interventions have an appropriate risk/benefit ratio, and whether subjects' interests are adequately protected. Provided these three requirements are satisfied, the ethical appropriateness of clinical research does not depend on what intentions investigators have in conducting it.

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

---

**Document 31**
Xin, Hao

**Research ethics. Questions from China snag U.S. trial of nerve-rerouting procedure.**
Science (New York, N.Y.) 2010 Nov 5; 330(6005): 741

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

---

**Document 32**
Hooper, Carwyn Rhys

**Ancillary care duties: the demands of justice.**

**Abstract:** Ancillary care is care that research participants need that is not essential to make the research safe or
scientifically valid and is not needed to remedy injuries that eventuate as a result of the research project itself. Ancillary care duties have recently been defended on the grounds of beneficence, entrustment, utility and consent. Justice has also been mentioned as a possible basis of ancillary care duties, but little attention has been paid to this approach. In this paper, the author seeks to rectify this omission by arguing that ancillary care duties can be based on a principle of justice as rectification.

Document 33

Rid, Annette; Emanuel, Ezekiel J; Wendler, David

Evaluating the risks of clinical research.


Abstract: The ethical appropriateness of clinical research depends on protecting participants from excessive risks. Yet no systematic framework has been developed to assess research risks, and as a result, investigators, funders, and review boards rely only on their intuitive judgments. Because intuitive judgments of risk are subject to well-documented cognitive biases, this approach raises concern that research participants are not being adequately protected. To address this situation, we delineate a method called the systematic evaluation of research risks (SERR), which evaluates the risks of research interventions by comparing these interventions with the risks of comparator activities that have been deemed acceptable. This method involves a 4-step process: (1) identify the potential harms posed by the proposed research intervention; (2) categorize the magnitude of the potential harms into 1 of 7 harm levels on a harm scale; (3) quantify or estimate the likelihood of each potential harm; and (4) compare the likelihood of each potential harm from the research intervention with the likelihood of harms of the same magnitude occurring as a result of an appropriate comparator activity. By explicitly delineating, quantifying, and comparing the risks of research interventions with the risks posed by appropriate comparator activities, SERR offers a way to minimize the influence of cognitive biases on the evaluation of research risks and thereby better protect research participants from excessive risks.

Document 34

Litton, Paul; Miller, Franklin G

What physician-investigators owe patients who participate in research.


Abstract: Grace to the creativity of surgeons and the introduction of new technologies, second half of the XXth century opened the era of innovations and decisive progress. At the same time, however, is born the feeling of distrust and claiming which has come with the graving and threatening juridiciarisation. The evolution of complex structures of our society joined the ingenuity researchers unlimited makes formal law and the legal framework constantly to adapt oneself to circumstances. In the field of surgery, it's necessary to make work in integrity the innovation and protection at the patient's and their dignity. The legal framework that governs today innovation in surgery must still to go further and will precise. Dignity, compelling paradigm for all those who seek to better understand and better protect human starred as impassable limit any search and any experimentation. To make this chapter more alive, we have supplemented it and illustrated by the testimony some of the most fruitful French last years innovative in order to enrich our thinking of the fruit of their large and brilliant experience.
Document 36
Johnson, Jane; Rogers, Wendy; Lotz, Mianna; Townley, Cynthia; Meyerson, Denise; Tomossy, George
**Ethical challenges of innovative surgery: a response to the IDEAL recommendations.**
Lancet 2010 Sep 25; 376(9746): 1113-5

Document 37
Angelos, Peter
**The ethical challenges of surgical innovation for patient care.**
Lancet 2010 Sep 25; 376(9746): 1046-7

Document 38
Parker, C
**The moral primacy of the human being.**
Journal of medical ethics 2010 Sep; 36(9): 563-6
**Abstract:** Can the view that medical science is more important than the individual properly persuade recruitment to trials? This paper considers the nature and interests of the person and their relationships to the concepts of science and society; and analyses a conception of value used to balance the interests of science and research subjects. The implications of arguments opposing the primacy of the individual are set out to indicate their implausibility; while the primacy principle is described to show its necessity in any moral society. Finally, the importance of fully informed consent to participate is explained with the requirement that the individual human life provide the criteria of moral value for human life.

Document 39
Perales, Alberto
**[Reflections about research ethics in humans]. = Reflexiones sobre ética de investigación en seres humanos.**
Revista peruana de medicina experimental y salud pública 2010 Sep; 27(3): 438-42
**Abstract:** In order to propose the necessary moral reflection about the personal responsibility that each researcher assumes when he performs scientific research in human beings, an essay of moral and scientific themes is presented, using information from the relevant scientific and ethical literature. Around the concepts of heteronymous and autonomous ethics, it is proposed that ultimately and beyond informed consent and training courses on research ethics, the behavior of the researcher will depend on his/her own moral responsibility, tested in different situational contexts. Two explanatory models are used in order to understand this dynamic, the one of normality in mental health and the one of moral development of men. We conclude that the research process in human beings is a scientific and moral activity that, depending in various situations of conflicts of interest, will always test the researcher's moral controls.

Document 40
Diller, Lawrence
100 years later, the Flexner report is still relevant.
The Hastings Center report 2010 Sep-Oct; 40(5): 49

Georgetown users check Georgetown Journal Finder for access to full text

Meyer, Michelle N
Against one-size-fits-all research ethics.
The Hastings Center report 2010 Sep-Oct; 40(5): 10-1

Georgetown users check Georgetown Journal Finder for access to full text

Ripley, Elizabeth; Macrina, Francis; Markowitz, Monika; Gennings, Chris
Who's doing the math? Are we really compensating research participants?
Journal of empirical research on human research ethics : JERHRE 2010 Sep; 5(3): 57-65
Abstract: Although compensation for expenses to participants in research projects is considered important and the primary reason for paying, there is no evidence to support that investigators and IRB members actually calculate participant cost. Payment recommendations for six hypothetical studies were obtained from a national survey of IRB chairpersons (N = 353) and investigators (N = 495). Survey respondents also recommended payment for specific study procedures. We calculated participant cost for the six hypothetical cases both by procedures and by time involvement. A large percentage recommended only token payments for survey, registry, and medical record review studies. Most chose payment for pharmaceutical studies but the recommended payment did not compensate for calculated costs. Results suggest that compensation and reimbursement as the primary reasons for paying research participants may not match actual practice.

Georgetown users check Georgetown Journal Finder for access to full text

Educational advantage.
Abstract: This issue examines topics relevant to the effects of communicating disclosure risk to participants in survey research, managing genetic data, paying research participants, and evaluating institutional research ethics. Educational activities are presented that will enable readers to consolidate their knowledge and understanding of these topics.

Georgetown users check Georgetown Journal Finder for access to full text

Dr. Karola Messner Foundation.

Georgetown users check Georgetown Journal Finder for access to full text

Baerlocher, Mark O; Detsky, Allan S
Performing socially sensitive research in the 21st century.
Valdman, Mikhail

**On the morality of guinea-pig recruitment**

Bioethics 2010 July; 24(6): 287-294

**Abstract:** Analyzing William Beaumont's relationship with his experimental subject, Alexis St. Martin, this article demonstrates how the "research ethics" of ante-bellum America were predicated on models of employment, servitude, and labor. The association between Beaumont and St. Martin drew from and was understood in terms of the ideas and practices of contract labor, informal domestic servitude, indentures, and military service. Beaumont and St. Martin lived through an important period of transition in which personal master-servant relations existed alongside the "free" contract labor of market capitalism. Their relationship reflected and helped constitute important developments in nineteenth-century American labor history.

Green, Alexa

**Working ethics: William Beaumont, Alexis St. Martin, and medical research in ante-bellum America.**

Bulletin of the history of medicine 2010 Summer, 84(2): 193-216

**Abstract:** Analyzing William Beaumont's relationship with his experimental subject, Alexis St. Martin, this article demonstrates how the "research ethics" of ante-bellum America were predicated on models of employment, servitude, and labor. The association between Beaumont and St. Martin drew from and was understood in terms of the ideas and practices of contract labor, informal domestic servitude, indentures, and military service. Beaumont and St. Martin lived through an important period of transition in which personal master-servant relations existed alongside the "free" contract labor of market capitalism. Their relationship reflected and helped constitute important developments in nineteenth-century American labor history.

Sharkey, Kerith; Savulescu, Julian; Aranda, Sanchia; Schofield, Penelope

**Clinician gate-keeping in clinical research is not ethically defensible: an analysis.**


**Abstract:** Clinician gate-keeping is the process whereby healthcare providers prevent access to eligible patients for research recruitment. This paper contends that clinician gate-keeping violates three principles that underpin international ethical guidelines: respect for persons or autonomy; beneficence or a favourable balance of risks and potential benefits; and justice or a fair distribution of the benefits and burdens of research. In order to stimulate further research and debate, three possible strategies are also presented to eliminate gate-keeping: partnership with professional researchers; collaborative research design and clinician education.

Chahal, Manik

**Off-trial access to experimental cancer agents for the terminally ill: balancing the needs of individuals and society.**


**Abstract:** The development of cancer therapies is a long and arduous process. Because it can take several years for a cancer agent to pass clinical testing and be approved for use, terminal cancer patients rarely have the time to see these experimental therapies become widely available. For most terminal cancer patients the only opportunity they have to access an experimental drug that could potentially improve their prognosis is by joining a clinical trial. Unfortunately, several aspects of clinical trial methodology that are set in place in order to optimise drug development for the benefit of future generations of cancer patients, pose significant limitations to current patient participation. Therefore, several terminal cancer patients believe that they should have the right to access
experimental agents that have passed initial safety testing without having to participate in clinical trials. However, granting off-trial access to patients could be detrimental to the scientific process of drug development, and thus could pose significant risks to the health of future patients relying on sound research. Examining this matter through two divergent ethical lenses, rights-based ethics and communitarian ethics, may provide new insight into the issues surrounding the balance between the autonomous rights of current terminal cancer patients, and the needs of future patients and the values of society.

Document 50

Sonderholm, Jorn

A theoretical flaw in the advance market commitment idea.


Abstract: Infectious and parasitic diseases cause massive health problems in the developing world. Research and development of drugs for diseases that mainly affect poor people in developing countries is limited. The advance market commitment (AMC) idea is an incentivising mechanism for research and development of drugs for neglected diseases. Discussion of the AMC idea is of renewed interest given the launch in June 2009 of the first AMC. This pilot AMC is designed to, among other things, test the idea for potential future applications. This paper is a critique of the AMC idea. It seeks to show that the idea has a hitherto unrecognised theoretical flaw that should make policymakers and donors hesitant to embrace future applications of the idea.

Document 51

Foster, Susan

The role of patients and patient advocacy groups in educating patients on the importance of legitimate scientific research.

The American journal of bioethics : AJOB 2010 May ; 10(5): 49

Document 52

Wanner, Florian

[Confidential medical research] = Die vertrauensärztliche Untersuchung.

Schweizer Archiv für Tierheilkunde 2010 Apr ; 152(4): 210-1, 212-3

Document 53

Endacott, Ruth; Benbenishty, Julie; Seha, Myriam

Challenges and rewards in multi-national research.


Document 54

Maloney, Dennis M.
In court: Research subject claims emotional distress
Georgetown users check Georgetown Journal Finder for access to full text

Document 55
Maloney, Dennis M.
Research subject safety and "adaptive design" studies
Georgetown users check Georgetown Journal Finder for access to full text

Document 56
Maloney, Dennis M.
New regulations on reporting falsification of research data
Georgetown users check Georgetown Journal Finder for access to full text

Document 57
Axelsson, Christen Kirk
[To colleagues, medical associations and the Danish Medical Society: Clinical research needs help] = Til kolleger, lægevidenskabelige selskaber og Lægeforeningen: Klinisk forskning traenger til hjælp.
Ugeskrift for læger 2010 March 22; 172(12): 985; author reply 985
Georgetown users check Georgetown Journal Finder for access to full text

* Document 58
Maloney, Dennis M.
In court: former research subject seeks monetary damages
Human Research Report 2010 March; 25(3): 10
Georgetown users check Georgetown Journal Finder for access to full text

Document 59
Maloney, Dennis M.
Revised guidance for safer and more ethical research
Georgetown users check Georgetown Journal Finder for access to full text

Document 60
Zealley, I.A.
RE: CT before lumbar puncture in meningitis—what every radiology trainee should know.
Clinical Radiology 2010 March; 65(3): 257; author reply 257-258
Testing times for clinical research.
Craven, Rebecca
Lancet Neurology 2010 February; 9(2): 144-145

The exceptional ethics of the investigator-subject relationship.
Sachs, Benjamin

Clinical research in context: reexamining the distinction between research and practice.
Anderson, James A.

An investigation of patients' motivations for their participation in genetics-related research.
Hallowell, N.; Cooke, S.; Crawford, G.; Lucassen, A.; Parker, M.; Snowdon, C.
experiences. Findings: Interviewees gave a range of explanations for research participation. These were categorised as (a) social—research participation benefits the wider society by progressing science and improving treatment for everyone; (b) familial—research participation may improve healthcare and benefit current or future generations of the participant's family; and (c) personal—research participation provides therapeutic or non-therapeutic benefits for oneself. CONCLUSIONS: We discuss the distinction drawn between motives for research participation focused upon self (personal) and others (familial/social), and observe that personal, social and familial motives can be seen as interdependent. For example, research participation that is undertaken to benefit others, particularly relatives, may also offer a number of personal benefits for self, such as enabling participants to feel that they have discharged their social or familial obligations. We argue for the need to move away from simple, static, individualised notions of research participation to a more complex, dynamic and inherently social account.

Georgetown users check Georgetown Journal Finder for access to full text

* Book Document 65
Hughes, Alain E., ed.
SCIENTIFIC AND ETHICAL APPROACHES FOR OBSERVATIONAL EXPOSURE STUDIES

* Book Document 66
Lo, Bernard
ETHICAL ISSUES IN CLINICAL RESEARCH: A PRACTICAL GUIDE
Call number: R853 .C55 L6 2010

* Book Document 67
EUROPEAN TEXTBOOK ON ETHICS IN RESEARCH
Call number: R853 .H8 E866 2010

* Book Document 68
Speid, Lorna
CLINICAL TRIALS: WHAT PATIENTS AND VOLUNTEERS NEED TO KNOW
Call number: R853 .C55 S625 2010

* Article Document 69
McKenzie, Joanne E.; Herbison, G. Peter; Roth, Paul; Paul, Charlotte
Obstacles to researching the researchers: a case study of the ethical challenges of undertaking methodological research investigating the reporting of randomised controlled trials.
Trials 2010; 11: 28
Abstract: Recent cohort studies of randomised controlled trials have provided evidence of within-study selective reporting bias; where statistically significant outcomes are more likely to be more completely reported compared to non-significant outcomes. Bias resulting from selective reporting can impact on meta-analyses, influencing the conclusions of systematic reviews, and in turn, evidence based clinical practice guidelines. In 2006 we received funding to investigate if there was evidence of within-study selective reporting in a cohort of RCTs submitted to New Zealand Regional Ethics Committees in 1998/99. This research involved accessing ethics applications, their amendments and annual reports, and comparing these with corresponding
publications. We did not plan to obtain informed consent from trialists to view their ethics applications for practical and scientific reasons. In November 2006 we sought ethical approval to undertake the research from our institutional ethics committee. The Committee declined our application on the grounds that we were not obtaining informed consent from the trialists to view their ethics application. This initiated a seventeen month process to obtain ethical approval. This publication outlines what we planned to do, the issues we encountered, discusses the legal and ethical issues, and presents some potential solutions. DISCUSSION AND CONCLUSION: Methodological research such as this has the potential for public benefit and there is little or no harm for the participants (trialists) in undertaking it. Further, in New Zealand, there is freedom of information legislation, which in this circumstance, unambiguously provided rights of access and use of the information in the ethics applications. The decision of our institutional ethics committee defeated this right and did not recognise the nature of this observational research. Methodological research, such as this, can be used to develop processes to improve quality in research reporting. Recognition of the potential benefit of this research in the broader research community, and those who sit on ethics committees, is perhaps needed. In addition, changes to the ethical review process which involve separation between those who review proposals to undertake methodological research using ethics applications, and those with responsibility for reviewing ethics applications for trials, should be considered. Finally, we contend that the research community could benefit from quality improvement approaches used in allied sectors.

Georgetown users check Georgetown Journal Finder for access to full text

*   Article Document 70
Dyer, Clare
Patients to be asked whether thier records can be used for research [news]
British Medical Journal 2009 December 5; 339(7733): 1277
Georgetown users check Georgetown Journal Finder for access to full text

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

*   Article Document 71
Weber, Anne M
Response to Wall and Brown: "Commercial pressures and professional ethics: troubling revisions to the recent ACOG Practice Bulletins on surgery for pelvic organ prolapse".
International urogynecology journal and pelvic floor dysfunction 2009 Dec ; 20(12): 1523; author reply 1525
Georgetown users check Georgetown Journal Finder for access to full text

*   Article Document 72
Lawrence, Hal C 3rd.
Comments on Wall and Brown: "Commercial pressures and professional ethics: troubling revisions to the recent ACOG Practice Bulletins on surgery for pelvic organ prolapse".
International urogynecology journal and pelvic floor dysfunction 2009 Dec ; 20(12): 1519-20; author reply 1521-2
Georgetown users check Georgetown Journal Finder for access to full text

*   Article Document 73
Sabisch, Katja
Abstract: This paper deals with the problem of representing human subjects in experimental records and focuses the early experimentation on human beings between 1750 and 1840. Unlike the scientific fragmentation of the body since
1840, which coincides with a specific technique of writing down experiments on human subjects by making them disappear behind numbers and charts, a close reading of different experimental records before the 'vivisectional turn' shows the status of the experimental subject as a witness or even as an agreer. Based on the assumption that the individual played a crucial role in representing experimental practices until the middle of the nineteenth century, the paper wants to point out how this was linked to the discursive practice of citation, legitimation, and affirmation.

Georgetown users check Georgetown Journal Finder for access to full text

---

**Document 74**

Grady, Denise

**Studies question using cement for spine fractures**

New York Times 2009 August 6; p. A18

[http://www.nytimes.com](http://www.nytimes.com) (link may be outdated)

---

**Document 75**

Kolata, Gina

**Lack of study volunteers is said to hobble fight against cancer**

New York Times 2009 August 3; p. A1, A14

[http://www.nytimes.com](http://www.nytimes.com) (link may be outdated)

---

**Document 76**

Guillemin, Marilys; Heggen, Kristin

**Rapport and respect: negotiating ethical relations between researcher and participant**

Medicine, Health Care, and Philosophy 2009 August; 12(3): 291-299

**Abstract:** Qualitative research is largely dependent on building good interpersonal relations between researcher and participant. This is necessary for generating rich data, while at the same time ensuring respect is maintained between researcher and participant. We argue for a better understanding of researcher-participant relations in research practice. Codes of ethics, although important, do not address these kinds of ethical challenges. Negotiating the ethical relations between researcher and participant is paramount in maintaining ethical rigour in qualitative research. In this paper we propose concepts that can assist in understanding how the ethics of research relations are negotiated in practice; the 'zone of the untouchable' from the Danish philosopher, Løgstrup, is combined with the notion of 'ethical mindfulness'. We argue how and why these concepts in tandem can heighten awareness and offer ways to address the ethically important moments in research.

Georgetown users check Georgetown Journal Finder for access to full text

[http://www.springerlink.com/content/102960/](http://www.springerlink.com/content/102960/) (link may be outdated)

---

**Document 77**

Motluk, Alison

**Occupation: lab rat**

New Scientist 2009 July 25-31; 203(2718): 41-43

Georgetown users check Georgetown Journal Finder for access to full text
Document 78
Watts, Geoff
Cutting truths
BMJ: British Medical Journal 2009 July 11; 339(7712): 74-75

Georgetown users check Georgetown Journal Finder for access to full text

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

Document 79
O'Dowd, Adrian
Doctors back new guidance on using patients' records [news]

Georgetown users check Georgetown Journal Finder for access to full text

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

Document 80
Schaefer, G. Owen; Emanuel, Ezekiel J.; Wertheimer, Alan
The obligation to participate in biomedical research.

Abstract: The current prevailing view is that participation in biomedical research is above and beyond the call of duty. While some commentators have offered reasons against this, we propose a novel public goods argument for an obligation to participate in biomedical research. Biomedical knowledge is a public good, available to any individual even if that individual does not contribute to it. Participation in research is a critical way to support an important public good. Consequently, all have a duty to participate. The current social norm is that individuals participate only if they have a good reason to do so. The public goods argument implies that individuals should participate unless they have a good reason not to. Such a shift would be of great aid to the progress of biomedical research, eventually making society significantly healthier and longer lived.

Georgetown users check Georgetown Journal Finder for access to full text

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

Document 81
Greece. National Bioethics Commission
A Guide for research ethics committees for biological research (RECs)

http://www.bioethics.gr/media/pdf/recommendations/guide.pdf (link may be outdated)

Document 82
Kmietowicz, Zosia
Website captures people's experiences of clinical trials [news]
BMJ: British Medical Journal 2009 June 27; 338(7710): 1520

Georgetown users check Georgetown Journal Finder for access to full text
Sheather, Julian

**Who would want to be medicine's sacrificial lamb?**

BMJ: British Medical Journal 2009 June 20; 338(7709): 1503

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

---

Greece. National Bioethics Commission

**Template of Code of Research Ethics for Biological Sciences**


---

Bavdekar, S.B.; Thatte, U.M.

**Compensation for research-related injury.**


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

---

Yarborough, Mark; Fryer-Edwards, Kelly; Geller, Gail; Sharp, Richard R.

**Transforming the culture of biomedical research from compliance to trustworthiness: insights from nonmedical sectors.**

Academic Medicine 2009 April; 84(4): 472-477

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

---

Markestad, Trond

[Use of the dataset "The Visible Human Project" in research] = Bruk av datasettet "The Visible Human Project" i forskning.

Tidsskrift for den Norske lægeforening : tidsskrift for praktisk medicin, ny række 2009 March 12; 129(6): 529-530

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

---

Dupree, Claretta Yvonne
Document 89
Jansen, Lynn A; Wall, Steven
**Paternalism and fairness in clinical research**
Bioethics 2009 March; 23(3): 172-182

*Abstract*: In this paper, we defend the ethics of clinical research against the charge of paternalism. We do so not by denying that the ethics of clinical research is paternalistic, but rather by defending the legitimacy of paternalism in this context. Our aim is not to defend any particular set of paternalistic restrictions, but rather to make a general case for the permissibility of paternalistic restrictions in this context. Specifically, we argue that there is no basic liberty-right to participate in clinical research and that considerations of distributive fairness justify some paternalistic protections of research subjects.

Document 90
Chan, Sarah; Harris, John
**Free riders and pious sons—why science research remains obligatory**
Bioethics 2009 March; 23(3): 161-171

*Abstract*: John Harris has previously proposed that there is a moral duty to participate in scientific research. This concept has recently been challenged by Iain Brassington, who asserts that the principles cited by Harris in support of the duty to research fail to establish its existence. In this paper we address these criticisms and provide new arguments for the existence of a moral obligation to research participation. This obligation, we argue, arises from two separate but related principles. The principle of fairness obliges us to support the social institutions which sustain us, of which research is one; while the principle of beneficence, or the duty of rescue, imposes upon us a duty to prevent harm to others, including by supporting potentially beneficial, even life-saving research. We argue that both these lines of argument support the duty to research, and explore further aspects of this duty, such as to whom it is owed and how it might be discharged.

Document 91
Hoggard, N.; Darwent, G.; Capener, D.; Wilkinson, I.D.; Griffiths, P.D.
**The high incidence and bioethics of findings on magnetic resonance brain imaging of normal volunteers for neuroscience research**
Journal of Medical Ethics 2009 March; 35(3): 194-199

*Abstract*: BACKGROUND: We were finding volunteers for functional magnetic resonance imaging studies with abnormalities requiring referral surprisingly frequently. The bioethics surrounding the incidental findings are not straightforward and every imaging institution will encounter this situation in their normal volunteers. Yet the implications for the individuals involved may be profound. Should all participants have review of their imaging by an expert and who should be informed? METHODS: The normal volunteers that were imaged with magnetic resonance (MR) which were reviewed by a consultant neuroradiologist. All participants completed a volunteer consent form in addition to a standard departmental MR safety screening form. The volunteer screening form requires the general practitioner details to be completed and asks the participant to consider closely the possibility and implications of finding an unexpected but potentially serious abnormality before signing. RESULTS: 525 different individuals were
scanned as normal volunteers, the mean age was 35-years and 330 were males. Of these 525, 46 had definite significant abnormalities (8.8%), mean age 50-years. CONCLUSION: We have found a high rate of incidental abnormalities amongst individuals participating in imaging studies at our institution. It is our current practice to inform the research study participant of the findings, counsel them and inform their primary care physician. We think that it is advisable for researchers utilising MR imaging of the brain to have access to trained neuroradiologists, a protocol in place to deal with this problem and take consent in a way that allows the participant to realise the possibility of an abnormal finding.

Georgetown users check Georgetown Journal Finder for access to full text

http://jme.bmj.com (link may be outdated)
Review of policies for injuries to research participants in India.
Thatte, U.M.; Kulkarni-Munshi, R.; Kalekar, S.A.
Journal of Medical Ethics 2009 February; 35(2): 133-139

Abstract: BACKGROUND: As there is little Indian data about severity, frequency and types of research related injuries, costs involved and policies regarding compensation, this study was conducted to review the present Indian scenario. METHODS: The study was carried out in three parts; a questionnaire-based survey, in-depth interviews, and a review of informed consent and insurance documents of projects submitted to three ethics committees. RESULTS: 47% of investigators were either unaware of, or had not understood, the legal requirements and depended on sponsors to manage these issues, whereas 74% of ethics committee members were aware of the requirements. Although 40% of investigators, 30% of ethics committee members and all sponsors had policies to manage compensation issues, these were mainly to provide immediate free medical care or reimbursement of expenses incurred for the acute management of an adverse event. Compensation for loss of time/wages, death, physical disability or long term incapacitation was not included. A review of informed consent and insurance documents showed that compensation issues were inadequately discussed, with only insurance certificates submitted to ethics committees. CONCLUSION: In India, there are no uniform policies and investigators are largely unaware of their responsibilities. Therefore, there is an urgent need to draft national guidelines regarding compensation for research injuries of research participants and highlight the responsibilities of each stakeholder. Potential research injuries should be categorised based on risk assessment, severity and seriousness of the injury. Further, it would be necessary to have arbitration committees to determine the extent of compensation. Training and awareness workshops for those involved in clinical research, including research participants, is also needed.

Georgetown users check Georgetown Journal Finder for access to full text

http://jme.bmj.com (link may be outdated)
Document 100
O'Meara, Alex
CHASING MEDICAL MIRACLES: THE PROMISE AND PERILS OF CLINICAL TRIALS
Call number: R853 .C56 C42 2009

Document 101
Fortin, Sabrina; Knoppers, Bartha Maria
Secondary uses of personal data for population research
Georgetown users check Georgetown Journal Finder for access to full text
http://www.gspjournal.com (link may be outdated)

Document 102
Lederer, Susan E.
The ethics of experimenting on human subjects
Call number: R724 .C3274 2009

Document 103
Council of Graduate Schools [CGS]
Global perspectives on research ethics and scholarly integrity

Document 104
John, Stephen
Is there an obligation to participate in medical research?
Call number: K3611 .I5 L558 2009

Document 105
Fisher, Johnna, ed.
Research with humans
Call number: R724 .B56 2009

Document 106
Steinbock, Bonnie; London, Alex John; Arras, John D., eds.

**Experimentation on human subjects**
Call number: R724 .E788 2009

---

Document 107

Dreifus, Claudia

**A conversation with: Mahmoud A. ElSohly**

[http://www.nytimes.com](http://www.nytimes.com) (link may be outdated)

---

Document 108

Dyer, Clare

**Charity sets up fund to defend researcher being sued for libel [news]**
BMJ: British Medical Journal 2008 December 6; 337(7682): 1313

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

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

---

Document 109

Raymond, J.; Long, H.

**Science and ethics, therapeutic misconception and mirage = Science et éthique, méprise et mirage thérapeutiques.**

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

---

Document 110

Czarkowski, Marek

**How to prevent hazards and to reduce risk in clinical trials? = Jak zapobiegac zagroeniom i ograniczac ryzyko w badaniach klinicznych?**
Polski Merkuriusz Lekarski 2008 December; 25(150): 534-538

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

---

Document 111

Christiansen, Stacy L.

**Ethical and legal guidance in biomedical publishing: the AMA manual of style, tenth edition.**
Chest 2008 December; 134(6): 1344-1346

Georgetown users check [Georgetown Journal Finder](http://www.bmj.com) for access to full text
* Document 112
Wang, Ruotao; Henderson, Gail E.
**Medical research ethics in China [comment]**
Lancet 2008 November 29-December 5; 372(9653): 1867-1868

Georgetown users check *Georgetown Journal Finder* for access to full text

http://www.thelancet.com/journals/lancet (link may be outdated)

* Document 113
Johansen, Maria Vang; Aagaard-Hansen, Jens; Riis, Povl
**Benefit—a neglected aspect of health research ethics.**
Danish Medical Bulletin 2008 November; 55(4): 216-218

Georgetown users check *Georgetown Journal Finder* for access to full text

* Document 114
Steinberg, David; Pomfret, E.A.
**A novel boundary issue: should a patient be an organ donor for their physician?**
Journal of Medical Ethics 2008 November; 34(11): 772-774

*Abstract:* It is argued that organ donation from a patient to the patient's physician is ethically dubious because donation decisions will be inappropriately influenced and the negative public perceptions will result in more harm than good. It is suggested that to protect the perception of the physician-patient relationship, avoid cynicism about medicine's attitude to patient welfare and maintain trust in the medical profession, a new professional boundary should be established to prevent physicians from receiving organs for transplantation donated by their patients.

Georgetown users check *Georgetown Journal Finder* for access to full text

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

* Document 115
Schroeder, Doris
**Double standards and benefit sharing: a response to Linda Barclay**
Monash Bioethics Review 2008 October; 27(4): 45-51

Georgetown users check *Georgetown Journal Finder* for access to full text

* Document 116
Barclay, Linda
**Exploitation and double standards in research in developed countries**
Monash Bioethics Review 2008 October; 27(4): 37-44

Georgetown users check *Georgetown Journal Finder* for access to full text

* Document 117
Cohen, Eric P.
HIPAA threatens clinical research.  
Georgetown users check Georgetown Journal Finder for access to full text

*  Article  Document 118
Rice, Todd W.  
How to do human-subjects research if you do not have an institutional review board 
Respiratory Care 2008 October; 53(10): 1362-1367
Georgetown users check Georgetown Journal Finder for access to full text

*  Article  Document 119
Lairumbi, Geoffrey Mbaabu; Molyneux, Sassy; Snow, Robert W.; Marsh, Kevin; Peshu, Norbert; English, Mike  
Promoting the social value of research in Kenya: examining the practical aspects of collaborative partnerships using an ethical framework. 
Social Science and Medicine 2008 September; 67(5): 734-747
Georgetown users check Georgetown Journal Finder for access to full text

*  Article  Document 120
Geissler, P. Wenzel; Kelly, Ann; Imoukhuede, Babatunde; Pool, Robert  
'He is now like a brother, I can even give him some blood'—relational ethics and material exchanges in a malaria vaccine 'trial community' in The Gambia. 
Social Science and Medicine 2008 September; 67(5): 696-707
Georgetown users check Georgetown Journal Finder for access to full text

*  Article  Document 121
Suenaga, Keiko  
Shomatsu Yokoyama, a physiologist who refused to conduct experiments on living human bodies [biography] 
Georgetown users check Georgetown Journal Finder for access to full text

*  Article  Document 122
Bambma, Deborah R.  
Supererogation in clinical research 
Medicine, Health Care, and Philosophy 2008 September; 11(3): 343-349  
Abstract: 'Supererogation' is the notion of going beyond the call of duty. The concept of supererogation has received scrutiny in ethical theory, as well as clinical bioethics. Yet, there has been little attention paid to supererogation in research ethics. Supererogation is examined in this paper from three perspectives: (1) a summary of two analyses of 'supererogation' in moral theory, as well as an examination as to whether acts of supererogation exist; (2) a discussion of supererogation in clinical practice, including arguments that both physicians and patients can practice acts of supererogation; (3) a discussion as to why researchers, qua researchers, are not routinely recognized to perform acts of supererogation, while at the same time the very nature of research subject participation involves supererogation. The article concludes by considering three examples of supererogation on the part of researchers,
with a plea that researchers' supererogatory actions be recognized as such.

**Document 123**
Ashwanden, Cordelia
_Ethics of research._
Journal of Renal Care 2008 September; 34(3): 111

**Document 124**
Sharav, Vera
_Profile: Vera Sharav. Interview by Charlie Schmidt_
Nature Biotechnology 2008 September; 26(9): 965

**Document 125**
Paul, G.
The remote prayer delusion: clinical trials that attempt to detect supernatural intervention are as futile as they are unethical
_Abstract: _Extreme rates of premature death prior to the advent of modern medicine, very low rates of premature death in First World nations with low rates of prayer, and the least flawed of a large series of clinical trials indicate that remote prayer is not efficacious in treating illness. Mass contamination of sample cohorts renders such clinical studies inherently ineffectual. The required supernatural and paranormal mechanisms render them implausible. The possibility that the latter are not benign, and the potentially adverse psychological impact of certain protocols, renders these medical trials unethical. Resources should no longer be wasted on medical efforts to detect the supernatural and paranormal._

**Document 126**
Shalowitz, D.I.; Miller, F.G.
The search for clarity in communicating research results to study participants
_Abstract: _Current guidelines on investigators' responsibilities to communicate research results to study participants may differ on (1) whether investigators should proactively re-contact participants, (2) the type of results to be offered, (3) the need for clinical relevance before disclosure, and (4) the stage of research at which results should be offered. Lack of consistency on these issues, however, does not undermine investigators' obligation to offer to disclose research results: an obligation rooted firmly in the principle of respect for research participants._
**Document 127**

Trommelmans, L.; Selling, J.; Dierickx, K.

**Ethical reflections on clinical trials with human tissue engineered products**


**Abstract:** Ex-vivo tissue engineering is an emerging medical technology. Its aim is to regenerate tissues and organs and to restore them to full physiological activity. Some clinical trials with human tissue engineered products (HTEPs) have been conducted and others will follow. These trials not only have to confirm the therapeutic value of the HTEP, they also have to provide insight in its regenerative activity, its safety and long-term effects. The development of these trials is aggravated by the complexity of the tissue engineering process and product. This paper investigates how this complexity influences the ethical conduct of clinical trials with HTEPs. We focus on the value and validity of the trial, the risk-benefit ratio and the protection of the trial participant. We argue that trials with HTEPs need a robust methodology. The risk-benefit ratio of a new HTEP must be determined and compared with available efficacious therapies. This requires the identification and minimisation of risks associated with tissue engineering. Finally a process as complex as tissue engineering presents serious challenges for the informed consent process, and for the protection of the trial participant during and after the trial.

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

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

---

**Document 128**

Kerrison, Susan; Laws, Sophie; Cane, Mary; Thompson, Alan

**The patient's experience of being a human subject.**

Journal of the Royal Society of Medicine 2008 August; 101(8): 416-422

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

---

**Document 129**

Thornton, H.

**Clinical trials—a brave new partnership: a new doctor-patient working relationship in research.**


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

---

**Document 130**

Bossuyt, Xavier; Louche, Céline; Wiik, Allan

**Standardisation in clinical laboratory medicine: an ethical reflection.**

Annals of the Rheumatic Diseases 2008 August; 67(8): 1061-1063

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

---

**Document 131**

Wandall, Hilary M.; Halpern, Scott D.

**Research recruitment via camouflaged sampling: addressing the legal and ethical aspects of privacy concerns**

Pharmacoepidemiology and Drug Safety 2008 August; 17(8): 798-800

Georgetown users check [Georgetown Journal Finder](http://www.jmedethics.com) for access to full text
Document 132
Firkins, Lester
Setting research priorities: a layman's experience
BMJ: British Medical Journal 2008 July 12; 337(7661): 114
Georgetown users check Georgetown Journal Finder for access to full text

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

* Document 133
Giles, Jim
Chelation heart trial under spotlight
New Scientist 2008 July 12­18; 199(2664): 17
Georgetown users check Georgetown Journal Finder for access to full text

Document 134
Sheehan, Helen E.
Case studies in biomedical research ethics [review of Ethical Issues in International Biomedical Research: A Casebook, edited by James V. Lavery, Christine Grady, Elizabeth R. Wahl and Ezekiel J. Emanuel]
Indian Journal of Medical Ethics 2008 July­September; 5(3): 141-142
Georgetown users check Georgetown Journal Finder for access to full text

http://www.ijme.in (link may be outdated)

* Document 135
Ananthamurthy, Anuradha
Use of human tissues for research: ethical concerns
Indian Journal of Medical Ethics 2008 July­September; 5(3): 126-127
Georgetown users check Georgetown Journal Finder for access to full text

http://www.ijme.in (link may be outdated)

Document 136
DiMichele, D.M
Ethical considerations in clinical investigation: exploring relevance in haemophilia research.
Haemophilia 2008 July; 14 (Suppl 3): 122-129
Georgetown users check Georgetown Journal Finder for access to full text

Document 137
Ramirez, Amelie G.; Wildes, Kimberly; Talavera, Greg; Nápoles-Springer, Anna; Gallion, Kipling; Pérez-Stable, Eliseo J.
Clinical trials attitudes and practices of Latino physicians.
Document 138
Sancho García, S.
**Research in oncology: legal and ethical aspects.**
Clinical and Translational Oncology 2008 July; 10(7): 383-384

Document 139
Metge, Colleen J.
**Ethically speaking: issues in the postmarketing evaluation of pharmaceuticals.**
Clinical Therapeutics 2008 July; 30(7): 1342-1344

Document 140
Miller, Franklin G.; Pearson, Steven D.
**Coverage with evidence development: ethical issues and policy implications.**
Medical Care 2008 July; 46(7): 746-751

Document 141
Wendler, David; Krohmal, Benjamin; Emanuel, Ezekiel J.; Grady, Christine
**Why patients continue to participate in clinical research**
Archives of Internal Medicine 2008 June 23; 168(12): 1294-1299

**Abstract:** BACKGROUND: Clinical research exposes patient participants to unproved methods and research procedures in order to gather generalizable knowledge to benefit others. While some commentators argue that this process inappropriately exploits patient participants, there are few data available to evaluate this claim. METHODS: Human immunodeficiency virus (HIV)-infected individuals from Argentina, Brazil, and Thailand who had been participating in the Evaluation of Subcutaneous Proleukin (Interleukin-2) in a Randomized International Trial (ESPRIT) study for at least 6 months were invited to complete a self-administered survey on their experience and were asked why they continued to participate. The ESPRIT study is a phase 3, multinational, randomized trial comparing antiretroviral therapy plus interleukin 2 (IL-2) with antiretroviral therapy alone in individuals with HIV disease. RESULTS: From a list of 12 possible reasons regarding why patient participants continue to participate, 8 options were selected as "very important" by 75% or more of 582 respondents, including the possibility of benefiting personally and the potential to help others. When asked to indicate the most important reason from this list, respondents in the IL-2 arm (n = 292) selected (1) increasing their CD4 lymphocyte count (26%); (2) finding better treatments for patients with HIV in their home country (22%); and (3) getting IL-2 (12%). Respondents in the no-IL-2 arm (n = 290) selected (1) finding better treatments for patients with HIV in their home country (32%); (2) finding better treatments for HIV-infected patients in other countries (12%); and (3) increasing their CD4 lymphocyte count (11%). Also, 90% of the respondents indicated that participation in ESPRIT involved making a "major" or "moderate" contribution to society, and 84% felt "very" or "somewhat" proud to be making this contribution. CONCLUSIONS: Most respondents continue to participate in the ESPRIT study in hopes of benefiting personally. The majority also recognized that by participating in ESPRIT they were contributing to helping others; they experienced pride regarding this contribution and considered it an important reason to continue to participate. These results indicate that it is possible for patient participants, even those seeking treatment for a life-threatening illness, to recognize and embrace the goals of the research in which they participate. Future studies will be needed to determine to what
extent these findings generalize to other studies and other countries and what steps can help patient participants recognize and embrace the goals of clinical research.

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

Document 142
Mfutso-Bengo, Joseph; Ndebele, Paul; Masiye, Francis
Disseminating research results to research participants and their communities.
Malawi Medical Journal 2008 June; 20(2): 64-66

http://www.mmj.medcol.mw/ (link may be outdated)

Mathiesen, Tiit
Arguments against the proposed randomised trial (ARUBA)
Neuroradiology 2008 June; 50(6): 469-471

Document 144
Alpert, Joseph S.
Dealing with ethical conflicts in clinical research.
American Journal of Medicine 2008 June; 121(6): 457

Document 145
Maloney, Dennis M.
Human subject protections at risk from lack of funds
Human Research Report 2008 May; 23(5): 5

Document 146
Krystal, John H.; Carter, Cameron S.; Geschwind, Daniel; Manji, Hussein K.; March, John S.; Nestler, Eric J.; Zubieta, Jon-Kar; Chamey, Dennis S.; Goldman, David; Gur, Raquel E.; Lieberman, Jeffrey A.; Roy-Byrne, Peter; Rubinow, David R.; Anderson, Stewart A.; Barondes, Samuel; Berman, Karen F.; Blair, James; Braff, David L.; Brown, E. Sherwood; Calabrese, Joseph R.; Carlezon, William A. Jr.; Cook, Edwin H. Jr.; Davidson, Richard J.; Davis, Michael; Desimone, Robert; Drevets, Wayne C.; Duman, Ronald S.; Essock, Susan M.; Faraone, Stephen V.; Freedman, Robert; Friston, Karl J.; Gelernter, Joel; Geller, Barbara; Gill, Michael; Gould, Elizabeth; Grace, Anthony A.; Grillon, Christian; Gueorguieva, Ralitza; Hariri, Ahmad R.; Innis, Robert B.; Jones, Edward G.; Kleinman, Joel E.; Koob, George F.; Krystal, Andrew D.; Leibenluft, Ellen; Levinson, Douglas F.; Levitt, Pat R.; Lewis, David A.; Liberzon, Israel; Lipska, Barbara K.; Marder, Stephen R.; Markou, Athina; Mason, Graeme F.; McDougle, Christopher J.; McEwen, Bruce S.; McMahon, Francis J.; Meaney, Michael J.; Meltzer, Herbert Y.;
Merikangas, Kathleen R.; Meyer-Lindenberg, Andreas; Mimics, Károly; Monteggia, Lisa M.; Neumeister, Alexander; O'Brien, Charles P.; Owen, Michael J.; Pine, Daniel S.; Rapoport, Judith L.; Rauch, Scott L.; Robbins, Trevor W.; Rosenbaum, Jerrold F.; Rosenberg, David R.; Ross, Christopher A.; Rush, A. John; Sackeim, Harold A.; Sanacora, Gerard; Schatzberg, Alan F.; Shaham, Yavin; Siever, Larry J.; Sunderland, Trey; Tecott, Laurence H.; Thase, Michael E.; Todd, Richard D.; Weissman, Myrna M.; Yehuda, Rachel; Yoshikawa, Takeo; Young, Elizabeth A.; McCandless, R.

It is time to take a stand for medical research and against terrorism targeting medical scientists.

Biological Psychiatry 2008 April 15; 63(8): 725-727

Georgetown users check Georgetown Journal Finder for access to full text

Document 147

Greece. National Bioethics Commission

Opinion on research ethics in the biological sciences


http://www.bioethics.gr/media/pdf/recommendations/reseth-opin-en.pdf (link may be outdated)

Document 148

Hager-Theodorides, A.; Vidalis, T. (in collaboration with Sourlas, P.)

Greece. National Bioethics Commission

Report on research ethics in the biological sciences


http://www.bioethics.gr/media/pdf/reports/reseth-rep-en.pdf (link may be outdated)

Document 149

Elliott, Carl

Guinea-pigging. Pharmaceutical industry research is relying more and more on professional human subjects.

Minnesota Medicine 2008 April; 91(4): 32-36

Georgetown users check Georgetown Journal Finder for access to full text

Document 150

Stanta, G.; Cescato, A.; Barbazza, R.

Bioethical considerations on medical research using human tissues: the researcher's viewpoint

Pathologica 2008 April; 100(2): 67-75

Georgetown users check Georgetown Journal Finder for access to full text

Document 151

Danovitch, Gabriel M.

From Helsinki to Istanbul: what can the transplant community learn from experience in clinical research?

Nephrology, Dialysis, Transplantation 2008 April; 23(4): 1089-1092

Georgetown users check Georgetown Journal Finder for access to full text
* Document 152

Romain, Paul L.

**Access to clinical care via clinical trials: is it ethically possible?**

Nature Clinical Practice. Rheumatology 2008 April; 4(4): 166-167

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

---

* Document 153

Ram, Natalie

**Tiered consent and the tyranny of choice**

Jurimetrics 2008 Spring; 48(3): 253-284

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

---

* Document 154

O'Brien, James M., Jr.; Aberegg, Scott K.

**Our failure to report failure.**

Critical Care Medicine 2008 March; 36(3): 1002-1003

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

---

* Document 155

Nunes, Everardo Duarte

**Ethical aspects considered by researchers who use qualitative approaches in health.**

Ciência and Saúde Coletiva 2008 March-April; 13(2): 351-360

[http://www.scielo.br/](http://www.scielo.br/) (link may be outdated)

---

* Document 156

Schramm, Fermin Roland; Palácios, Marisa; Rego, Sergio

**O modelo bioético principalista para a análise da moralidade da pesquisa científica envolvendo seres humanos ainda é satisfatório? = Is the principlist model still satisfactory for the analysis of the morality of the scientific research involving human beings?**

Ciência and Saúde Coletiva 2008 March-April; 13(2): 361-370

[http://www.scielo.br/](http://www.scielo.br/) (link may be outdated)

---

* Document 157

van den Hoon-aard, Will C.

**Re-imagining the "subject:" conceptual and ethical considerations on the participant in qualitative research.**

Ciência and Saúde Coletiva 2008 March-April; 13(2): 371-379

[http://www.scielo.br/](http://www.scielo.br/) (link may be outdated)
Document 158

Jansen, Lynn A.

Doctor vs. scientist?
Hastings Center Report 2008 March-April; 38(2): 3

Abstract: Qualitative research poses ethical issues and challenges unique to the study of human beings. In developing the interpersonal relationship that is critical to qualitative research, investigator and participant engage in a dialogic process that often evokes stories and memories that are remembered and reconstituted in ways that otherwise would not occur. Ethical issues are raised when this relationship not only provides qualitative research data, but also leads to some degree of therapeutic interaction for the participant. The purpose of this article is to examine some of the controversies inherent in the researcher's dilemma when this occurs, set within the context of a nursing caring theory (Swanson), and the International Council of Nurses Code of ethics for nurses, which provides guidance on global nursing practice.

Document 159

Eide, Phyllis; Kahn, David

Ethical issues in the qualitative researcher-participant relationship
Nursing Ethics 2008 March; 15(2): 199-207

Abstract: Modern medicine is built on a long history of medical experimentation. Experiments in the past often exploited more vulnerable patients. Questionable ethics litter the history of medicine. Without such experiments, however, millions of lives would be forfeited. This paper asks whether all the “unethical” experiments of the past were unjustifiable, and do we still exploit the poorer members of the community today? It concludes by wondering if Harris is right in his advocacy of a moral duty to participate in medical research.

Document 160

Brazier, M.

Exploitation and enrichment: the paradox of medical experimentation
Journal of Medical Ethics 2008 March; 34(3): 180-183

Abstract: Modern medicine is built on a long history of medical experimentation. Experiments in the past often exploited more vulnerable patients. Questionable ethics litter the history of medicine. Without such experiments, however, millions of lives would be forfeited. This paper asks whether all the “unethical” experiments of the past were unjustifiable, and do we still exploit the poorer members of the community today? It concludes by wondering if Harris is right in his advocacy of a moral duty to participate in medical research.

Document 161

Groopman, Jerome

Buying a cure: what business know-how can do for disease.
New Yorker 2008 January 28: 38-43

Document 162

Groves, Trish
Mandatory disclosure of trial results for drugs and devices: new US law will require public posting of all the main results and data on harms
BMJ: British Medical Journal 2008 January 26; 336(7637): 170

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

* Document 163
Slater, Leo; Humphreys, Margaret
Parasites and progress: ethical decision-making and the Santee-Cooper Malaria study, 1944-1949.
Perspectives in Biology and Medicine 2008 Winter; 51(1): 103-120

* Document 164
Helgesson, Gert; Eriksson, S.
Against the principle that the individual shall have priority over science
Journal of Medical Ethics 2008 January; 34(1): 54-56
Abstract: This paper highlights a feature common to many ethical guidelines—namely, the idea that the interests of the individual shall always prevail over the interests of science and society. The paper presents how some major ethical guidelines treat the balancing of research interests against those of research subjects and spells out the difficulties in interpreting the principle of the primacy of the individual in a way that can be action-guiding. It suggests various alternative interpretations of the primacy of the individual and argues that they do not hold. Finally, the implications of this analysis for ethical guidelines are discussed.

* Document 165
Patenaude, Johane; Grant, Andrew M.; Xhignesse, Marianne; Leblanc, Frédéric; Corteau, Josiane
Evaluation of clinical innovation: a gray zone in the ethics of modern clinical practice?
JGIM: Journal of General Internal Medicine 2008 January; 23(Supplement 1): 27-31

* Document 166
Hawkins, Jennifer S. and Emanuel, Ezekiel, eds.
EXPLOITATION AND DEVELOPING COUNTRIES: THE ETHICS OF CLINICAL RESEARCH
Call number: R853 .C55 E97 2008

* Document 167
Rohn, Jennifer L.
EXPERIMENTAL HEART: A NOVEL
Call number: PS3618 .O486 E97 2009
* Document 168
National Catholic Bioethics Center [and] Catholic Medical Association
A CATHOLIC GUIDE TO ETHICAL CLINICAL RESEARCH
Call number: R725.56.C368 2008

* Document 169
Emanuel, Ezekiel J.; Grady, Christine; Crouch, Robert A.; Lie, Reidar K.; Miller, Franklin G.; and Wendler, David, eds.
THE OXFORD TEXTBOOK OF CLINICAL RESEARCH ETHICS
Call number: R853.H8 O96 2008

* Document 170
Pringle, Dorothy
How well protected are Canadian research participants: who knows?
Nursing Leadership 2008; 21(4): 1-5
Georgetown users check Georgetown Journal Finder for access to full text

* Document 171
Shamoo, Adil E.
The myth of equipoise in phase 1 clinical trials.
Georgetown users check Georgetown Journal Finder for access to full text

* Document 172
Emanuel, Ezekiel J., et al.
Addressing exploitation: reasonable availability versus fair benefits
Call number: R853.C55 E97 2008

* Document 173
Hawkins, Jennifer S.
Exploitation and placebo controls
Call number: R853.C55 E97 2008

* Document 174
Carse, Alisa L.; Little, Margaret Olivia
Exploitation and the enterprise of medical research
Siegel, Andrew W.

Kantian ethics, exploitation, and multinational clinical trials
Call number: R853.C55.E97.2008

Arneson, Richard J.

Broadly utilitarian theories of exploitation and multinational clinical research
Call number: R853.C55.E97.2008

Pogge, Thomas

Testing our drugs on the poor abroad
Call number: R853.C55.E97.2008

Wertheimer, Alan

Exploitation in clinical research
Call number: R853.C55.E97.2008

Hawkins, Jennifer S.

Research ethics, developing countries, and exploitation: a primer
Call number: R853.C55.E97.2008

May, William E.

Experimentation on human subjects
Call number: R725.56.M325.2008
Fox, Jacqueline

**Reinvigorating the concept of benefit: the failure of drug company-sponsored research on human subjects.**

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

---

King, Nancy M.P.; Churchill, Larry R.

**Assessing and comparing potential benefits and risks of harm**

Call number: [R853 .H8 O96 2008](#)

---

Miller, Franklin G.

**Recruiting research participants**

Call number: [R853 .H8 O96 2008](#)

---

Dickert, Neal; Grady, Christine

**Incentives for research participants**

Call number: [R853 .H8 O96 2008](#)

---

Levine, Robert J.

**The nature, scope, and justification of clinical research: what is research? who is a subject?**

Call number: [R853 .H8 O96 2008](#)

---

Tzamaloukas, Antonios H.; Konstantinov, Konstantin N.; Agaba, Emmanuel I.; Raj, Dominic S.C.; Murata, Glen H.; Glew, Robert H.

**Twenty-first Century ethics of medical research involving human subjects: achievements and challenges.**

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

---

Sampson, Heather
Research ethics and the ethics of research: should we offer clinical trial participation or clinical research partnership to oncology patients in the new millennium?
Call number: RC262 .E86 2008

Clinical research and the physician-patient relationship: the dual roles of physician and researcher
Call number: QH332 .C36 2008

Clinical trials
Call number: QH332 .C36 2008

Research ethics
Call number: QH332 .C36 2008

Ethical issues in research
Call number: RC346 .B479 2008

Diary of a lab rat
New Scientist 2007 December 8-14; 196(2633): 38-41
Georgetown users check Georgetown Journal Finder for access to full text

Ethical, legal, and policy issues: dominating the biospecimen discussion
Cancer Epidemiology, Biomarkers and Prevention 2007 December; 16(12): 2521-2523
Georgetown users check Georgetown Journal Finder for access to full text
Miller, Frances H.

Review of Carl H. Coleman, Jerry A. Menikoff, Jesse A. Goldner, and Nancy Neveloff Dubler (eds.), The Ethics and Regulation of Research with Human Subjects [book review]
American Journal of Bioethics 2007 December; 7(12): 57-58

Georgetown users check Georgetown Journal Finder for access to full text

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

Shamoo, Adil E.; Schwartz, Jack

Universal and uniform protections of human subjects in research
American Journal of Bioethics 2007 December; 7(12): 7-9

Georgetown users check Georgetown Journal Finder for access to full text

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

Klitzman, Robert; Albala, Ilene; Siragusa, Joseph; Nelson, Kristen N.; Appelbaum, Paul S.

The reporting of monetary compensation in research articles

Abstract: STUDY PARTICIPANT COMPENSATION IS OF increasing concern, yet few investigations have explored it; none have examined whether published journal articles report it. Medline searches for articles in six areas—HIV, substance abuse (heroin and cocaine), depression, essential hypertension, and cardiac surgery—reveal very low mention of payment (0–32.1%). Of 207 articles, only 13.5% mentioned financial compensation in any way, and only 11.1% listed amounts. Of the 207 studies, 92 involved more than minimal risk interventions, but were not more likely to mention compensation. Studies that included substance users were significantly more likely than others to mention payment (p < .001). These overall low rates are concerning as they can hamper evaluation of ethical issues, and impact study replicability. Publication requirements should consider discussion of compensation.

Georgetown users check Georgetown Journal Finder for access to full text

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

Qiu, Jane

To walk again
New Scientist 2007 November 10-16; 196(2629): 57-59

Georgetown users check Georgetown Journal Finder for access to full text

Schweigert, Francis J.

The priority of justice: a framework approach to ethics in program evaluation.
Evaluation and Program Planning 2007 November; 30(4): 394-399

Georgetown users check Georgetown Journal Finder for access to full text
* Document 199
Schwandt, Thomas A.
**Expanding the conversation on evaluation ethics.**
Evaluation and Program Planning 2007 November; 30(4): 400-403

* Document 200
Morris, Michael
**Foundation officers, evaluation, and ethical problems: a pilot investigation.**
Evaluation and Program Planning 2007 November; 30(4): 410-415

* Document 201
Rodi, Michael S.; Paget, Kathleen D.
**Where local and national evaluators meet: unintended threats to ethical evaluation practice.**

* Document 202
Kimmelman, Jonathan
**The therapeutic misconception at 25: treatment, research, and confusion**
Hastings Center Report 2007 November-December; 37(6): 36-42

**Abstract:** "Therapeutic misconception" has been misconstrued, and some of the newer, mistaken interpretations are troublesome. They exaggerate the distinction between research and treatment revealing problems in the foundations of research ethics and possibly weakening informed consent.

* Document 203
Liao, S. Matthew; Goldschmidt [Goldschmidt-Clermont], Pascal J.; Sugarman, Jeremy
**Ethical and policy issues relating to progenitor-cell-based strategies for prevention of atherosclerosis**
Journal of Medical Ethics 2007 November; 33(11): 643-646

**Abstract:** OBJECTIVE: To examine important ethical and societal issues relating to the use of progenitor-cell-based strategies for disease prevention, particularly atherosclerosis. BACKGROUND: Several nascent lines of evidence suggest the feasibility of using progenitor cells to reverse the health consequence of atherosclerosis. Such potential uses of progenitor cells are scientifically exciting, yet they raise important ethical and societal issues. METHOD: The Working Group on Ethics of Progenitor Cell-based Strategies for Disease Prevention met to discuss the relevant issues. Several drafts of a report were then circulated to the entire Working Group for comments until a consensus was reached. RESULTS: Scientific evidence suggests the appropriateness of using progenitor-cell-based strategies for some rare conditions involving atherosclerosis, but additional preclinical data are needed for other, more prevalent conditions before human trials begin. All such trials raise a set of ethical issues, especially since trials aimed at prevention rather than treatment may involve persons who do not yet have disease but will be exposed to the risks of interventions. In addition, enrolment in prevention trials may be hazardous and harmful if participants erroneously believe experimental interventions will necessarily prevent disease. Finally, given the high prevalence of atherosclerosis, there are some important public policy implications of taking such an approach to prevention,
including the sources of progenitor cells for such interventions as well as the allocation of health resources.

CONCLUSION: Potential uses of progenitor-cell-based strategies for preventing atherosclerosis must be considered in the context of a range of social and ethical issues.

http://www.jmedethics.com (link may be outdated)
* Document 209
Endacott, R.
Clinical research 2: legal and ethical issues in research.

Georgetown users check Georgetown Journal Finder for access to full text

* Document 210
Bramstedt, Katrina A.
Exploring the gap in healthcare for injured and uninsured research participants in the United States
Monash Bioethics Review 2007 July; 26(3): 11-20

Georgetown users check Georgetown Journal Finder for access to full text

* Document 211
Hyder, Adnan A.; Harrison, Rachel A.; Kass, Nancy; Maman, Suzanne
A case study of research ethics capacity development in Africa
Academic Medicine 2007 July; 82(7): 675-683

Georgetown users check Georgetown Journal Finder for access to full text

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

* Document 212
Shapshay, Sandra; Pimple, Kenneth D.
Participation in biomedical research is an imperfect moral duty: a response to John Harris
Journal of Medical Ethics 2007 July; 33(7): 414-417

Abstract: In his paper "Scientific research is a moral duty", John Harris argues that individuals have a moral duty to participate in biomedical research by volunteering as research subjects. He supports his claim with reference to what he calls the principle of beneficence as embodied in the "rule of rescue" (the moral obligation to prevent serious harm), and the principle of fairness embodied in the prohibition on "free riding" (we are obliged to share the sacrifices that make possible social practices from which we benefit). His view that biomedical research is an important social good is agreed upon, but it is argued that Harris succeeds only in showing that such participation and support is a moral good, among many other moral goods, while failing to show that there is a moral duty to participate in biomedical research in particular. The flaws in Harris's arguments are detailed here, and it is shown that the principles of beneficence and fairness yield only a weaker discretionary or imperfect obligation to help others in need and to reciprocate for sacrifices that others have made for the public good. This obligation is discretionary in the sense that the individuals are free to choose when, where, and how to help others in need and reciprocate for earlier sacrifices. That Harris has not succeeded in claiming a special status for biomedical research among all other social goods is shown here.

Georgetown users check Georgetown Journal Finder for access to full text

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

* Document 213
Lenzer, Jeanne
Nigeria files criminal charges against Pfizer
Butcher, James

**Clinical trials will suffer if electronic system is delayed**

BMJ: British Medical Journal 2007 June 2; 334(7604): 1132

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

---

Plemmons, Dena K.; Kalichman, Michael W.

**Reported goals for knowledge to be learned in responsible conduct of research courses**


**Abstract:** Education in responsible conduct of research (RCR) has been a required part of training for students on U. S. National Institutes of Health (NIH) training grants for over 15 years. However, there is little evidence of commonly accepted goals for RCR instruction, making it difficult to assess effectiveness. As part of a larger study examining RCR instructors’ goals for RCR education, this report focuses on those reported goals categorized as knowledge. To identify RCR instructors, e-mail requests were sent to the 116 recipients of NIH training grants awarded in 2000. Of 67 verified RCR instructors, 50 (75% response rate) from 37 different institutions were successfully interviewed. Despite a shared sense of the basics to be taught in RCR courses, these instructors were diverse in their views and understanding of goals for RCR education. This diversity suggests a challenge to be overcome not only for improving the effectiveness of RCR education, but also for attempts to assess that effectiveness.

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

---

Criner, Gerard J.

**Framing the forum: medical ethics in large-scale, interventional respiratory clinical trials.**


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

---

Simon, Alan E.; Wu, Albert W.; Lavori, Philip W.; Sugarman, Jeremy

**Preventive misconception: its nature, presence, and ethical implications for research.**

American Journal of Preventive Medicine 2007 May; 32(5): 370-374

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

---

Rahmahi, Ibrahim; El-Setouhy, Maged; Silverman, Henry

**Middle East Research Ethics Training Initiative: a program to enhance research ethics capacity in the Middle...**
**East [abstract]**
Eubios Journal of Asian and International Bioethics 2007 May; 17(3): 92

Georgetown users check [Georgetown Journal Finder](http://www.eubios.info/EJAIB52007.pdf) for access to full text

**Document 219**
Dalmacion, Godoffreda V.

**Ethical dilemmas in public health research [abstract]**
Eubios Journal of Asian and International Bioethics 2007 May; 17(3): 88

Georgetown users check [Georgetown Journal Finder](http://www.eubios.info/EJAIB52007.pdf) for access to full text

**Document 220**
Hewege, Suwin; Sumathipala, Athula; Siribaddana, Sisira; Lekamwattage, Maura; Athukorale, Manjula; Murray, Joanna; Prince, Martin

**Informed consent in Sri Lanka: review of research conducted in Sri Lanka to understand the process of informed consent process [abstract]**
Eubios Journal of Asian and International Bioethics 2007 May; 17(3): 83-84

Georgetown users check [Georgetown Journal Finder](http://www.eubios.info/EJAIB52007.pdf) for access to full text

**Document 221**
Working Group on Disaster Research and Ethics (WGDRE)

**Statement on ethical issues in disaster-related research - a developing world perspective (draft of 16 January 2007) [abstract]**
Eubios Journal of Asian and International Bioethics 2007 May; 17(3): 82-83

Georgetown users check [Georgetown Journal Finder](http://www.eubios.info/EJAIB52007.pdf) for access to full text

**Document 222**
Sumathipala, Athula

Working Group on Disaster Research and Ethics (WGDRE)

**Ethical issues in post disaster clinical interventions and research [abstract]**
Eubios Journal of Asian and International Bioethics 2007 May; 17(3): 82

Georgetown users check [Georgetown Journal Finder](http://www.eubios.info/EJAIB52007.pdf) for access to full text

**Document 223**
Bagheri, Alireza
**Externally-sponsored research in developing countries: a challenge for research ethics committees [abstract]**
Eubios Journal of Asian and International Bioethics 2007 May; 17(3): 81

Georgetown users check [Georgetown Journal Finder](http://www.eubios.info/EJAIB52007.pdf) for access to full text

http://www.eubios.info/EJAIB52007.pdf (link may be outdated)

---

Promta, Somparn
**What to be known and what to be unknown in biomedical research: a view from Buddhism [abstract]**
Eubios Journal of Asian and International Bioethics 2007 May; 17(3): 73

Georgetown users check [Georgetown Journal Finder](http://www.eubios.info/EJAIB52007.pdf) for access to full text

http://www.eubios.info/EJAIB52007.pdf (link may be outdated)

---

* Document 225

Singapore. Bioethics Advisory Committee
**Personal Information in Biomedical Research: A Report By the Bioethics Advisory Committee**

http://www.bioethics-singapore.org/resources/reports5.html (link may be outdated)

---

Aldhous, Peter
**Questions follow reports of stem cell diabetes cure**
New Scientist 2007 April 21-27; 194(2600): 13

Georgetown users check [Georgetown Journal Finder](http://www.eubios.info/EJAIB52007.pdf) for access to full text

---

Steffen, Christian
**The dilemma of approving antidotes.**
Toxicology 2007 April 20; 233(1-3): 13-19

Georgetown users check [Georgetown Journal Finder](http://www.eubios.info/EJAIB52007.pdf) for access to full text

---

* Document 228

Madsen, S.M.; Holm, S.; Riis, P.
**Attitudes towards clinical research among cancer trial participants and non-participants: an interview study using a grounded theory approach**
Journal of Medical Ethics 2007 April; 33(4): 234-240

**Abstract:** The attitudes of women patients with cancer were explored when they were invited to participate in one of three randomised trials that included chemotherapy at two university centres and a satellite centre. Fourteen patients participating in and 15 patients declining trials were interviewed. Analysis was based on the constant comparative method. Most patients voiced positive attitudes towards clinical research, believing that trials are necessary for further medical development, and most spontaneously argued that participation is a moral obligation. Most trial decliners, however, described a radical change in focus as they faced the actual personal choice. Almost no one got
an impression of clinical equipoise between treatments in the trials, and most patients expressed discomfort with randomisation. A patient's choice to participate was mainly determined by whether the primary focus was on treatment effect or on adverse effects. Both knowledge about and feelings towards trials originated mostly from the media, although paradoxically the media were largely seen as untrustworthy. Mistrust was shown towards the pharmaceutical industry, and although most patients originally trusted that doctors primarily pursued the interest of patients, they did not trust the adequacy of doctors or industry in maintaining self-regulation. Thus, public control measures were judged to be essential.

Georgetown users check Georgetown Journal Finder for access to full text

http://www.jmedethics.com (link may be outdated)
Abstract: John Harris suggests that participation in or support for research, particularly medical research, is a moral duty. One kind of defence of this position rests on an appeal to the past, and produces two arguments. The first of these arguments is that it is unfair to accept the benefits of research without contributing something back in the form of support for, or participation in, research. A second argument is that we have a social duty to maintain those practices and institutions that sustain us, such as those which contribute to medical knowledge. This argument is related to the first, but it does not rely so heavily on fairness. Another kind of defence of the duty to research rests on an appeal to the future benefits of research: research is an effective way to discharge a duty to rescue others from serious illness or death, therefore we have a duty to research. I suggest that all three of Harris' lines fail to provide a compelling duty to research and spell out why. Moreover, not only do the lines of argument fail in their own terms: in combination, they turn out to be antagonistic to the very position that Harris wants to defend. While it is not my intention here to deny that there might be a duty to research, I claim that Harris' argument for the existence of such a duty is not the best way to establish it.

Georgetown users check Georgetown Journal Finder for access to full text

* Article
Document 234
Bracken, Wendy; Simon, Gayle; Cox, Susan; McDonald, Michael; Fitzgerald, Maureen
Protecting researchers

Georgetown users check Georgetown Journal Finder for access to full text

* Article
Document 235
Special section of research agendas: ethical issues and empirical questions

Georgetown users check Georgetown Journal Finder for access to full text

* Article
Document 236
London, Alex John
Two dogmas of research ethics and the integrative approach to human-subjects research
Abstract: This article argues that lingering uncertainty about the normative foundations of research ethics is perpetuated by two unfounded dogmas of research ethics. The first dogma is that clinical research, as a social activity, is an inherently utilitarian endeavor. The second dogma is that an acceptable framework for research ethics must impose constraints on this endeavor whose moral force is grounded in role-related obligations of either physicians or researchers. This article argues that these dogmas are common to traditional articulations of the equipoise requirement and to recently articulated alternatives, such as the non-exploitation approach. Moreover, important shortcomings of these approaches can be traced to their acceptance of these dogmas. After highlighting these shortcomings, this article illustrates the benefits of rejecting these dogmas by sketching the broad outlines of an alternative called the "integrative approach" to clinical research.

Georgetown users check Georgetown Journal Finder for access to full text

* Article
Document 237
Blustein, J.
The history and moral foundations of human-subject research

Georgetown users check Georgetown Journal Finder for access to full text
Document 238
Spielman, Bethany
Faulty premise, premature conclusion: that money was extraneous to the research ethics of the TGN1412 study
Georgetown users check Georgetown Journal Finder for access to full text
http://bioethics.net (link may be outdated)

Document 239
Shamoo, Adil; Woeckner, Elizabeth
Ethical flaws in the TeGenero trial
Georgetown users check Georgetown Journal Finder for access to full text
http://bioethics.net (link may be outdated)

Document 240
Phillips, Trisha B.
Money, advertising and seduction in human subjects research
Georgetown users check Georgetown Journal Finder for access to full text
http://bioethics.net (link may be outdated)

Document 241
Hale, Benjamin
Risk, judgment and fairness in research incentives
American Journal of Bioethics 2007 February; 7(2): 82-83
Georgetown users check Georgetown Journal Finder for access to full text
http://bioethics.net (link may be outdated)

Emanuel, Ezekiel J.; Miller, Franklin G.
Money and distorted ethical judgments about research: ethical assessment of the TeGenero TGN1412 trial
American Journal of Bioethics 2007 February; 7(2): 76-81
Abstract: The recent TeGenero phase I trial of a novel monoclonal antibody in healthy volunteers produced a drastic inflammatory reaction in participants receiving the experimental agent. Commentators on the ethics of the research have focused considerable attention on the role of financial considerations: the for-profit status of the biotechnology company and Contract Research Organization responsible respectively for sponsoring and conducting the trial and the amount of monetary compensation to participants. We argue that these financial considerations are largely irrelevant and distort ethical appraisal of this tragic research. Except for administering the antibody to all 6 participants nearly simultaneously, the trial appears to fulfill all of the critical ethical requirements for clinical research—social value, scientific validity, fair subject selection, favorable risk-benefit ratio, independent review,
informed consent, and respect for enrolled participants.

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

Document 243
Weiss, Anthony P.
Measuring the impact of medical research: moving from outputs to outcomes

http://ajp.psychiatryonline.org (link may be outdated)

Document 244
Sofaer, N.; Jafarey, A.; Lei, R.P.; Zhang, X.; Wikler, D.
Unconditional compensation: reducing the costs of disagreement about compensation for research subjects.

http://www.emro.who.int/ (link may be outdated)

Document 245
Deming, Nicole; Fryer-Edwards, Kelly; Dudzinski, Denise; Starks, Helene; Culver, Julie; Hopley, Elizabeth; Robins, Lynne; Burke, Wylie
Incorporating principles and practical wisdom in research ethics education: a preliminary study
Academic Medicine 2007 January; 82(1): 18-23

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

Document 246
Maloney, Dennis M.
Agency’s human protection system has significant flaws

http://find.in.library.georgetown.edu (link may be outdated)

Document 247
Resnik, David B.
Intentional exposure studies of environmental agents on human subjects: assessing benefits and risks

http://find.in.library.georgetown.edu (link may be outdated)
Document 248
Edwards, Martin
CONTROL AND THE THERAPEUTIC TRIAL: RHETORIC AND EXPERIMENTATION IN BRITAIN, 1918-48
Call number: R853 .C55 E39 2007

* Document 249
Cheung, Philip
PUBLIC TRUST IN MEDICAL RESEARCH? ETHICS, LAW AND ACCOUNTABILITY
Call number: R724 .C474 2007

* Document 250
Leong, Stanley P.L., ed.
CANCER CLINICAL TRIALS: PROACTIVE STRATEGIES
Call number: RC267 .C347 2007

* Document 251
Lavery, James V.; Grady, Christine; Wahl, Elizabeth R.; and Emanuel, Ezekiel J., eds.
ETHICAL ISSUES IN INTERNATIONAL BIOMEDICAL RESEARCH: A CASEBOOK
Call number: R852 .E826 2007

* Document 252
Lafleur, William R.; Böhme, Gernot; and Shimazono, Susumu, eds.
DARK MEDICINE: RATIONALIZING UNETHICAL MEDICAL RESEARCH
Call number: R853 .H8 D37 2007

* Document 253
Gallin, John I. and Ognibene, Frederick P., eds.
PRINCIPLES AND PRACTICE OF CLINICAL RESEARCH
Call number: R850 .G35 2007

* Document 254
Lederer, Susan E.
Hollywood and human experimentation: representing medical research in popular film
Document 255
Panicola, Michael R.; Belde, David M.; Slosar, John Paul; Repenshek, Mark F.
**Medical research on humans**
Call number: R724 .I63 2007

Document 256
Ashcroft, Richard E.
**Scientific or social priorities for brain science?—making a difference.**
Nutrition and Health 200; 19(1-2): 135-137
Georgetown users check Georgetown Journal Finder for access to full text

Document 257
Morreim, E. Haavi
**A matter of obligation: physicians versus clinical investigators**
Call number: R725.57 .P588 2007

Document 258
Cherry, Mark J.; Iltis, Ana Smith
**Moral casuistry, medical research and innovation, and rabbinical decision-making**
Call number: R725.57 .P588 2007

Document 259
Lo, Bernard; Garan, Nesrin
**Historical perspective and evolving concerns for human research**
Call number: RC267 .C347 2007

Document 260
Leavitt, Frank J.
**How to save the world: alternatives to biomedical research**
In: Häyry, Matti; Takala, Tuia; Herissone-Kelly, Peter, eds. Ethics in Biomedical Research: International Perspectives. Amsterdam; New York: Rodopi, 2007: 193-211
Call number: R724 .E8445 2007

Document 261
de Castro, Leonardo D.
**Is there a duty to serve as research subjects?**
In: Häyry, Matti; Takala, Tuia; Herissone-Kelly, Peter, eds. Ethics in Biomedical Research: International Perspectives. Amsterdam; New York: Rodopi, 2007: 151-166
**Document 262**

Beecher, H.

*Ethics and clinical research. From the anaesthesia laboratory of the Harvard Medical School at the Massachusetts General Hospital. 1966*

International Anesthesiology Clinics 2007 Fall; 45(4): 65-78

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

**Document 263**

Pessini, Leo; Martin, Leonard M.

*Brazilian research ethics: a north-south dialogue aiming to build a new culture of respect*


Call number: [R724 .E8445 2007](#)

**Document 264**

Häyry, Matti

*Some current issues in the ethics of biomedical research and their background in the protection of the dignity and autonomy of the vulnerable*


Call number: [R724 .E8445 2007](#)

**Document 265**

Benatar, Solomon R.

*New perspectives on international research ethics*


Call number: [R724 .E8445 2007](#)

**Document 266**

Gasmelseed, Nagla

*Biomedical researches in Sudan*


Call number: [R854 .A5 G38 2007](#)

**Document 267**

Nussenblatt, Robert B.; Gottesman, Michael M.

*Rules to prevent conflict of interest for clinical investigators conducting human subjects research*


Call number: [R850 .G35 2007](#)
Kvochak, Patricia A.

**Legal issues**


Call number: R850.G35 2007

---

Grady, Christine

**Ethical principles in clinical research**


Call number: R850.G35 2007

---

Koren, Ahuva

**Benefits of conducting clinical trials in Israel for multinational life science companies**


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

---

LaFleur, William R.

**Refusing utopia's bait: research, rationalizations, and Hans Jonas**


Call number: R853.H8 D37 2007

---

Frewer, Andreas

**Medical research, morality, and history: the German journal Ethik and the limits of human experimentation**


Call number: R853.H8 D37 2007

---

Chalmers, Iain

**TGN1412 and The Lancet's solicitation of reports of phase I trials**


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

http://www.thelancet.com/journal (link may be outdated)
Watts, Geoff
Iain Chalmers: maverick master of medical evidence
Lancet 2006 December 23-2007 January 5; 368(9554): 2203
Georgetown users check Georgetown Journal Finder for access to full text

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

* Document 275
Sugarman, Jeremy; Levine, Carol; Bames, Michael R.; Holbrook, Joanna; Feild, John A.; Searls, David B.; Sanseau, Philippe; Ohresser, Marc; Olive, Daniel; Vanhove, Bernard; Watier, Hervé; Focosi, Daniele
Risk in drug trials [correspondence]
Lancet 2006 December 23-2007 January 5; 368(9554): 2205-2206
Georgetown users check Georgetown Journal Finder for access to full text

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

* Document 276
Groopman, Jerome
The right to a trial: should dying patients have access to experimental drugs?
New Yorker 2006 December 18: 40-47
Georgetown users check Georgetown Journal Finder for access to full text

* Document 277
Near-fatal flaw [news]
New Scientist 2006 December 16-22; 192(2582): 6
Georgetown users check Georgetown Journal Finder for access to full text

* Document 278
Toffoli, Luisa; Rudge, Trudy
Organizational predicaments: ethical conditions for nursing research
Journal of Advanced Nursing 2006 December; 56(6): 600-606
Georgetown users check Georgetown Journal Finder for access to full text

* Document 279
Ripley, Elizabeth B.D.; Macrina, Frank L.; Markowitz, Monika
Paying clinical research participants: one institution's research ethics committees' perspective
Abstract: REGULATORY GUIDELINES LEAVE determination of coercion and undue influence of research participants open to interpretation. A web-based survey was conducted of the research ethics committees members at Virginia Commonwealth University (VCU) to evaluate their perspectives on paying participants in clinical research via general questions, as well as 8 short cases involving hypertension placebo-controlled trials, a pilot exercise study, a survey of substance abusers, a healthy-volunteer pharmacokinetic study, a twin study involving DNA samples, and an asthma medication study in children. Research ethics committee members were asked to state
what payment they would consider appropriate for a given type of protocol. The results suggest that risk, time required, reimbursement for expenses, and inconvenience were important in determining appropriate payment, while income and funding source were not. The case studies revealed wide variation in recommended payments both within type of study and between studies.

* 
Document 280
Ripley, Elizabeth B.D.
**A review of paying research participants: it's time to move beyond the ethical debate**
*Abstract:* CURRENT REGULATORY GUIDELINES REQUIRE the ethical review committee to consider one question when evaluating payment: Is the payment to the participant undue or coercive? Although this is a seemingly simple question, determining appropriate payment involves a series of complex issues. There is limited empirical knowledge to assist with this determination and little consensus on which elements of a study should be considered in making these decisions. For example, should the culture of the study population or the potential risks and benefits of the research be considered in the selection of appropriate payment? Following a review of national and international guidelines, the concerns and benefits of paying research participants are presented, and prior ethical debate is outlined. The current research literature on the practice of paying participants and the impact of payment on participants and study integrity are reviewed. Finally, given continued debate with limited data to help determine best practices, a research agenda is proposed to assist in the development of an empirical basis to aid investigators and ethical review committees in making appropriate decisions about payment to research participants.

* 
Document 281
Pearson, Helen
**The bitterest pill**
Nature 2006 November 30; 444(7119): 532-533

* 
Document 282
Hall, Mark A.; Camacho, Fabian; Lawlor, Janice S.; Depuy, Venita; Sugarman, Jeremy; Weinfurt, Kevin
**Measuring trust in medical researchers**
Medical Care 2006 November; 44(11): 1048-1053

* 
Document 283
Murff, Harvey J.; Pichert, James W.; Byrne, Daniel W.; Hedstrom, Christa; Black, Margo; Churchill, Larry; Speroff, Ted
**IRB:Research participants safety and systems factors in general clinical research centers**
Ethics and Human Research 2006 November-December; 28(6): 8-14
Pearson, Helen

Missing results might have rung warning bell over trial drug
Nature 2006 October 19; 443(7113): 730

Georgetown users check Georgetown Journal Finder for access to full text

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

Ethique de la recherche et santé publique: où en est-on?, edited by C. Hervé, B.M. Knoppers, P.A. Molinari, G. Moutel, M.A. Grimaud [Ethics of research and public health: where are we?] [book review]
Les Cahiers du Comité Consultatif National d’Éthique pour les Sciences de la Vie et de la Santé 2006 October-December; (49): 53-54

Georgetown users check Georgetown Journal Finder for access to full text

Maloney, Dennis M.

In court: former research subjects share their multimillion dollar settlement
Human Research Report 2006 October; 21(10): 8

Georgetown users check Georgetown Journal Finder for access to full text

Harrison, Jayne

Lancet 2006 September 9-15; 368(9539): 909-910

Georgetown users check Georgetown Journal Finder for access to full text

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

Easter, Michele M.; Henderson, Gail E.; Davis, Arlene M.; Churchill, Larry R.; King, Nancy M.P.

The many meanings of care in clinical research
Sociology of Health and Illness 2006 September; 28(6): 695-712

Call number: Special Issue shelf
Georgetown users check Georgetown Journal Finder for access to full text

McGregor, Joan

Does the use of human subjects in research in developing nations violate their human rights? If so, are reparations an appropriate response?
Journal of Social Philosophy 2006 Fall; 37(3): 441-463
**Document 290**

Allmark, P.; Mason, S.

**Should desperate volunteers be included in randomised controlled trials?**

Journal of Medical Ethics 2006 September; 32(9): 548-553

**Abstract:** Randomised controlled trials (RCTs) sometimes recruit participants who are desperate to receive the experimental treatment. This paper defends the practice against three arguments that suggest it is unethical first, desperate volunteers are not in equipoise. Second clinicians, entering patients onto trials are disavowing their therapeutic obligation to deliver the best treatment; they are following trial protocols rather than delivering individualised care. Research is not treatment; its ethical justification is different. Consent is crucial. Third, desperate volunteers do not give proper consent: effectively, they are coerced. This paper responds by advocating a notion of equipoise based on expert knowledge and widely shared values. Where such collective, expert equipoise exists there is a prima facie case for an RCT. Next the paper argues that trial entry does not involve clinicians disavowing their therapeutic obligation; individualised care based on insufficient evidence is not in patients best interest. Finally, it argues that where equipoise exists it is acceptable to limit access to experimental agents; desperate volunteers are not coerced because their desperation does not translate into a right to receive what they desire.

**Document 291**

Miller, P.B.; Weijer, C.

**Trust based obligations of the state and physician-research to patient subjects**

Journal of Medical Ethics 2006 September; 32(9): 542-547

**Abstract:** When may a physician enroll a patient in clinical research? An adequate answer to this question requires clarification of trust-based obligations of the state and the physician-researcher respectively to the patient-subject. The state relies on the voluntarism of patient-subjects to advance the public interest in science. Accordingly, it is obligated to protect the agent-neutral interests of patient-subjects through promulgating standards that secure these interests. Component analysis is the only comprehensive and systematic specification of regulatory standards for benefit-harm evaluation by research ethics committees (RECs). Clinical equipoise, a standard in component analysis, ensures the treatment arms of a randomised control trial are consistent with competent medical care. It thus serves to protect agent-neutral welfare interests of the patient-subject. But REC review occurs prior to enrolment, highlighting the independent responsibility of the physician-researcher to protect the agent-relative welfare interests of the patient-subject. In a novel interpretation of the duty of care, we argue for a "clinical judgment principle" which requires the physician-researcher to exercise judgment in the interests of the patient-subject taking into account evidence on treatments and the patient-subject's circumstances.

**Document 292**

Coghlan, Andy

**What really happened in drug trial disaster?**

New Scientist 2006 August 19-25; 191(2565): 9
Turner, D.D.

**Just another drug? A philosophical assessment of randomised controlled studies on intercessory prayer**

Journal of Medical Ethics 2006 August; 32(8): 487-490

*Abstract:* The empirical results from recent randomised controlled studies on remote, intercessory prayer remain mixed. Several studies have, however, appeared in prestigious medical journals, and it is believed by many researchers, including apparent sceptics, that it makes sense to study intercessory prayer as if it were just another experimental drug treatment. This assumption is challenged by (1) discussing problems posed by the need to obtain the informed consent of patients participating in the studies; (2) pointing out that if the intercessors are indeed conscientious religious believers, they should subvert the studies by praying for patients randomised to the control groups; and (3) showing that the studies in question are characterised by an internal philosophical tension because the intercessors and the scientists must take incompatible views of what is going on: the intercessors must take a causation-first view, whereas the scientists must take a correlation-first view. It therefore makes no ethical or methodological sense to study remote, intercessory prayer as if it were just another drug.

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

---

Lewens, T.

**Distinguishing treatment from research: a functional approach**

Journal of Medical Ethics 2006 July; 32(7): 424-429

*Abstract:* The best way to distinguish treatment from research is by their functions. This mode of distinction fits well with the basic ethical work that needs to be carried out. The distinction needs to serve as an ethical flag, highlighting areas in which the goals of doctors and patients are more likely than usual to diverge. The distinction also allows us to illuminate and understand some otherwise puzzling elements of debates on research ethics: it shows the peculiarity of exclusive conceptions of the distinction between research and treatment; it allows us to frame questions about therapeutic obligations in the research context, and it allows us to consider whether there may be research obligations in the therapeutic context.

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

---

Decullier, Evelyne; Chapuis, François

**Impact of funding on biomedical research: a retrospective cohort study**

BMC Public Health 2006 June 22; 6: 165

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

---

**Research agendas: an invitation to readers**


*Abstract:* THE AIM OF JERHRE IS TO identify and promote meritorious research and collaboration that will enhance human research and promote the evolution of best research practices. The purpose of this column is to identify topics in need of research and to invite collaboration, as set forth in the March 2006 issue. (See [http://caliber.ucpress.net/loi/jer](http://caliber.ucpress.net/loi/jer).) An agenda proposed in this issue is research on harms to those who gather data. The scientific and ethical quality of human research depends, in large measure, on the persons who work day-to-day gathering data. Persons who work under conditions of high stress, or in fear of bodily harm are not in the best...
position to gather high quality data or attend fully to ethical aspects of research conduct.

Georgetown users check Georgetown Journal Finder for access to full text

Document 297
Mayo, Susan
PLoS launches open access journal for trials [news]
BMJ: British Medical Journal 2006 May 20; 332(7551): 1174
Georgetown users check Georgetown Journal Finder for access to full text

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

Document 298
Medical Research Council [MRC] (Great Britain)
Improving health, improving lives: MRC-funded research in Africa

http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002425 (link may be outdated)

Document 299
Steinbrook, Robert
Compensation for injured research subjects
Georgetown users check Georgetown Journal Finder for access to full text

http://content.nejm.org (link may be outdated)

Document 300
Wood, Alastair J.J.; Darbyshire, Janet
Injury to research volunteer -- the clinical-research nightmare
New England Journal of Medicine 2006 May 4; 354(18): 1869-1871
Georgetown users check Georgetown Journal Finder for access to full text

http://content.nejm.org (link may be outdated)

Document 301
Wadman, Meredith
The quiet rise of the clinical contractor
Nature 2006 May 4; 441(7089): 22-23
Georgetown users check Georgetown Journal Finder for access to full text

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

Document 302
United Kingdom. Academy of Medical Sciences

Medical research: assessing the benefits to society. A report by the UK Evaluation Forum, supported by the Academy of Medical Sciences, Medical Research Council and Wellcome Trust


http://www.acmedsci.ac.uk/p99puid64.html (link may be outdated)

Document 303

Mayor, Susan

All change for funding of medical research in the United Kingdom [news]

BMJ: British Medical Journal 2006 April 29; 332(7548): 994

Georgetown users check Georgetown Journal Finder for access to full text

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

Document 304

Day, Michael

US scientists urge overhaul of clinical trials to restore confidence [news]

BMJ: British Medical Journal 2006 April 29; 332(7548): 991

Georgetown users check Georgetown Journal Finder for access to full text

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

Document 305

Dyer, Owen

Payment offered to injured trial participants has strings attached [news]

BMJ: British Medical Journal 2006 April 29; 332(7548): 990

Georgetown users check Georgetown Journal Finder for access to full text

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

Document 306


Guidance on informed consent of in vitro diagnostic device studies using leftover human specimens that are not individually identifiable


http://www.fda.gov/cdrh/oivd/guidance/1588.pdf (link may be outdated)

Document 307

Johnston, S. Claiborne; Rootenberg, John D.; Katrak, Shereen; Smith, Wade S.; Elkins, Jacob S.
Effect of a US National Institutes of Health programme of clinical trials on public health and costs
Lancet 2006 April 22-28; 367(9519): 1319-1327
Georgetown users check Georgetown Journal Finder for access to full text
http://www.thelancet.com/journal (link may be outdated)

Document 308
Blakemore, Colin; Davidson, John
Putting a value on medical research [comment]
Lancet 2006 April 22-28; 367(9519): 1293-1295
Georgetown users check Georgetown Journal Finder for access to full text
http://www.thelancet.com/journal (link may be outdated)

Document 309
Loscalzo, Joseph
The NIH budget and the future of biomedical research [opinion]
Georgetown users check Georgetown Journal Finder for access to full text
http://content.nejm.org (link may be outdated)

Document 310
Griffiths, Pauline
Being a research participant: the nurse's ethical and legal rights
British Journal of Nursing 2006 April 13-26; 15(7): 386-390
Georgetown users check Georgetown Journal Finder for access to full text

Document 311
Kapp, M.B.
Ethical and legal issues in research involving human subjects: do you want a piece of me?
Journal of Clinical Pathology 2006 April; 59(4): 335-339
Georgetown users check Georgetown Journal Finder for access to full text

Document 312
Bhattacharya, Shaoni; Coghlan, Andy
One drug, six men, disaster . . . [news]
New Scientist 2006 March 25-31; 189(2544): 10-11
Georgetown users check Georgetown Journal Finder for access to full text
**Document 313**

**Educational advantage**

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

---

**Document 314**

**Research agendas: an invitation to readers**

**Abstract:** Ethical problem solving in human research is a continuing dialectic. Each question that is investigated leads to new questions calling for research. Articles published in JERHRE include a research agenda, and questions raised elsewhere suggest research agendas publishable here. Pursuit of these research agendas will lead to a more comprehensive understanding of effective approaches to ethical problem solving. Readers are invited to propose agendas, form collaborations, and publish their findings.

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

---

**Document 315**

Austriaco, Nicanor Pier Giorgio

**Science [news]**
*National Catholic Bioethics Quarterly* 2006 Spring; 6(1): 139-142

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

---

**Document 316**

**Deaths halt enrollments in a drug trial**
*New York Times* 2006 February 14; p. C4

[http://www.nytimes.com](http://www.nytimes.com) (link may be outdated)

---

**Document 317**

Cleaton-Jones, Peter

**Research injury in clinical trials in South Africa**
*Lancet* 2006 February 11-17; 367(9509): 458-459

[http://thelancet.com/journal](http://thelancet.com/journal) (link may be outdated)

---

**Document 318**

Schrag, Brian

**Research Ethics: Cases and Commentaries, Volume 7**
Bloomington, IN: Association for Practical and Professional Ethics (APPE), 2006 February: 185 p.

Supported by: NSF Grant Number SES-9817880
Document 319
Barnes, Barbara E.; Friedman, Charles P.; Rosenberg, Jerome L.; Russell, Joanne; Beedle, Ari; Levine, Arthur S.
Creating an infrastructure for training in the responsible conduct of research: the University of Pittsburgh's experience
Academic Medicine 2006 February; 81(2): 119-127
Georgetown users check Georgetown Journal Finder for access to full text

Document 320
Murillo, Horacio; Recce, Albert; Snyderman, Ralph; Sung, Nancy S.
Meeting the challenges facing clinical research: solutions proposed by leaders of medical specialty and clinical research societies
Academic Medicine 2006 February; 81(2): 107-112
Georgetown users check Georgetown Journal Finder for access to full text

Document 321
United States. Environmental Protection Agency [EPA]
Request for Nominations for a Human Studies Review Board [HSRB]: Notice
Federal Register 2006 January 3; 71(1): 116-118
Georgetown users check Georgetown Journal Finder for access to full text

http://www.gpoaccess.gov/fr/ (link may be outdated)

Document 322
Markman, Maurie
Assuring the ethical conduct of clinical cancer trials in the developing world
Cancer 2006 January 1; 106(1): 1-3
Georgetown users check Georgetown Journal Finder for access to full text

Document 323
Labon, Marek
Conducting clinical research in Polish conditions
Georgetown users check Georgetown Journal Finder for access to full text

Document 324
Dresser, Rebecca
Private-sector research ethics: marketing or good conflicts management? The 2005 John L. Conley Lecture on Medical Ethics
Theoretical Medicine and Bioethics 2006; 27(2): 115-139
Georgetown users check Georgetown Journal Finder for access to full text
The relevance of empirical research in bioethics


Georgetown users check Georgetown Journal Finder for access to full text
EthxWeb Search Results

Search Detail:
Result=(("18.1".PC.) AND (@YD >= "20000000")) NOT (EDITORIAL OR LETTER)
 Documents: 326 - 650 of 753

Document 326
Hamilton, Jennifer A.; Sharp, Richard R.
Revisiting the stored tissue issue [review of The Stored Tissue Issue: Biomedical Research, Ethics, and Law in the Area of Genomic Medicine, by Robert F. Weir, Robert S. Olick, and Jeffrey C. Murray]
Georgetown users check Georgetown Journal Finder for access to full text

Document 327
Heinrichs, Bert
FORSchung AM MenschEn: Elemente EinEr Ethischen Theorie Biomedizinischer HumanExperimente
Call number: R853.H8 H392 2006

Document 328
Evans, Imogen; Thornton, Hazel; and Chalmers, Iain
TESTing Treatments: Better Research For Better Healthcare
Call number: R850.E98 2006

Document 329
Lemmens, Trudo and Waring, Duff R., eds.
Law And Ethics In Biomedical REsearch: Regulation, Conflict Of Interest, And Liability
Call number: KE3663.M38 L39 2006

Document 330
Ittis, Ana Smith, ed.
Research Ethics
Call number: R853.H8 R45 2006

Document 331

**Placing ethics in the centre: negotiating new spaces for ethical research in conflict situations.**
Global Public Health 2006; 1(3): 264-277

Georgetown users check [Georgetown Journal Finder](http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002428) for access to full text

---

**Document 332**

Council of Graduate Schools [CGS]

**Graduate education for the responsible conduct of research**

**Document 333**

Medical Research Council [MRC] (Great Britain)

**The Medical Research Council: leading research for better health**
London: Medical Research Council [MRC], 2006 [30 p.]

[http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002428](http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002428) (link may be outdated)

---

**Document 334**

Pattinson, Shaun D.

**Medical research**
In his: Medical Law and Ethics. London: Sweet and Maxwell, 2006: 335-381
Call number: KD3395 .P38 2006

---

**Document 335**

King, Patricia A.; Areen, Judith; Gostin, Lawrence O.

**The human body**
Call number: KF3821 .A7 K56 2006

---

**Document 336**

Ferguson, Pamela R.

**Human 'guinea pigs': why patients participate in clinical trials**
Call number: K3601 .F57 2006

---

**Document 337**

Grady, Christine

**Ethics of vaccine research**
Call number: R853 .H8 R45 2006

---

**Document 338**

Iltis, Ana Smith

**Human subjects research: ethics and compliance**
Call number: R853 .H8 R45 2006
**Document 339**
Budinger, Thomas F.; Budinger, Miriam D.
**Ethics of human and animal experimentation**
Call number: T14 .B784 2006

**Document 340**
Rollin, Bernard E.
**Ethics and research on human beings.**
Call number: R852 .R67 2006

**Document 341**
Baron, Jonathan
**Drug research**
Call number: R725.5 .B25 2006

**Document 342**
Fry, Sara T.; Veatch, Robert M.
**Experimentation on human beings.**
Call number: RT85 .V4 2006

**Document 343**
Caja Costarricense de Seguro Social, Centro de Desarrollo Estrategico e Informacion en Salud y Seguridad Social [CENDEISS-CCSS] [Costa Rican Agency for Social Security, Center for the Strategic Development and Information in Health and Social Security]
**Reglamento Para la Investigacion Biomedica en los Servicios Asistenciales de la Caja Costarricense de Seguro Social: Aprobado por Junta Directiva en Articulo 9 de la Sesion 8009 del 17 de Noviembre del 2005; Publicado en Diario Oficial La Gaceta del 02 de Diciembre, 2005 [Regulation for Biomedical Investigation for the Assistance Services of the Costa Rican Agency for Social Security: Approved by the Law Directive in Article 9 in Session 8009 on November 17, 2005]
La Uruca, San Jose, Costa Rica: Centro para el Desarrollo Estrategico e Informacion en Salud y Seguridad Social [CENDEISS-CCSS], 2005 December 2; 20 p.

**Document 344**
WHO Task Force on Research Priorities for Equity in Health; WHO Equity Team
**Priorities for research to take forward the health equity policy agenda**
Bulletin of the World Health Organization 2005 December; 83(12): 948-953
Georgetown users check [Georgetown Journal Finder](http://whqlibdoc.who.int/bulletin/2005/Vol83-No12/bulletin_2005_83(12)_948-953.pdf) for access to full text
Document 345
Hess, Rachel; Matthews, Karen; McNeil, Melissa; Chang, ChungChou H.; Kapoor, Wishwa; Bryce, Cindy
Health services research in the privacy age
Georgetown users check Georgetown Journal Finder for access to full text
http://www.pubmedcentral.nih.gov (link may be outdated)

Document 346
Roberts, Laura Weiss; Warner, Teddy D.; Hammond, Katherine A. Green
Coexisting commitments to ethics and human research: a preliminary study of the perspectives of 83 medical students
Georgetown users check Georgetown Journal Finder for access to full text
http://bioethics.net (link may be outdated)

Document 347
Zerhouni, Elias A.
Translational and clinical science – time for a new vision
Georgetown users check Georgetown Journal Finder for access to full text
http://content.nejm.org (link may be outdated)

Document 348
Roberts, Laura Weiss; Warner, Teddy D.; Hammond, Katherine A. Green; Brody, Janet L.; Kaminsky, Alexis; Roberts, Brian B.
Teaching medical students to discern ethical problems in human clinical research studies
Academic Medicine 2005 October; 80(10): 925-930
Georgetown users check Georgetown Journal Finder for access to full text

Document 349
Kahn, Jeffrey
A multi-faceted history [review of Useful Bodies: Human in the Service of Medical Science in the Twentieth Century, by Jordan Goodman, Anthony McElligott, and Laura Marks, eds.]
IRB: Ethics and Human Research 2005 September-October; 27(5): 19
Georgetown users check Georgetown Journal Finder for access to full text

Document 350
Paying research participants: a study of current practices in Australia
Journal of Medical Ethics 2005 September; 31(9): 542-547

Abstract: OBJECTIVE: To examine current research payment practices and to inform development of clearer guidelines for researchers and ethics committees. DESIGN: Exploratory email based questionnaire study of current research participant reimbursement practices. A diverse sample of organisations and individuals were targeted. SETTING: Australia. PARTICIPANTS: Contacts in 84 key research organisations and select electronic listservers across Australia. A total of 100 completed questionnaires were received with representations from a variety of research areas (for example, market, alcohol and drug, medical, pharmaceutical and social research). MAIN MEASUREMENTS: Open-ended and fixed alternative questions about type of research agency; type of research; type of population under study; whether payment is standard; amounts and mechanisms of payment; factors taken into account when deciding on payment practices; and whether payment policies exist. RESULTS: Reimbursement practice is highly variable. Where it occurs (most commonly for drug dependent rather than health professional or general population samples) it is largely monetary and is for time and out-of-pocket expenses. Ethics committees were reported to be often involved in decision making around reimbursement. CONCLUSIONS: Research subject payment practices vary in Australia. Researchers who do provide payments to research participants generally do so without written policy and procedures. Ethics committees have an important role in developing guidelines in this area. Specific guidelines are needed considering existing local policies and procedures; payment models and their application in diverse settings; case study examples of types and levels of reimbursement; applied definitions of incentive and inducement; and the rationale for diverse payment practices in different settings.

Georgetown users check Georgetown Journal Finder for access to full text

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

* Article Document 351
Rigby, Heather; Fernandez, Conrad V.
Providing research results to study participants: support versus practice of researchers presenting at the American Society of Hematology annual meeting
Blood 2005 August 15; 106(4): 1199-1202

Georgetown users check Georgetown Journal Finder for access to full text

* Article Document 352
Shalowitz, David I.; Miller, Franklin G.
Disclosing individual results of clinical research: implications of respect for participants

Georgetown users check Georgetown Journal Finder for access to full text

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

* Book Document 353
United States. National Institutes of Health [NIH]. National Institute on Aging [NIA]
Understanding risk: what do those headlines really mean?

http://www.niapublications.org/engagepages/Understanding_Ri sk-What_Do_Those_Headlines_Really_Mean.pdf (link may be outdated)
Critics claim even babies could be exposed to pesticides in research
Maloney, Dennis M.
Georgetown users check Georgetown Journal Finder for access to full text

Undue inducement in clinical research in developing countries: is it a worry? [opinion]
Emanuel, Ezekiel J.; Currie, Xolani E.; Herman, Allen
Georgetown users check Georgetown Journal Finder for access to full text
http://www.thelancet.com/journal (link may be outdated)

Undue inducement in clinical research
Martin, Robyn
Georgetown users check Georgetown Journal Finder for access to full text
http://www.thelancet.com/journal (link may be outdated)

Putting clinical trials into context [opinion]
Young, Charles; Horton, Richard
Georgetown users check Georgetown Journal Finder for access to full text
http://www.thelancet.com/journal (link may be outdated)

Ethical issues in international research, Harvard School of Public Health, Boston, USA, 13-17 June 2005
Goel, Ashish
Georgetown users check Georgetown Journal Finder for access to full text

Human histological research: is it necessary? Humane? Ethical?
Leib, Alden M.; Kowalski, Charles J.
Journal of Periodontology 2005 July; 76(7): 1207-1210
Document 360
Caron-Flinterman, J. Francisca; Broerse, Jacqueline E.W.; Bunders, Joske F.G.
The experiential knowledge of patients: a new resource for biomedical research?
Social Science and Medicine 2005 June; 60(11): 2575-2584
Georgetown users check Georgetown Journal Finder for access to full text

Document 361
Newberg, Andrew B.; Lee, Bruce Y.
The neuroscientific study of religious and spiritual phenomena: or why God doesn't use biostatistics
Zygon 2005 June; 40(2): 469-489
Georgetown users check Georgetown Journal Finder for access to full text

Document 362
Flynn, Terry N.; Peters, Tim J.
Cluster randomized trials: another problem for cost-effectiveness ratios
International Journal of Technology Assessment in Health Care 2005 Summer; 21(3): 403-409
Georgetown users check Georgetown Journal Finder for access to full text

* Document 363
Grady, Christine; Dickert, Neal; Jawetz, Tom; Gensler, Gary; Emanuel, Ezekiel
An analysis of U.S. practices of paying research participants
Contemporary Clinical Trials 2005 June; 26(3): 365-375
Abstract: Four principal arguments have been offered in support of requiring public and private third-party payers to help fund medical research: (1) many of the costs associated with clinical trial participation are for routine care that would be reimbursed if delivered outside of a trial; (2) there is a need to promote scientific research and medical progress and lack of coverage is an impediment to enrollment; (3) to cover the costs of trials expands health care and treatment options for the sick; and (4) it is beneficial for private insurers to cover the costs associated with cancer clinical trials because doing so makes such companies more attractive to consumers. Although many see third-party-payer coverage as a victory for patients and for the future of research, requiring coverage of services provided in a trial beyond those that would be provided to a comparable patient outside the research context raises a number of concerns.
Georgetown users check Georgetown Journal Finder for access to full text

* Document 364
Iltis, Ana S.
Third-party payers and the costs of biomedical research
Abstract: Four principal arguments have been offered in support of requiring public and private third-party payers to help fund medical research: (1) many of the costs associated with clinical trial participation are for routine care that would be reimbursed if delivered outside of a trial; (2) there is a need to promote scientific research and medical progress and lack of coverage is an impediment to enrollment; (3) to cover the costs of trials expands health care and treatment options for the sick; and (4) it is beneficial for private insurers to cover the costs associated with cancer clinical trials because doing so makes such companies more attractive to consumers. Although many see third-party-payer coverage as a victory for patients and for the future of research, requiring coverage of services provided in a trial beyond those that would be provided to a comparable patient outside the research context raises a number of concerns.
Georgetown users check Georgetown Journal Finder for access to full text
**Document 365**
Imai, Kumiko; Zhang, Ping
*Integrating economic analysis into clinical trials*

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

**Document 366**
Couzin, Jennifer
*Advocating, the clinical way*
Science 2005 May 13; 308(5724): 940-942

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

**Document 367**
Khanlou, N.; Peter, E.
*Participatory action research: considerations for ethical review*
Social Science and Medicine 2005 May; 60(10): 2333-2340

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

**Document 368**
Beh, Hazel
*Compensation for research injuries*
IRB: Ethics and Human Research 2005 May-June; 27(3): 11-15

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

**Document 369**
Rivera, Roberto; Borasky, David; Rice, Robert; Carayon, Florence
*Many worlds, one ethic: design and development of a global research ethics training curriculum*
Developing World Bioethics 2005 May; 5(2): 169-175

**Abstract:** The demand for basic research ethics training has grown considerably in the past few years. Research and education organizations face the challenge of providing this training with limited resources and training tools available. To meet this need, Family Health International (FHI), a U.S.-based international research organization, recently developed a Research Ethics Training Curriculum (RETC). It was designed as a practical, user-friendly tool that provides basic, up-to-date, standardized training on the ethics of human research. The curriculum can easily be adapted to different audiences and training requirements. The RETC was reviewed by a group of international experts and field tested in five countries. It is available in English, French, and Spanish as a three-ring binder and CD-ROM, as well as on the Web. It may be used as either an interactive self-study program or for group training.

Georgetown users check [Georgetown Journal Finder](http://www.sciencemag.org) for access to full text
**Document 370**
National Institutes of Health [NIH] (United States)

NIH public access policy on enhancing public access to archived publications resulting from NIH-funded research: questions and answers

Georgetown users check [Georgetown Journal Finder](http://publicaccess.nih.gov/publicaccess_QandA.htm) for access to full text

[http://publicaccess.nih.gov/publicaccess_QandA.htm](http://publicaccess.nih.gov/publicaccess_QandA.htm) (link may be outdated)

---

**Document 371**
Harris, John

Scientific research is a moral duty
Journal of Medical Ethics 2005 April; 31(4): 242-248

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

[http://www.jmedethics.com](http://www.jmedethics.com) (link may be outdated)

---

**Document 372**
Kong, W.M.

Legitimate requests and indecent proposals: matters of justice in the ethical assessment of phase I trials involving competent patients
Journal of Medical Ethics 2005 April; 31(4): 205-208

Abstract: The death of Jesse Gelsinger in 1999 during a gene therapy trial raised many questions about the ethical review of medical research. Here, the author argues that the principle of justice is interpreted too narrowly and receives insufficient emphasis and that what we permit in terms of bodily invasion affects the value we place on individuals. Medical research is a societally supported activity. As such, the author contends that justice requires that invasive medical research demonstrates sufficiently compelling societal benefit. Many consider this societal benefit to be self evident. However, medical research is a complex activity; it yields new treatments but also creates financial rewards and affects health resource allocation. As research evolves into a multibillion pound, multinational enterprise, justice requires a much broader analysis of societal benefit. Without such evaluation we risk undermining the value of bodily integrity and of research participants.

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

[http://www.jmedethics.com](http://www.jmedethics.com) (link may be outdated)

---

**Document 373**

National Institutes of Health [NIH] (United States)

Final NIH public access policy implementation

Georgetown users check [Georgetown Journal Finder](http://publicaccess.nih.gov/publicaccess_imp.htm) for access to full text

[http://publicaccess.nih.gov/publicaccess_imp.htm](http://publicaccess.nih.gov/publicaccess_imp.htm) (link may be outdated)
Document 374
Maschke, Karen J.
The pressure to tolerate risk in human subjects research [review of Lesser Harms: The Morality of Risk in Medical Research by Sydney A. Halpern]
Medical Humanities Review 2005 Spring-Fall; 19(1-2): 39-44
Georgetown users check Georgetown Journal Finder for access to full text

Document 375
Rodriguez-Arias, David; Herve, Christian
Case Studies in Biomedical Research Ethics, by Timothy F. Murphy [book review]
Georgetown users check Georgetown Journal Finder for access to full text

Document 376
Kavanaugh, A.
Ethical and practical issues in conducting clinical trials in psoriasis and psoriatic arthritis
Annals of the Rheumatic Diseases 2005 March; 64(Supplement 2): ii46-ii48
Georgetown users check Georgetown Journal Finder for access to full text

Document 377
Multiple choice questions
Developing World Bioethics 2005 March; 5(1): 109-120
Georgetown users check Georgetown Journal Finder for access to full text

Document 378
Schuklenk, Udo
Module one: introduction to research ethics
Abstract: This module will introduce you to the ethical concepts underlying applied ethical decision-making in the area of research involving human participants. We will also learn what the issues are that people involved in research on research ethics are concerned with. Ethics without an understanding of historical and legal context makes arguably little sense. It is for this reason that this module will begin with a brief history of research ethics and ends with a brief overview of the relevant national and international guidelines pertaining to ethical issues in research involving human participants.
Georgetown users check Georgetown Journal Finder for access to full text

Document 379
Dossey, L.
Exploritis, and a welcome
Thye, Woo Keng
**Quality assurance and medical research**
SMA News 2005 January; 36(1): 9-10

Merritt, Maria
**Moral conflict in clinical trials**

Morreim, E. Haavi
**Clinical trials litigation: practical realities as seen from the trenches**

Slomka, Jacquelyn
**Case Studies in Biomedical Research Ethics, by Timothy F. Murphy [book review]**

Coleman, Carl H.; Menikoff, Jerry A.; Goldner, Jesse A.; and Dubler, Nancy Neveloff
**THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS: TEACHER'S MANUAL**
**Document 386**

**Baader, Gerhard; Lederer, Susan E; Low, Morris; Schmaltz, Florian; Schwerin, Alexander V**

**Pathways to human experimentation, 1933-1945: Germany, Japan, and the United States.**

Osiris 2005; 20: 205-31

**Abstract:** The history of human experimentation in the twelve years between Hitler's rise to power and the end of the Second World War is notorious in the annals of the twentieth century. The horrific experiments conducted at Dachau, Auschwitz, Ravensbrueck, Birkenau, and other National Socialist concentration camps reflected an extreme indifference to human life and human suffering. Unfortunately, they do not reflect the extent and complexity of the human experiments undertaken in the years between 1933 and 1945. Following the prosecution of twenty-three high-ranking National Socialist physicians and medical administrators for war crimes and crimes against humanity in the Nuremberg Medical Trial (United States v. Karl Brandt et al.), scholars have rightly focused attention on the nightmarish researches conducted by a small group of investigators on concentration camp inmates. Less well known are alternative pathways that brought investigators to undertake human experimentation in other laboratories, settings, and nations.

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

---

**Document 387**

**United Kingdom. Academy of Medical Sciences**

**Consultation response: Human Tissue Act**

London: Academy of Medical Sciences, 2005: 8 p.

**Call number:** citation only

**Document 388**

**Swerdlow, Paul S.**

**Use of humans in biomedical experimentation.**


**Call number:** Q180.5_M67_M33_2005

**Document 389**

**Long, Jeffrey C.**

**Commentary: an overview of human subjects research in biological anthropology.**


**Call number:** GN62_B55_2005

**Document 390**

**Crooks, Glenna M.**

**The rights of patients to participate in clinical research**

In: Santoro, Michael A.; Gorrie, Thomas M., eds. Ethics and the Pharmaceutical Industry. Cambridge; New York:
* Document 391
Mason, J.K.; Laurie, G.T.
**Biomedical human research and experimentation**
Call number: K3601 .M38 2005

* Document 392
Spike, Jeffrey P.
**Human subjects research**
Call number: Q175.35 .E53 2005 v.2

* Document 393
Nucho, Eileen N.
**Principal investigators and clinical trials**
Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Document 394
Gillon, John J., Jr.
**More subject and less human: the pain-filled journey of human subjects protection... and some differences in the United States and the European Union**
Georgetown users check [Georgetown Journal Finder](#) for access to full text

* Document 395
Vidalis, T.; Manolakou, K.
Hellenic National Bioethics Commission
**Report: On Biomedical Experimentations Involving Human Subjects and Clinical Trials of Medicinal Products**

* Document 396
Koplow, Bret
**Clinical trial databases: a potential new source of liability for drug manufacturers**
Document 397

Dula, Rusinovic-Sunara; Maja, Proso

**Some Experience on Medical Researches in Croatia**


http://www.pravapacijenata.hr/klinicka_ispitivanja_eng.htm (link may be outdated)

Document 398


**NIH implementation of Office for Human Research Protections (OHRP) guidance on research involving coded private information of biological specimens**


http://grants.nih.gov/ (link may be outdated)

Document 399

Raja, Asad J.; Singer, Peter A.

**Transatlantic divide in publication of content relevant to developing countries**


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

Document 400

Bankhead, Charles

**Privacy regulations have mixed impact on cancer research community [news]**

Journal of the National Cancer Institute 2004 December 1; 96(23): 1738-1740

Document 401

Minkler, Meredith

**Ethical challenges for the "outside" researcher in community-based participatory research**

Health Education and Behavior 2004 December; 31(6): 684-697

Document 402

Green, Lawrence W.

**Ethics and community-based participatory research: commentary on Minkler**
Document 403

Human Experimentation and Research, edited by G. Tomossy and D.N. Weisstub [book review]
Bulletin of Medical Ethics 2004 December-2005 January; (204): 20-21

http://www.bullmedeth.info/ (link may be outdated)

Document 404

Hakimian, Rina; Korn, David
Ownership and use of tissue specimens for research

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

Document 405

Edwards, Martin
Historical keywords: trial
Lancet 2004 November 6-12; 364(9446): 1659

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

Document 406

Beskow, Laura M.; Botkin, Jeffrey R.; Daly, Mary; Juengst, Eric T.; Lehmann, Lisa Soleymani; Merz, Jon F.; Pentz, Rebecca; Press, Nancy A.; Ross, Lainie Friedman; Sugarman, Jeremy; Susswein, Lisa R.; Terry, Sharon F.; Austin, Melissa A.; Burke, Wylie
Ethical issues in identifying and recruiting participants for familial genetic research
American Journal of Medical Genetics 2004 November 1; 130A(4): 424-431

Document 407

Al-Sulaiman, Abdulsalam A.; Al-Gindan, Yussuf M.
The dilemma of clinical research. Historical and philosophical consideration of physicians' ambitions and patients' fear

Georgetown users check Georgetown Journal Finder for access to full text
Document 408
Illes, Judy; Kirschen, Matthew P.; Karetsky, Kim; Kelly, Megan; Saha, Arnold; Desmond, John E.; Raffin, Thomas A.; Glover, Gary H.; Atlas, Scott W.
**Discovery and disclosure of incidental findings in neuroimaging research**
Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 409
McNeil, Caroline
**Clinical trial accrual efforts: some progress amid ongoing debate**
Journal of the National Cancer Institute 2004 October 6; 96(19): 1417-1418
Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 410
Langer, Ana; Díaz-Olavarrieta, Claudia; Berdichevsky, Karla; Villar, José,
**Why is research from developing countries underrepresented in international health literature, and what can be done about it?**
Georgetown users check [Georgetown Journal Finder](#) for access to full text


Document 411
Lertsithichai, Panuwat
**Medical research ethics in Thailand: what should be the most appropriate approach? An analysis based on Western ethical principles**
Journal of the Medical Association of Thailand 2004 October; 87(10): 1253-1261
Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 412
Bernstein, Mark
**Assessing the bioethical integrity of a clinical trial in surgery**
Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 413
Travis, Kate
**For phase I studies, ethical and practical concerns abound [news]**
Journal of the National Cancer Institute 2004 September 15; 96(18): 1354-1355
Notice on implementation of Office for Human Research Protections (OHRP) guidance on research involving coded private information and biological specimens


Ethical issues in participatory action research


Focus group interviews examining attitudes towards medical research among the Japanese: a qualitative study

Bioethics 2004 September; 18(5): 448-470

Abstract: Objectives: the purpose of this study is to explore laypersons' attitudes towards and experiences of medical research, and to compare them with those of physicians in Japan. Designs and Participants: fourteen Japanese adults from the general public and seven physicians participated in one of three focus interviews. Setting: Osaka, Japan. Results: trust and distrust in the physician by whom the participants were invited to participate in research played a considerable role in their decisions about participation. That the participants felt an obligation to participate was also expressed. The lay participants perceived medical research as something entirely outside of their world. A greater willingness to volunteer for research was expressed if there were direct benefits to themselves or their families. Research methods such as use of placebos, double blinds, and randomisations seemed to cause negative attitudes to medical research. All physicians were convinced of the need for medical research, including double-blinded randomised control trials, and its significant role in medical progress. Most physicians thought that the greater awareness of the need for medical research in the community and a better understanding of the psychology of potential research participants were necessary and urgent. Conclusions: there is a good possibility that the lay public and medical professionals have sharply different beliefs about and attitudes towards every aspect of medical research. Building up a better and equal patient-doctor relationship based on trust is a key issue in medical research, and it is mandatory to fill the gap in perception regarding medical research between them through fully informed debates.
Document 419

http://www.ahrq.gov/clinic/epcsums/cbprsum.pdf (link may be outdated)

Document 420
Shi, Leiyu; Stevens, Gregory D.; Wulu, John T., Jr.; Politzer, Robert M.; Xu, Jiahong
America's health centers: reducing racial and ethnic disparities in perinatal care and birth outcomes
Health Services Research 2004 August; 39(6, Part 1): 1881-1901

* Document 421
Herranz, Gonzalo
The ethics of medical research: a Christian view
Bulletin of Medical Ethics 2004 August; (200): 13-19

* Document 422
Fitzgerald, Mary
Advocate for access to medical data: linguist wants patients to understand (Alexa McCray)
Washington Post 2004 July 28; p. A17

* Document 423
Kent, David M.; Mwamburi, D. Mkaya; Bennish, Michael L.; Kupelnick, Bruce; Ioannidis, John P.A.
Clinical trials in sub-Saharan Africa and established standards of care: a systematic review of HIV, tuberculosis, and malaria trials
Document 424
Bower, E.J.; Newton, J.T.; Williams, A.C.
Research in primary dental care part 5: devising a proposal, obtaining funding and ethical considerations
British Dental Journal 2004 July 10; 197(1): 17-19

Georgetown users check Georgetown Journal Finder for access to full text

Document 425
Markman, Maurie
Translating the results of phase III randomized cancer trials into the language of physician obligation to patients.
Current Oncology Reports 2004 July; 6(4): 243-244

Georgetown users check Georgetown Journal Finder for access to full text

Document 426
Aronson, J.K.
What is a clinical trial?

Georgetown users check Georgetown Journal Finder for access to full text

Document 427
Paradiso, Angelo; Bruno, Michele; Cicoria, Onofrio; Digennaro, Maria; Longo, Salvatore; Rinaldi, Michele; Schittulli, Francesco
Analysis of the reasons for accepting or declining participation in genetic research for breast cancer: a hospital-based population study
Tumori 2004 July-August; 90(4): 435-436

Georgetown users check Georgetown Journal Finder for access to full text

Document 428
Samanta, Ash; Samanta, Jo; Price, David
Who owns my body -- thee or me? The human tissue story continues
Clinical Medicine 2004 July-August; 4(4): 327-331

Georgetown users check Georgetown Journal Finder for access to full text

Document 429
Holaday, Bonnie; Mills, Debra M.
Clinical research and the development of new drugs: issues for nurses
Dimensions of Critical Care Nursing 2004 July-August; 23(4): 179-186

Georgetown users check Georgetown Journal Finder for access to full text
**Document 430**
Daikos, George K.

**Ethical dilemmas encountered during clinical drug trials**

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

**Document 431**
Cooper, John A.D.

**Biomedical research**
Academic Medicine 2004 July; 79(7): 710

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

**Document 432**
Shamoo, Adil E.; Cole, John W.

**Fear of influence: conflict of interest in biomedical and genetic research**
GeneWatch 2004 July-August; 17(4): 12-13

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

**Document 433**
Davies, H.

**Can Mary Shelley's Frankenstein be read as an early research ethics text?**
Medical Humanities 2004 June; 30(1): 32-35

**Abstract:** The current popular view of the novel Frankenstein is that it describes the horrors consequent upon scientific experimentation; the pursuit of science leading inevitably to tragedy. In reality the importance of the book is far from this. Although the evil and tragedy resulting from one medical experiment are its theme, a critical and fair reading finds a more balanced view that includes science's potential to improve the human condition and reasons why such an experiment went awry. The author argues that Frankenstein is an early and balanced text on the ethics of research upon human subjects and that it provides insights that are as valid today as when the novel was written. As a narrative it provides a gripping story that merits careful analysis by those involved in medical research and its ethical review, and it is more enjoyable than many current textbooks! To support this thesis, the author will place the book in historical, scientific context, analyse it for lessons relevant to those involved in research ethics today, and then draw conclusions.

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

[http://www.medicalhumanities.com](http://www.medicalhumanities.com) (link may be outdated)

**Document 434**
Rochon, Paula A.; Mashari, Azad; Cohen, Ariel; Misra, Anjali; Laxer, Dara; Streiner, David L.; Dergal, Julie M.; Clark, Jocelyn P.; Gold, Jennifer; Binns, Malcolm A.

**Relation between randomized controlled trials published in leading medical journals and the global burden of disease**

Georgetown users check [Georgetown Journal Finder](#) for access to full text
Document 435
Burgermeister, Jane
EU trials database is criticised for lack of openness [news]
BMJ: British Medical Journal 2004 May 8; 328(7448): 1094
Georgetown users check Georgetown Journal Finder for access to full text

Document 436
Haynes, R. Brian; Wilczynski, Nancy L.
Optimal search strategies for retrieving scientifically strong studies of diagnosis from Medline: analytical survey
BMJ: British Medical Journal 2004 May 1; 328(7447): 1040-1042
Georgetown users check Georgetown Journal Finder for access to full text

Document 437
Dresser, Rebecca
Subjects of the state [review of Useful Bodies: Humans in the Service of Medical Science, edited by Jordan Goodman, Anthony McElligott and Lara Marks]
Nature Medicine 2004 May; 10(5): 450
Georgetown users check Georgetown Journal Finder for access to full text

Document 438
Condit, Celeste
Science reporting to the public: does the message get twisted?
CMAJ/JAMC: Canadian Medical Association Journal 2004 April 27; 170(9): 1415-1416
Georgetown users check Georgetown Journal Finder for access to full text

Document 439
Sadana, Ritu; D'Souza, Carol; Hyder, Adnan A.; Chowdhury, A. Mushtaque R.
Importance of health research in South Asia
BMJ: British Medical Journal 2004 April 3; 328(7443): 826-830
Georgetown users check Georgetown Journal Finder for access to full text
Document 440
Colling, Joyce
Procedures, ethics, and funding sources
Urologic Nursing 2004 April; 24(2): 130-133
Georgetown users check Georgetown Journal Finder for access to full text

Document 441
Youngson, George
Research ethics – new standards
Pediatric Surgery International 2004 April; 20(4): 222-223
Georgetown users check Georgetown Journal Finder for access to full text

Document 442
Schroter, Sara; Morris, Julie; Chaudhry, Samena; Smith, Richard; Barrat, Helen
Does the type of competing interest statement affect readers’ perceptions of the credibility of research? Randomised trial
BMJ: British Medical Journal 2004 March 27; 328(7442): 742-743
Georgetown users check Georgetown Journal Finder for access to full text

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

Document 443
Erwin, Cheryl
Lessons from the past, challenges for the future: biomedical research ethics and accountability [review of Case Studies in Biomedical Research Ethics by Timothy F. Murphy]
Medical Humanities Review 2004 Spring-Fall; 18(1-2): 83-86
Georgetown users check Georgetown Journal Finder for access to full text

Document 444
Hoemi, Bernard
Juste un mot: exigences ethiques pour les remedes ineprouves / Foreword: ethical requirements for untested remedies
Georgetown users check Georgetown Journal Finder for access to full text

Document 445
Schwarz, M. Roy
Closing remarks: the use of human subjects in research conference
Georgetown users check Georgetown Journal Finder for access to full text
**Document 446**

Stern, David T.

**Future challenges from the U.S. perspective: trust as the key to clinical research**


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

**Document 447**

Capron, Alexander Morgan

**When experiments go wrong: the U.S. perspective**


**Abstract:** The view that once prevailed in the U.S.—that research is no more dangerous than the activities of daily life—no longer holds in light of recent experience. Within the past few years, a number of subjects (including normal volunteers) have been seriously injured or killed in research conducted at prestigious institutions. Plainly, when we are talking about research going wrong, we're talking about something very important. We have seen that experiments can go wrong in several ways. Subjects can be injured—physically, mentally, or by having other interests violated. Investigators can commit fraud in data collection or can abuse subjects. And review mechanisms—such as IRBs—don't always work. The two major issues when research goes wrong in any of these ways are, first: What will be done for subjects who have suffered an injury or other wrong? and second: How will future problems be prevented? The present system in the U.S. is better at the second task than the first one. Part of the difficulty in addressing the first lies in knowing what "caused" an apparent injury. Moreover, since until recently the problem of research-related injuries was thought to be a small one, there was considerable resistance to setting up a non-fault compensation system, for fear that it would lead to payment in many cases where such compensation was not deserved. Now, with a further nudge from the NBAC there is renewed interest in developing a formal system to compensate for research injuries. Finally, I have tried to show that our system of local oversight is only partially effective in improving the design of experiments and the consent process in light of "unexpected (adverse) results." As many observers, including the federal General Accounting Office (GAO), have reported, the requirement for "continuing review" of approved research projects is the weak point in the IRB system. The probable solution would be to more strictly apply the requirement that investigators report back any adverse results, de-emphasizing the "screen" introduced by the present language about "unexpected" findings. Yet, despite its weaknesses, there are good aspects to the local basis of our oversight system, and when problems become severe enough, OHRP is likely to evaluate a system and insist on local improvements. Thus, while the U.S. system is far from perfect in responding when research goes wrong, our experience may be useful to others in crafting a system appropriate to their own circumstances. One of the major tasks will be to adequately define what triggers oversight—that is, who reports what to whom and when? The setting of this trigger needs to balance appropriate incentives and penalties. Any system, including our own, will, in my opinion, work much better once an accreditation process is in place, which will offer much more current and detailed information on how each IRB is functioning and what steps are needed to help avoid "experiments going wrong."

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

**Document 448**

Levine, Robert J.

**Ethical principles for the conduct of research involving human subjects: historical considerations**


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

**Document 449**

Cheng, Zhen

**Tests involving humans [sic; human] subjects: old and new in China**
Document 450
Howe, Edmund G.
**What research practices in China may teach the U.S.**

Georgetown users check [Georgetown Journal Finder](http://georgetownjournalfinder.georgetown.edu) for access to full text

Document 451
Reiser, Stanley J.
**What Price Better Health? Hazards of the Research Imperative, by Daniel Callahan [book review]**

Georgetown users check [Georgetown Journal Finder](http://georgetownjournalfinder.georgetown.edu) for access to full text

[http://content.nejm.org](http://content.nejm.org) (link may be outdated)

Document 452
Watson, Rory
**Scientists beg EU to repeal new rules for clinical trials [news]**
BMJ: British Medical Journal 2004 January 24; 328(7433): 187

Georgetown users check [Georgetown Journal Finder](http://georgetownjournalfinder.georgetown.edu) for access to full text

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

Document 453
Richardson, Henry S.; Belsky, Leah
**The ancillary-care responsibilities of medical researchers: an ethical framework for thinking about the clinical care that researchers owe their subjects**

Georgetown users check [Georgetown Journal Finder](http://georgetownjournalfinder.georgetown.edu) for access to full text

Document 454
Morreim, E. Haavi
**High-profile research and the media: the case of the AbioCor artificial heart**

Georgetown users check [Georgetown Journal Finder](http://georgetownjournalfinder.georgetown.edu) for access to full text

Document 455
Flamm, Anne Lederman
**Medical research and media circuses**

Georgetown users check [Georgetown Journal Finder](link may be outdated)

---

* Article  Document 456
Im, Eun-Ok; Chee, Wonshik
**Issues in Internet survey research among cancer patients**
Cancer Nursing 2004 January-February; 27(1): 34-42

Georgetown users check [Georgetown Journal Finder](link may be outdated)

---

* Book  Document 457
Nesbitt, Lori A.
**CLINICAL RESEARCH: WHAT IT IS AND HOW IT WORKS**

Call number: [R850 .N47 2004](link may be outdated)

---

* Book  Document 458
Halpern, Sydney A.
**LESSER HARMS: THE MORALITY OF RISK IN MEDICAL RESEARCH**

Call number: [R853 .H8 H357 2004](link may be outdated)

---

* Book  Document 459
Smyth, Marie and Williamson, Emma, eds.
**RESEARCHERS AND THEIR SUBJECTS: ETHICS, POWER, KNOWLEDGE AND CONSENT**

Call number: [Q180.55 .M67 R492 2004](link may be outdated)

---

* Book  Document 460
Roelcke, Volker and Maio, Giovanni, eds.
**TWENTIETH CENTURY ETHICS OF HUMAN SUBJECTS RESEARCH: HISTORICAL PERSPECTIVES ON VALUES, PRACTICES, AND REGULATIONS**

Call number: [R853 .H8 T93 2004](link may be outdated)

---

* Book  Document 461
Murphy, Timothy F.
**CASE STUDIES IN BIOMEDICAL RESEARCH ETHICS**

Call number: [R724 .M876 2004](link may be outdated)
United Kingdom. Academy of Medical Sciences

**Statement on the Human Tissue Bill**
Call number: citation only

[http://www.acmedsci.ac.uk/p100puid73.html](http://www.acmedsci.ac.uk/p100puid73.html) (link may be outdated)

Agency for Health Care Research and Quality (AHRQ)

**Community-Based participatory research: assessing the evidence**

Brody, Baruch

**The ethics of controlled clinical trials**
Call number: R725.5 .H36 2004

Richardson, A.; Sitton-Kent, L.

**Research ethics**
Call number: RT85 .I687 2004

Chan, David Kum-Wah

**Autonomy, humane medicine, and research ethics: an East Asian perspective.**
Call number: TP248.23 .C76 2004

Pence, Gregory E.

**Classic cases about research and experimental treatments.**
Call number: R724 _P36 2004

Doerflinger, Richard M.

**Experimentation on human subjects and stem cell research.**
Call number: R725.56 .M68 2004
Nagashima, Takashi

**Freedom of scientific research and human dignity: Japanese discussions following wartime human experimentation and implications for today's debates on medical ethics.**


Call number: R853 .H8 T93 2004

Simek, Jiri

**Human experimentation in the Czech Republic during the last decades.**


Call number: R853 .H8 T93 2004

Maio, Giovanni

**Medical ethics and human experimentation in France after 1945.**


Call number: R853 .H8 T93 2004

Edelson, Paul J.

**Henry K. Beecher and Maurice Pappworth: honor in the development of the ethics of human experimentation.**


Call number: R853 .H8 T93 2004

Hazelgrove, Jenny

**British research ethics after the Second World War: the controversy at the British postgraduate medical school, Hammersmith Hospital.**


Call number: R853 .H8 T93 2004

Weindling, Paul

"No mere murder trial": the discourse on human experiments at the Nuremberg medical trial.


Call number: R853 .H8 T93 2004
Human subjects research during the National Socialist era, 1933-1945: programs, practices, and motivations.
Call number: R853.H8 T93 2004

* Chapter  Document 476
Frewer, Andreas
Debates on human experimentation in Weimar and early Nazi Germany as reflected in the journal "Ethik" (1922-1938) and its context.
Call number: R853.H8 T93 2004

* Chapter  Document 477
Bonah, Christian; Menut, Philippe
BCG vaccination around 1930: dangerous experiment or established prevention? Debates in France and Germany.
Call number: R853.H8 T93 2004

* Chapter  Document 478
Yudin, Boris
Human experimentation in Russia/the Soviet Union in the first half of the 20th century.
Call number: R853.H8 T93 2004

* Chapter  Document 479
Gradmann, Christoph
"It seemed about time to try one of those modern medicines": animal and human experimentation in the chemotherapy of sleeping sickness 1905-1908.
Call number: R853.H8 T93 2004

* Chapter  Document 480
Baader, Gerhard
Jewish halachic medical ethics and human experimentation.
Call number: R853.H8 T93 2004

* Chapter  Document 481
Lepicard, Etienne
The construction of human experimentation ethics: Catholic voices in context.
Document 482
Elkeles, Barbara

The German debate on human experimentation between 1880 and 1914.

Document 483
Wecht, Cyril H.

Research and experimentation.

Document 484
Rothman, David J.

Other people's bodies: human experimentation on the fiftieth anniversary of the Nuremberg Code.

Document 485
Beck, Norbert

Proteomics in pathology, research and practice: ethical considerations
Pathology, Research and Practice 2004; 200(2): 179-180

Georgetown users check Georgetown Journal Finder for access to full text

Document 486
Rothman, David J.

Research, human: historical aspects.

Document 487
De Ville, Kenneth Allen; Brody, Howard

Commercialism in scientific research.
**Document 488**
Bedford Stem Cell Research Foundation

**Bedford Stem Cell Research Foundation Guidelines for Research with Human Eggs**

http://www.bedfordresearch.org/stemcell/stemcell.php?item=stemcell_guidelines (link may be outdated)

**Document 489**
Dute, Jos

Clinical trial insurance in a comparative law perspective

*Abstract*: This paper presents the results of a comparative legal study on liability and insurance of clinical trials, including Belgium, France, Germany, the Netherlands, Spain, Switzerland, Sweden and the United Kingdom. In most countries the right to compensation of the trial subject is safeguarded, but the existing regimes show much variety. Seen from the perspective of the trial subject there is no justification for linking the extent of compensation to the object of the trial (involving drugs or not), to the nature of the trial (therapeutic or non-therapeutic) or to the status of the researcher (public entity or not).

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

**Document 490**
Elkeles, B.

Der medizinische Menschenversuch als literarisches Motiv / Human medical experimentation as literary topic
Deutsche Medizinische Wochenschrift 2003 December 19; 128(51-52): 2720-2722

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

**Document 491**
Murphy, Timothy F.

When good institutions behave badly
Chronicle of Higher Education 2003 December 19; 50(17): B15

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

**Document 492**
Schiermeier, Quirin

Shortcomings halt study of Swiss cancer vaccine [news]
Nature 2003 December 4; 426(6966): 484

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

**Document 493**
Cotton, Antoinette H.

Ensnaring webs and nets: ethical issues in Internet-based research
**Document 494**

Schwartz, L.

*Parallel experience: how art and art theory can inform ethics in human research*

Medical Humanities 2003 December; 29(2): 59-64

**Abstract:** Trends in ethical research involving humans emphasise the importance of collaboration, of involving research subjects, alongside the researchers in the construction and implementation of research. This paper will explore parallels derived from another tradition of investigation of the human: art and art theory. An artist's inquiry into the problems of human research will be described, followed by the application of arguments from art theory to research practice. Recently artist Christine Borland has provided examples in which the lack of collaboration in research has caused injustice. Borland's work reflects these ethical dilemmas and questions the procedures and assumptions involved. In most cases the value of subject anonymity is called into question because it reduces the subjects' control over themselves. The application of art theory, which has already considered these problems, helps question and explore the ways in which the subject turned object of artistic or scientific interpretation can maintain some control and dignity.

*Georgetown users check Georgetown Journal Finder for access to full text*

[http://www.medicalhumanities.com](http://www.medicalhumanities.com) (link may be outdated)

**Document 495**

Seigel, Daniel

*Clinical trials, epidemiology, and public confidence*

Statistics in Medicine 2003 November 15; 22(21): 3419-3425

*Georgetown users check Georgetown Journal Finder for access to full text*

**Document 496**

Hair, J.F.; McNicol, A.M.; Gusterson, B.A.

*Is research on human tissues at a crossroads?* [opinion]

European Journal of Cancer 2003 November; 39(16): 2253-2255

*Georgetown users check Georgetown Journal Finder for access to full text*

**Document 497**

Watson, Rory

*Pressure grows for EU to set up a European Research Council* [news]

BMJ: British Medical Journal 2003 October 4; 327(7418): 768

*Georgetown users check Georgetown Journal Finder for access to full text*

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

**Document 498**

Zlotnik-Shaul, Randi; McKneally, Martin F.
Ethical considerations for innovations and clinical trials

Mitka, Mike
Help wanted: participants for clinical trials [news]

Julian, Desmond G.
What is right and what is wrong about evidence-based medicine?
Journal of Cardiovascular Electrophysiology 2003 September; 14(9, Supplement): S2-S5

Hannigan, Ben; Allen, Davina
A tale of two studies: research governance issues arising from two ethnographic investigations into the organisation of health and social care
International Journal of Nursing Studies 2003 September; 40(7): 685-695

Willerson, James T.; Kereiakes, Dean J.
Clinical research and future improvement in clinical care: the Health Insurance Portability and Accountability Act (HIPAA) and future difficulties but optimism for the way forward
Circulation 2003 August 19; 108(7): 919-920

Reymond, Marc A.; Steinert, Ralf; Eder, Frank; Lippert, Hans
Ethical and regulatory issues arising from proteomic research and technology
Proteomics 2003 August; 3(8): 1387-1396

Mello, Michelle M.; Studdert, David M.; Brennan, Troyen A.
**The rise of litigation in human subjects research**
Annals of Internal Medicine 2003 July 1; 139(1): 40-45

**Abstract:** Owing to widespread public concern about the adequacy of protections for human research subjects and recent instances of serious injury to subjects at several major research institutions, lawsuits against investigators, institutional review boards, and academic institutions are becoming increasingly common. Several claim-promoting conditions are ripe to promote the further growth of this litigation and raise the stakes for research institutions. While this litigation may serve a valuable compensation function for injured subjects, it will also have profound effects on institutional review boards, leading to a more legalistic, mechanistic approach to ethical review that does not further the interests of human subjects or scientific progress.

Georgetown users check Georgetown Journal Finder for access to full text

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

---

**Document 505**

Montmarquet, James

**Moral character and social science research**
Philosophy 2003 July; 78(3): 355-368

Georgetown users check Georgetown Journal Finder for access to full text

---

**Document 506**

Davis, John K.

**Self-experimentation**
Accountability in Research 2003 July-September; 10(3): 175-187

**Abstract:** Except in certain cases of unusual risk, self-experimentation should not be encouraged. It is usually scientifically inadequate for lack of proper controls and sufficient subjects to generate meaningful results. It is also inadequate as an ethical test because even if lay persons are also enrolled, self-experimentation is neither necessary nor sufficient to establish that they may participate. It is not necessary to establish that lay persons may participate because institutional ethics review and informed consent are better ways to determine this. It is not sufficient because the investigator may be more risk accepting or not medically typical. Moreover, because scientific research is now done in teams, self-experimentation may involve undue influence when junior investigators participate as research.

Georgetown users check Georgetown Journal Finder for access to full text

---

**Document 507**

Neill, Kathleen M.

**Research subject advocate: a new protector of research participants**
Accountability in Research 2003 July-September; 10(3): 159-174

**Abstract:** In 2001, the National Center for Research Resources (NCRR) directed the 78 General Clinical Research Centers (GCRC) to develop a Research Subject Advocate (RSA) position. The RSA would report directly to the Principal Investigator (PI) of each GCRC and assure compliance of studies conducted on the GCRC with federal regulations and policies. Seven RSAs agreed to be interviewed about their new role. Website documents, electronic correspondence, and presentations at the first annual national meeting of RSAs were scrutinized using discursive analysis to shed light on this new organizational form and its potential for increased protection of human research participants. The RSA role actualizes the ethical principles of respect for persons, justice, and beneficence that are the foundation of the protection of research participants. The results also reveal the regulatory, institutional, collegial, and personal resources and barriers that assist the RSA in the successful implementation of the RSA role. In addition, issues important to the RSAs are described.

Georgetown users check Georgetown Journal Finder for access to full text
Document 508
Cooley, Dennis
**Responsible Conduct of Research, by Adil E. Shamoo and David B. Resnik [book review]**
Georgetown users check Georgetown Journal Finder for access to full text

Document 509
Mountney, John; Parnham, Jill
**Lessons from cadaveric research in the UK**
Bulletin of Medical Ethics 2003 June-July; (189): 13-17
Georgetown users check Georgetown Journal Finder for access to full text

Document 510
Moreno, Jonathan D.
**Remember Saddam's human guinea pigs**
Georgetown users check Georgetown Journal Finder for access to full text
http://bioethics.net (link may be outdated)

Document 511
Sollitto, Sharmon; Hoffman, Sharona; Mehlman, Maxwell; Lederman, Robert J.; Youngner, Stuart J.; Lederman, Michael M.
**Intrinsic conflicts of interest in clinical research: a need for disclosure**
Kennedy Institute of Ethics Journal 2003 June; 13(2): 83-91
**Abstract:** Protection of human subjects from investigators' conflicts of interest is critical to the integrity of clinical investigation. Personal financial conflicts of interest are addressed by university policies, professional society guidelines, public standards, and government regulation, but "intrinsic conflict of interest"—conflicts of interest inherent in all clinical research—have received relatively less attention. Such conflicts arise in all clinical research endeavors as a result of the tension among professionals' responsibilities to their research and to their patients and both academic and financial incentives. These conflicts should be disclosed to research subjects and managed as assiduously as are financial conflicts of interest.
Georgetown users check Georgetown Journal Finder for access to full text

Document 512
Alvina, Lori A.
**Who's watching the watchdogs? Responding to the erosion of research ethics by enforcing promises**
Columbia Law Review 2003 May; 103(4): 893-924
Georgetown users check Georgetown Journal Finder for access to full text
http://www.columbialawreview.org (link may be outdated)
**Document 513**
Department of Health

*The use of human organs and tissue*
Bulletin of Medical Ethics 2003 May; (188): 13-16

Georgetown users check Georgetown Journal Finder for access to full text

---

**Document 514**
Chen, Donna T.; Miller, Franklin G.; Rosenstein, Donald L.

*Clinical research and the physician-patient relationship*
Annals of Internal Medicine 2003 April 15; 138(8): 669-672

Abstract: All practicing physicians should be prepared to respond to requests from patients for advice about participating in clinical trials research. Even physicians who choose not to conduct clinical trials but rather devote their practice to clinical care may have patients who consider volunteering for research. In advising patients about clinical research, physicians enhance the physician-patient relationship and contribute to the overall goals of evidence-based medicine. We discuss several ethical and practical challenges facing physicians who wish to help their patients make decisions about volunteering for clinical trials. In addition, we suggest how preparation for advising patients about clinical research participation can be incorporated into the medical education process.

Georgetown users check Georgetown Journal Finder for access to full text

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

---

**Document 515**
The Baltimore Sun

*Controversy over use of 'living dead' patients in research [news brief]*
Monash Bioethics Review 2003 April; 22(2): 3

Georgetown users check Georgetown Journal Finder for access to full text

---

**Document 516**

Federal Register 2003 March 31; 68(61): 15456-15460

Georgetown users check Georgetown Journal Finder for access to full text

http://www.access.gpo.gov/su_docs/ (link may be outdated)

---

**Document 517**
Pontifical Academy for Life

*Ethics and biomedical research*
Medical Ethics and Bioethics / Medicinska Etika & Bioetika 2003 Spring-Summer; 10(1-2): 13-14

Georgetown users check Georgetown Journal Finder for access to full text

---

**Document 518**
Ferguson, Pamela R.

**Legal and ethical aspects of clinical trials: the views of researchers**

Georgetown users check [Georgetown Journal Finder](http://journals.georgetown.edu) for access to full text

---

Maloney, Dennis M.

**Human research subjects must have confidence that they will be protected**

Georgetown users check [Georgetown Journal Finder](http://journals.georgetown.edu) for access to full text

---

Bosch, Xavier

**Improve trials in poor nations, say EC's ethics advisers**
Lancet 2003 February 15; 361(9357): 579

Georgetown users check [Georgetown Journal Finder](http://journals.georgetown.edu) for access to full text

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

---

Mitka, Mike

**EPA [Environmental Protection Agency] ponders pesticide toxicity testing**

Georgetown users check [Georgetown Journal Finder](http://journals.georgetown.edu) for access to full text

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

---


**Opinion on ethical aspects of clinical research in developing countries: Opinion No. 17 -- Accompanying Document**

http://europa.eu.int/comm/european_group_ethics/docs/avis17_complet.pdf (link may be outdated)

---


**Ethical Aspects of Clinical Research in Developing Countries**

http://europa.eu.int/comm/european_group_ethics/docs/avis17_en.pdf (link may be outdated)
Document 524

Mulhall, Anne
In the field: notes on observation in qualitative research

Georgetown users check Georgetown Journal Finder for access to full text.

Document 525

Maloney, Dennis M.
Institutional conflicts of interest and research with human subjects

Georgetown users check Georgetown Journal Finder for access to full text.

Document 526

Kaiser, Jocelyn
Academy panel mulls ethics of human pesticide experiments [pesticides] [dosing] [news]
Science 2003 January 17; 299(5605): 327, 329

Georgetown users check Georgetown Journal Finder for access to full text.

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

Document 527

McGrath, Pam
Benefits of participation in a longitudinal qualitative research study
Monash Bioethics Review 2003 January; 22(1): 63-78

Georgetown users check Georgetown Journal Finder for access to full text.

Document 528

Moreno, Jonathan D.
A new world order for human experiments
Accountability in Research 2003 January-March; 10(1): 47-56

Georgetown users check Georgetown Journal Finder for access to full text.

Document 529

I'm a Veteran. Should I Participate in Research? Here Are Some Things You NEED to Know (2003)
Department of Veterans Affairs

Abstract: "This 8-minute video is intended for veterans and families who are interested in learning more about human research in the Department of Veterans Affairs (VA). It has a balanced view of VA research and summarizes patients' rights and welfare when they participate as subjects of research. The video is a companion to the brochure of the same title. The video and the brochure are appropriate for persons who are currently participate in research or those individuals who may consider doing so in the future." [description taken from cassette box]
Document 530
Minkler, Meredith and Wallerstein, Nina, eds.
COMMUNITY BASED PARTICIPATORY RESEARCH FOR HEALTH
Call number: RA440.85 .C65 2003

Document 531
Weyers, Wolfgang
THE ABUSE OF MAN: AN ILLUSTRATED HISTORY OF DUBIOUS MEDICAL EXPERIMENTATION
Call number: R853 .H8 W49 2003

Document 532
Bonah, Christian; Lepicard, Etienne; and Roelcke, Volker
LA MEDECINE EXPERIMENTALE AU TRIBUNAL: IMPLICATIONS ETHIQUES DE QUELQUES PROCES MEDICAUX DU XXe SIECLE EUROPEEN
Call number: R854 .E85 M43 2003

Document 533
Goodman, Jordan; McElligott, Anthony; and Marks, Lara, eds.
USEFUL BODIES: HUMANS IN THE SERVICE OF MEDICAL SCIENCE IN THE TWENTIETH CENTURY
Call number: R853 .H8 U846 2003

Document 534
Tomossy, George F. and Weisstub, David N., eds.
HUMAN EXPERIMENTATION AND RESEARCH
Call number: K3611 .H86 H86 2003

Document 535
Roach, Mary
STIFF: THE CURIOUS LIVES OF HUMAN CADAVERS
Call number: R853 .H8 R635 2003

Document 536
Boomgaarden, Jurgen; Louhiala, Pekka; and Wiesing, Urban, eds.
ISSUES IN MEDICAL RESEARCH ETHICS
Call number: R724 .I83 2003
* Document 537
Frinsina, Michael E.
**Medical ethics in military biomedical research.**
Call number: RC971 .M638 2003 v.2

* Document 538
Peart, Nicola; Adams, Jane; Dunckley, Catherine
**Research on human tissue.**
Call number: KUQ1672 .L39 2003

* Document 539
Elster, Nanette R.; Hoffman, Richard E.; Livengood, John R.
**Public health research and health information.**
Call number: KF3775 .L384 2003

* Document 540
Shapiro, Michael H., Spece, Roy G.; Dresser, Rebecca; Clayton, Ellen Wright
**Biomedical research law and policy.**
Call number: KF3821 .A7 S47 2003

* Document 541
Steinberg, Avraham
**Human experimentation.**
Call number: BM538 .H43 S7413 2003 v.2

* Document 542
Harmer, Michael
**Clinical research.**
Call number: RD82 .E87 2003

* Document 543
Boleyn-Fitzgerald, Patrick
**Experimentation and human subjects.**
* Chapter Document 544
Lidz, Victor
Renee Fox, human experimentation, and therapeutic innovation: a career of values and observations.
Call number: RA418 .S6723 2003

* Chapter Document 545
Shamoo, Adil E.; Resnik, David B.
The use of human subjects in research.
Call number: R852 .S47 2003

* Article Document 546
Hutt, Leah E.
Paying research subjects: historical considerations
Georgetown users check Georgetown Journal Finder for access to full text

* Article Document 547
Avellone, Joseph
Strategic considerations in Internet-enabled patient recruitment
Georgetown users check Georgetown Journal Finder for access to full text

* Article Document 548
Pain, Stephanie
Inactive service
New Scientist 2002 December 14; 176(2373): 52-53
Georgetown users check Georgetown Journal Finder for access to full text

* Article Document 549
Bassand, Jean-Pierre; Martin, John; Ryden, Lars; Simoons, Maarten
The need for resources for clinical research: the European Society of Cardiology calls for European, international collaboration
Lancet 2002 December 7; 360(9348): 1866-1869
Georgetown users check Georgetown Journal Finder for access to full text

http://www.thelancet.com/journal (link may be outdated)
Nicholson, Richard

Georgetown users check Georgetown Journal Finder for access to full text

Document 557
How good are clinical trial websites? [news]
Bulletin of Medical Ethics 2002 November; (183): 3-4

Georgetown users check Georgetown Journal Finder for access to full text

* Document 558
Maloney, Dennis M.
Research firm changes subject notification procedure after complaint by potential subject
Human Research Report 2002 November; 17(11): 6-7

Georgetown users check Georgetown Journal Finder for access to full text

* Document 559
Iltis, Ana Smith
Biomedical research ethics

Georgetown users check Georgetown Journal Finder for access to full text

Document 560
Federman, Daniel D.; Hanna, Kathi E.; Rodriguez, Laura Lyman; Azarnoff, Daniel L.; Beauchamp, Tom; Jost, Timothy Stoltzfus; King, Patricia A.; Little, Roderick J.A.; McNulty, James; Petersen, Anne; Ramsey, Bonnie W.; Villa-Komaroff, Lydia; Visco, Fran
Institute of Medicine (United States). Committee on Assessing the System for Protecting Human Research Participants
Responsible Research: A Systems Approach to Protecting Research Participants [Front Matter (20 p.) and Executive Summary (28 p.)] [Full report available online]

Georgetown users check Georgetown Journal Finder for access to full text
Document 561
Federman, Daniel D.; Hanna, Kathi E.; Rodriguez, Laura Lyman; Azarnoff, Daniel L.; Beauchamp, Tom; Jost, Timothy Stoltzfus; King, Patricia A.; Little, Roderick J.A.; McNulty, James; Petersen, Anne; Ramsey, Bonnie W.; Villa-Komaroff, Lydia; Visco, Fran
Institute of Medicine (United States). Committee on Assessing the System for Protecting Human Research Participants
Responsible Research: A Systems Approach to Protecting Research Participants: Summary

Document 562
Savulescu, Julian
No consent should be needed for using leftover body material for scientific purposes [debate] [against]
BMJ: British Medical Journal 2002 September 21; 325(7365): 649-651

Document 563
van Diest, Paul J.
No consent should be needed for using leftover body material for scientific purposes [debate] [for]
BMJ: British Medical Journal 2002 September 21; 325(7365): 648-649

Document 564
Stegmayr, Birgitta; Asplund, Kjell
Informed consent for genetic research on blood stored for more than a decade: a population based study [see correction in BMJ 2002 October 19; 325(7369): 900]
BMJ: British Medical Journal 2002 September 21; 325(7365): 634-635

Document 565
Trial and Error: [A Family's Quest for Answers [Jesse Gelsinger] (2002)
Dateline
Abstract: Jesse Gelsinger. Story of his life, his involvement in the gene therapy trials, his father Paul's efforts to find out what happened to his son and to bring about change to the oversight of human subject research, especially gene
therapy trials. [Framed by the story of Jesse Gelsinger, an 18-year-old volunteer who died while involved in a gene therapy trial, this Dateline Story describes efforts to review medical research in America.]

http://www.msnbc.com/news/809196.asp (link may be outdated)

Document 566
Kahn, Jeffrey P.
**Building public trust in research**
Journal of Andrology 2002 September-October; 23(5): 610
Georgetown users check [Georgetown Journal Finder](http://www.msnbc.com/news/809196.asp) for access to full text

Document 567
**Consumers in NHS [National Health Service] research [news]**
Bulletin of Medical Ethics 2002 September; (181): 6
Georgetown users check [Georgetown Journal Finder](http://www.msnbc.com/news/809196.asp) for access to full text

Document 568
Moreno, Jonathan D.
**The brief career of a government advisory committee: one member's perspective**
Georgetown users check [Georgetown Journal Finder](http://www.msnbc.com/news/809196.asp) for access to full text

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

Document 569
Blakeslee, Sandra
**Surgeons are warned about heart valves**

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

Document 570
Serour, Gamal I.
**Ethics in Health Research: Issues, Needs and Strategies for Ethics Practices in health Research in EMRO**

Document 571
Blakeslee, Sandra
**Recall is ordered at large supplier of implant tissue: company cited by F.D.A. [Food and Drug Administration]: 27 infections found, one fatal - U.S. says CryoLife can't ensure product safety**
* Article

Document 572
Halpern, Scott D.; Karlawish, Jason H.T.; Berlin, Jesse A.
The continuing unethical conduct of underpowered clinical trials
Abstract: Despite long-standing critiques of the conduct of underpowered clinical trials, the practice not only remains widespread, but also has garnered increasing support. Patients and healthy volunteers continue to participate in research that may be of limited clinical value, and authors recently have offered 2 related arguments to support the validity and value of underpowered clinical trials: that meta-analysis may "save" small studies by providing a means to combine the results with those of other similar studies to enable estimates of an intervention's efficacy, and that although small studies may not provide a good basis for testing hypotheses, they may provide valuable estimates of treatment effects using confidence intervals. In this article, we examine these arguments in light of the distinctive moral issues associated with the conduct of underpowered trials, the disclosures that are owed to potential participants in underpowered trials so they may make autonomous enrollment decisions, and the circumstances in which the prospects for future meta-analyses may justify individually underpowered trials. We conclude that underpowered trials are ethical in only 2 situations: small trials of interventions for rare diseases in which investigators document explicit plans for including their results with those of similar trials in a prospective meta-analysis, and early-phase trials in the development of drugs or devices, provided they are adequately powered for defined purposes other than randomized treatment comparisons. In both cases, investigators must inform prospective subjects that their participation may only indirectly contribute to future health care benefits.

Georgetown users check Georgetown Journal Finder for access to full text

Document 573
Bartlett, Christopher; Sterne, Jonathan; Egger, Matthias
What is newsworthy? Longitudinal study of the reporting of medical research in two British newspapers
BMJ: British Medical Journal 2002 July 13; 325(7355): 81-84
Abstract: OBJECTIVE: To assess the characteristics of medical research that is press released by general medical journals and reported in newspapers. DESIGN: Longitudinal study. DATA SOURCES: All original research articles published in Lancet and BMJ during 1999 and 2000. MAIN OUTCOME MEASURES: Inclusion of articles in Lancet or BMJ press releases, and reporting of articles in Times or Sun newspapers. RESULTS: Of 1193 original research articles, 517 (43%) were highlighted in a press release and 81 (7%) were reported in one or both newspapers. All articles covered in newspapers had been press released. The probability of inclusion in press releases was similar for observational studies and randomised controlled trials, but trials were less likely to be covered in the newspapers (odds ratio 0.15 (95% confidence interval 0.06 to 0.37)). Good news and bad news were equally likely to be press released, but bad news was more likely to be reported in newspapers (1.74 (1.07 to 2.83)). Studies of women's health, reproduction, and cancer were more likely to be press released and covered in newspapers. Studies from industrialised countries other than Britain were less likely to be reported in newspapers (0.51 (0.31 to 0.82)), and no studies from developing countries were covered. CONCLUSIONS: Characteristics of articles were more strongly associated with selection for reporting in newspapers than with selection for inclusion in press releases, although each stage influenced the reporting process. Newspapers underreported randomised controlled trials, emphasised bad news from observational studies, and ignored research from developing countries.

Georgetown users check Georgetown Journal Finder for access to full text

Document 574
Risch, Neil; Burchard, Esteban; Ziv, Elad; Tang, Hua
Categorization of humans in biomedical research: genes, race and disease
Document 575

Report on a workshop on ethics in biomedical research, Trivandrum
Issues in Medical Ethics 2002 July-September; 10(3): 61

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

Document 576

Mill, Judy E.; Ogilvie, Linda D.
Ethical decision making in international nursing research
Qualitative Health Research 2002 July; 12(6): 807-815

Document 577

Dembner, Alice
Lawsuits target medical research

Document 578

Gottlieb, Scott
Researchers discover adult cell that acts like stem cell from embryos [news]
BMJ: British Medical Journal 2002 June 29; 324(7353): 1544

Document 579

Kaufman, Marc
FDA [Food and Drug Administration] reapproves bowel drug after pulling it for safety [Lotronex]
Washington Post 2002 June 8; p. A4

Document 580

Consumers in NHS research: who are we?
CERES (Consumers for Ethics in Research) NEWS 2002 Summer; (32): 5
Document 581
Wright, Thomas A.; Wright, Vincent P.
Organizational researcher values, ethical responsibility, and the committed-to-participant research perspective

Document 582
Larsen, Richard; Jacob, Ethel; Marinetti, Camille
Human subjects database
Protecting Human Subjects 2002 Summer-Fall; (7): 14

Document 583
Maloney, Dennis M.
Objectivity of research data and public reaction

Document 584
Evans, Donald
The use of human tissue: an outsider's view

Document 585
Jones, D. Gareth
The use of human tissue: an insider's view
New Zealand Bioethics Journal 2002 June; 3(2): 8-12

Document 586
Cave, Emma
The Ethics of Medical Research on Humans, by Claire Foster [book review]
John Paul II, Pope

**The profit motive behind too much medical research**
Origins 2002 April 25; 31(45): 754-755

Georgetown users check [Georgetown Journal Finder](http://journalfinder.georgetown.edu) for access to full text

---

Stevens, Lise M.; Lynm, Cassio; Glass, Richard M.

**Basic science research**

Georgetown users check [Georgetown Journal Finder](http://journalfinder.georgetown.edu) for access to full text

---

Coleman, Laura; Holdsworth, Stacy

**A review of current events in human subjects protection**

Georgetown users check [Georgetown Journal Finder](http://journalfinder.georgetown.edu) for access to full text

---

Byk, Christian

**Conflicts of interest and access to information from medical research**
Bulletin of Medical Ethics 2002 April; (177): 18-19

Georgetown users check [Georgetown Journal Finder](http://journalfinder.georgetown.edu) for access to full text

---

Torpy, Janet M.


Georgetown users check [Georgetown Journal Finder](http://journalfinder.georgetown.edu) for access to full text

---

**How to be DNA chic [news]**
Nature Genetics 2002 March; 30(3): 249

Georgetown users check [Georgetown Journal Finder](http://journalfinder.georgetown.edu) for access to full text

[http://genetics.nature.com](http://genetics.nature.com) (link may be outdated)
* Document 593

Trachtman, Howard

**I thought we were in this together?**
American Journal of Bioethics 2002 Spring; 2(2): 30-31

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

* Document 594

Resnik, David B.

**Exploitation and the ethics of clinical trials**

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

* Document 595

Steinberg, David

**Clinical research should not be permitted to escape the ethical orbit of clinical care**

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

* Document 596

Singapore. Bioethics Advisory Committee. Human Genetics Sub-Committee [HGS]
**Human Tissue Research. Consultation Paper**

* Document 597

Dayton, Leigh

**Return of the skulls [craniometry]**
New Scientist 2002 February 23; 173(2331): 34-37

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

* Document 598

Pain, Stephanie

**This won't hurt a bit**
New Scientist 2002 February 16; 173(2330): 48-49

Georgetown users check [Georgetown Journal Finder](#) for access to full text.
**Managing conflicts of interest in the conduct of clinical trials**

**JAMA: The Journal of the American Medical Association** 2002 January 2; 287(1): 78-84

**Abstract:** The interaction between medical research and for-profit corporations is not new, but it has expanded considerably in recent years. Some of the recent trends may accelerate the research process, particularly when large clinical trials are required. However, a renewed commitment to the application of high ethical standards is essential to ensure that societal trust in research is not eroded, subjects enrolled in trials do not become merely a means to an end, and medical research is efficiently translated into clinical advances that will benefit future patients. This article focuses on the analysis of conflicts of interest in the conduct of clinical trials in both academic and community-based settings. Specifically, it discusses how the roles of research scientists and clinical practitioners differ and the importance of ensuring that participants' consent to enroll in clinical trials is not the result of confusion about the goals of an experimental treatment that may resemble clinical care. The article also discusses the potential conflicts of interest that can arise when clinicians stand to gain from enrolling their own patients as subjects in clinical trials and examines various instances in which disclosure of information regarding funding and compensation may serve to minimize such conflicts. This article emphasizes that to preserve the integrity of research and to protect the welfare of human subjects who enroll in trials, physicians should have adequate training in the conduct of research and be familiar with the ethics of research. When a physician has treated or continues to treat a patient who is eligible to enroll as a subject in a clinical trial conducted by the same physician, someone other than the treating physician should obtain the participant's informed consent. Finally, the article addresses disclosure of financial incentives and related funding issues.

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

**Restoring and preserving trust in biomedical research**

**Academic Medicine** 2002 January; 77(1): 8-14

**Abstract:** This essay examines and analyzes the recent and dramatic series of personal injury lawsuits instituted against those individuals and institutions that conduct and monitor human research. It discusses the social engineering functions of tort litigation, outlines the legal elements and viability of lawsuits against those who conduct and monitor human research, and evaluates and predicts what role tort litigation will play in fulfilling the goals of accountability in the context of human research and human research regulation. In general, tort law engenders two forms of accountability: retrospective and prospective. Retrospective accountability is backward looking, focusing on harms that have already occurred, their culprits, and the reimbursement of individuals for their injuries. Prospective
Accountability is forward looking in that it encourages actors and institutions to fulfill responsibilities toward individuals in order that harm does not occur, or at least that the risk of harm is decreased. This article argues that research litigation is not, and will probably never become, an effective means of ensuring retrospective accountability in regard to research injuries and ethical violations. Paradoxically though, the current wave of research litigation may serve an important and even key role in encouraging and ensuring prospective accountability.

Georgetown users check Georgetown Journal Finder for access to full text

---

**Document 603**

**Why Did Jesse Have to Die? (2002)**
Gruppe 5 Filmproduktion GmbH

[http://www.gruppe5film.de](http://www.gruppe5film.de) (link may be outdated)

**Document 604**

Singapore. Bioethics Advisory Committee

**HUMAN TISSUE RESEARCH**
Call number: **RD127.H86 2002**

[http://www.bioethics-singapore.org/](http://www.bioethics-singapore.org/) (link may be outdated)

**Document 605**

Duley, Lelia and Farrell, Barbara, eds.

**CLINICAL TRIALS**
Call number: **R853.C55 C57 2002**

**Document 606**

Gallin, John I.

**PRINCIPLES AND PRACTICE OF CLINICAL RESEARCH**
Call number: **R850.G35 2002**

**Document 607**

Helms, Robert, ed.

**GUINEA PIG ZERO: AN ANTHOLOGY OF THE JOURNAL FOR HUMAN RESEARCH SUBJECTS**
Call number: **R853.H8 H45 2002**

**Document 608**

Thornton, Hazel

"Empowering" patient choice about participation in trials?
Call number: **R853.C55 C57 2002**
* Chapter Document 609
Straus, Stephen E.
**Unanticipated risk in clinical research.**
Call number: R850 .G35 2002

* Chapter Document 610
Grady, Christine
**Ethical principles in clinical research.**
Call number: R850 .G35 2002

* Chapter Document 611
Niu, Huei-Chih
**Human subject research -- ethical and legal approaches for compensation for research induced injury in Taiwan**
Call number: QH332 .A85 2002

* Chapter Document 612
Van Eys, Jan
**The devil's being God's best inspiration: the boundary between research and care.**
Call number: R725.5 .C668 2002

* Chapter Document 613
Delfosse, Marie-Luce
**Experiments carried out on human subjects and the doctor- patient relationship: epistemology and ethics.**
Call number: R724 .H35 2002

* Chapter Document 614
Ashcroft, Richard
**Clinical research and patients: an ethical perspective -- nursing research.**
Call number: KD2968 .N8 N87 2002

* Chapter Document 615
Fox, Marie
**Clinical research and patients: the legal perspective.**
252-277.
Call number:  KD2968 .N8 N87 2002

*  Article  Document 616
Walther, Joseph B.
**Research ethics in Internet-enabled research: human subjects issues and methodological myopia**
Ethics and Information Technology 2002; 4(3): 205-216
Georgetown users check  Georgetown Journal Finder  for access to full text

*  Article  Document 617
Ferguson, Steven M.
**Products, partners and public health: transfer of biomedical technologies from the U.S. [United States] government**
Georgetown users check  Georgetown Journal Finder  for access to full text

*  Chapter  Document 618
Luna, Florencia
**Research in developing countries: the ethical issues.**
Call number:  QH332 .B48 2002

*  Article  Document 619
Reuland, A.
"100 Ratten und 20 Kinder!" -- Julius Moses und die Debatte über Menschenexperimente in der Weimarer Republik ["100 rats and 20 children!" -- Julius Moses and the debate on human experimentation during the Weimar Republic] [English abstract]
Wiener Medizinische Wochenschrift 2002; 152(1-2): 45-48
Georgetown users check  Georgetown Journal Finder  for access to full text

*  News  Document 620
Washburn, Jennifer
**Informed consent [Alan Milstein, Jesse Gelsinger]**
Washington Post Magazine 2001 December 30; p. 8-13, 23-26
[http://www.washingtonpost.com](http://www.washingtonpost.com) (link may be outdated)

*  News  Document 621
Vedantam, Shankar
**EPA calls for pause in pesticide tests on humans: After evaluating results of three such trials, agency seeks advice on ethics and utility of practice**
Washington Post 2001 December 15; p. A2
Document 622
American Association of Medical Colleges [AAMC]. Task Force on Financial Conflicts of Interest in Clinical Research
Protecting Subjects, Preserving Trust, Promoting Progress: Principles and Recommendations for Oversight of Individual Financial Interests in Human Subjects Research
Georgetown users check Georgetown Journal Finder for access to full text

Document 623
Jeffers, Brenda Recchia
Human biological materials in research: ethical issues and the role of stewardship in minimizing research risks
Advances in Nursing Science 2001 December; 24(2): 32-46
Georgetown users check Georgetown Journal Finder for access to full text

Document 624
Agency for Health Care Research and Quality (AHRQ)
Community-based participatory research: conference summary report

Document 625
Francisco, Michael
Patient waiting [review of Human Trials: Scientists, Investors, and Patients in the Quest for a Cure, by Susan Quinn]
Nature Biotechnology 2001 November; 19(11): 1009
Georgetown users check Georgetown Journal Finder for access to full text

Document 626
Nelson, Robert M.
Nontherapeutic research, minimal risk, and the Kennedy Krieger lead abatement study
IRB: Ethics and Human Research 2001 November-December; 23(6): 7-11
Georgetown users check Georgetown Journal Finder for access to full text

http://kie.georgetown.edu/nrcbl/documents/irb/v23/i23n6p07.pdf (link may be outdated)
Document 627

Tsuchiya, Takashi

*In the Shadow of the Past Atrocities: Research Ethics with Human Subjects in Contemporary Japan*


Document 628

Ramsay, Sarah

*No closure in sight for the 10/90 health-research gap [news]*

Lancet 2001 October 20; 358(9290): 1348

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

Document 629

Kincaid, Harold

*The ethical and epistemic issues in inferior treatment in clinical research*

Formosan Journal of Medical Humanities 2001 October; 2(1-2): 34-40

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

Document 630

Dean, Cornelia

*A conversation with Joseph E. Murray: On surgical innovation and the questions it can raise*


[http://www.nytimes.com](http://www.nytimes.com) (link may be outdated)

Document 631

Vastag, Brian

*Clinical trials to receive a boost, but how big? [news]*


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

Document 632

Albanese, Andrew

*Could librarians' help have prevented Hopkins tragedy?*

Library Journal 2001 September 1; 126(14): 16

Georgetown users check [Georgetown Journal Finder](http://www.thelancet.com) for access to full text
Document 633
Douglas-Vidas, Jenny; Ferraro, Aimee; Reichman, Marsha E.
Analysis of Guidelines for the Conduct of Research Adopted by Medical Schools or Their Components

http://ori.dhhs.gov/publications/studies.shtml (link may be outdated)

Document 634
Quigley, Rosemary B.
Whither the advocate? A struggle for voice and hope in medical research [review of When Science Offers Salvation: Patient Advocacy and Research Ethics, by Rebecca Dresser]
Medical Humanities Review 2001 Fall; 15(2): 93-97
Georgetown users check Georgetown Journal Finder for access to full text

Document 635
Pendo, Elizabeth A.
Georgetown users check Georgetown Journal Finder for access to full text

Document 636
Karigan, Maria
Ethics in clinical research: The nursing perspective
AJN: American Journal of Nursing 2001 September; 101(9): 26-31
Georgetown users check Georgetown Journal Finder for access to full text

Document 637
Njie, Veronica P. S.; Thomas, Anne C.
Quality issues in clinical research and the implications on health policy (QICRHP)
Journal of Professional Nursing 2001 September-October; 17(5): 233-242
Georgetown users check Georgetown Journal Finder for access to full text

Document 638
Silverstein, Samuel C.
From genomics and informatics to medical practice
Issues in Science and Technology 2001 Fall; 18(1): 37-41
Georgetown users check Georgetown Journal Finder for access to full text
* Document 639
Sibbald, Barbara
*Asthma research claims life of test participant [news]*
CMAJ/JAMC: Canadian Medical Association Journal 2001 August 21; 165(4): 464
Georgetown users check *Georgetown Journal Finder* for access to full text

* Document 640
Man-Son-Hing, Malcolm; Hart, Robert G.; Berquist, Renee; O'Connor, Annette M.; Laupacis, Andreas
*Differences in treatment preferences between persons who enrol and do not enrol in a clinical trial*
Georgetown users check *Georgetown Journal Finder* for access to full text

* Document 641
Groopman, Jerome
*Clinical Trials, Human Errors*
[http://www.nytimes.com](http://www.nytimes.com) *(link may be outdated)*

* Document 642
Friele, Minou Bernadette
*The extent of collective responsibility in medical science*
Georgetown users check *Georgetown Journal Finder* for access to full text

* Document 643
Maloney, Dennis M.
*National Institutes of Health [NIH]*
Human Research Report 2001 July; 16(7): 11
Georgetown users check *Georgetown Journal Finder* for access to full text

* Document 644
Nelson-Rees, Walter A.
*Responsibility for truth in research*
Philosophical Transactions of the Royal Society of London B Biological Sciences 2001 June 29; 356(1410): 849-851
Georgetown users check *Georgetown Journal Finder* for access to full text

* Document 645
Stacpoole, Peter W.
"Bench-to-bedside" -- the wrong paradigm for patient-oriented investigation [opinion]
Academic Medicine 2001 June; 76(6): 616

Georgetown users check Georgetown Journal Finder for access to full text

---

Les Richtlinien du conseil de sante de l'empire Allemand de 1931 [The Richtlinien of the Health Council of the German Empire of 1931]

Georgetown users check Georgetown Journal Finder for access to full text

---

Resnik, David
Setting Biomedical Research Priorities: Justice, Science, and Public Participation
Kennedy Institute of Ethics Journal 2001 June; 11(2): 181-204

Georgetown users check Georgetown Journal Finder for access to full text

---

European Science Foundation
European Science Foundation Policy Briefing: Controlled Clinical Trials
France: European Science Foundation, European Science Foundation Policy Briefing, No. 13, 2001 May; 6 p.

http://www.esf.org/publication/90/ESPB13.pdf (link may be outdated)

---

Nelson, Robert M.
Protocol 126 and "The Hutch"
IRB: Ethics and Human Research 2001 May-June; 23(3): 14-16

Georgetown users check Georgetown Journal Finder for access to full text

http://kie.georgetown.edu/nrcbl/documents/irb/v23/irb23n3p14.pdf (link may be outdated)

---

Pritchard, Ivor A.
Searching for "research involving human subjects" -- What is examined? What is exempt? What is exasperating?
IRB: Ethics and Human Research 2001 May-June; 23(3): 5-13

Georgetown users check Georgetown Journal Finder for access to full text

http://kie.georgetown.edu/nrcbl/documents/irb/v23/irb23n3p05.pdf (link may be outdated)
EthxWeb Search Results

Search Detail:
Result=(("18.1".PC.) AND (@YD >= "20000000")) NOT (EDITORIAL OR LETTER)
2=1 :
Documents: 651 - 753 of 753

Document 651
The Hastings Center
IRB: Ethics & Human Research
Hastings Center Report 2001 May-June; 31(3): 28

Georgetown users check [Georgetown Journal Finder](http://kie.georgetown.edu/nrcbl/documents/hcr/v31/h31n3p28.pdf) for access to full text

Document 652
Reidpath, Daniel D.; Allotey, Pascale A.
Data Sharing in Medical Research: An Empirical Investigation
Bioethics 2001 April; 15(2): 125-134

Georgetown users check [Georgetown Journal Finder](http://kie.georgetown.edu/nrcbl/documents/hcr/v31/h31n3p28.pdf) for access to full text

Document 653
Richter, Elihu D.; Barach, Paul; Berman, Tamar; Ben-David, G.; Weinberger, Zvi
Extending the Boundaries of the Declaration of Helsinki: A Case Study of an Unethical Experiment in a Non-Medical Setting
Journal of Medical Ethics 2001 April; 27(2): 126-129

Georgetown users check [Georgetown Journal Finder](http://kie.georgetown.edu/nrcbl/documents/hcr/v31/h31n3p28.pdf) for access to full text

Document 654
Concar, David; Ainsworth, Claire; Young, Emma
Fetal Cell Transplants: Special Report
New Scientist 2001 March 24; 169(2283): 10-11

Georgetown users check [Georgetown Journal Finder](http://kie.georgetown.edu/nrcbl/documents/hcr/v31/h31n3p28.pdf) for access to full text

Document 655
Visser, Henk K. A.
Non-therapeutic research in the EU [European Union] in adults incapable of giving consent? [Good Clinical Practice (GCP) Guideline] [commentary]
Lancet 2001 March 17; 357(9259): 818-819
Georgetown users check Georgetown Journal Finder for access to full text

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

Document 656

Thomas, Paul; Griffiths, Frances; Kai, Joe; O'Dwyer, Aislinn

*Networks for Research in Primary Health Care*

BMJ: British Medical Journal 2001 March 10; 322(7286): 588-590

Georgetown users check Georgetown Journal Finder for access to full text

Document 657

Varmus, Harold

*Proliferation of National Institutes of Health*

Science 2001 March 9; 291(5510): 1903, 1905

Georgetown users check Georgetown Journal Finder for access to full text

Document 658

Djulbegovic, Benjamin; Clarke, Mike

*Scientific and Ethical Issues in Equivalence Trials*

JAMA: The Journal of the American Medical Association 2001 March 7; 185(9): 1206-1208

Georgetown users check Georgetown Journal Finder for access to full text

Document 659

Savulescu, Julian

*Taking the Plunge*

New Scientist 2001 March 3; 169(2280): 50-51

Georgetown users check Georgetown Journal Finder for access to full text

Document 660

Katz, Paula

*A Kantian claim permitting the randomized clinical trial*


Georgetown users check Georgetown Journal Finder for access to full text

Document 661

Grinyer, Anne

*Ethical Dilemmas in Nonclinical Health Research from a UK Perspective*

Nursing Ethics 2001 March; 8(2): 123-132

Georgetown users check Georgetown Journal Finder for access to full text
Document 662
Eckenwiler, Lisa
*Moral Reasoning and the Review of Research Involving Human Subjects*
Kennedy Institute of Ethics Journal 2001 March; 11(1): 37-69
Georgetown users check *Georgetown Journal Finder* for access to full text

Document 663
Newman, Judith
*Drug Trials Reach Out for Patients (and Vice Versa) on the Web*
New York Times 2001 February 27; p. F5, F8
[http://www.nytimes.com](http://www.nytimes.com) (link may be outdated)

Document 664
Safire, William
*Proteomics: the word that just whizzed past genomics*
New York Times Magazine 2001 February 18; p. 16
[http://www.nytimes.com](http://www.nytimes.com) (link may be outdated)

Document 665
Dickens, Bernard M.
*Limits of confidentiality in human research*
Canadian Bioethics Society Newsletter 2001 February; 6(1): 10-11
Georgetown users check *Georgetown Journal Finder* for access to full text
[http://www.bioethics.ca/english/newsletter/](http://www.bioethics.ca/english/newsletter/) (link may be outdated)

Document 666
Price, James H.; Dake, Joseph A.; Islam, Rafat
*Selected ethical issues in research and publication: perceptions of health education faculty*
Health Education and Behavior 2001 February; 28(1): 51-64
Georgetown users check *Georgetown Journal Finder* for access to full text

Document 667
Wray, Emma
*UNDUE RISK - SECRET STATE EXPERIMENTS ON HUMANS, by J.D. Moreno [book review]*
Bulletin of Medical Ethics 2001 February; (165): 24
Georgetown users check *Georgetown Journal Finder* for access to full text
Document 668
Margo, Curtis E.
**When Is Surgery Research? Towards an Operational Definition of Human Research**
Journal of Medical Ethics 2001 February; 27(1): 40-43
Georgetown users check [Georgetown Journal Finder](http://www.georgetown.edu/nrcbl/documents/jme/v27/issue/issue1/2001/0112001.pdf) for access to full text

Document 669

**The Way It Is: A Clinical Trial**
Lancet 2001 January 20; 357(9251): 238
Georgetown users check [Georgetown Journal Finder](http://www.georgetown.edu/nrcbl/documents/jme/v27/issue/issue1/2001/0112001.pdf) for access to full text

Document 670
Wertz, Dorothy C.
**Archived specimens: ethics concerns**
Acta Tropica 2001 January 15; 78(Supplement): S77-S84
Georgetown users check [Georgetown Journal Finder](http://www.georgetown.edu/nrcbl/documents/jme/v27/issue/issue1/2001/0112001.pdf) for access to full text

Document 671
Martindale, Diane
**Bodies of Evidence**
New Scientist 2001 January 6; 169(2272): 24-28
Georgetown users check [Georgetown Journal Finder](http://www.georgetown.edu/nrcbl/documents/jme/v27/issue/issue1/2001/0112001.pdf) for access to full text

Document 672
Ramakrishna, Jayashree
**Values and obligations in qualitative research**
Issues in Medical Ethics 2001 January-March; 9(1): 5-6
[http://www.medicalethicsindia.org](http://www.medicalethicsindia.org) (link may be outdated)

Document 673
Reily, Philip Key
**Been there; done that (we've been there; they've done that)**
[http://kie.georgetown.edu/nrcbl/documents/irb/v23/irb23n1p08.pdf](http://kie.georgetown.edu/nrcbl/documents/irb/v23/irb23n1p08.pdf) (link may be outdated)
Document 674

Hesse, Hans

**Augen aus Auschwitz: Ein Lehrstück über nationalsozialistischen Rassenwahn und medizinische Forschung—Der Fall Dr. Karin Magnussen**


Call number: R509 .H47 2001

---

Document 675

Bell, James Scott

**The Nephilim Seed: A Novel**


Call number: PS3552 .E5158 N4 2001

---

Document 676

Foster, Claire

**The Ethics of Medical Research on Humans**


Call number: R853 .H8 F67 2001

---

Document 677

Quinn, Susan

**Human Trials: Scientists, Investors, and Patients in the Quest for a Cure**


Call number: R853 .C55 Q56 2001

---

Document 678

Dresser, Rebecca

**When Science Offers Salvation: Patient Advocacy and Research Ethics**


Call number: R727.45 .D74 2001

---

Document 679

Vere, Duncan

**Human experiments**


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

---

Document 680

Warner, John Harley; Tighe, Janet Ann

**The culture of biomedical research: human subjects, power, and the scientific method, 1920-1965**

Document 681

Weijer, Charles

The ethical analysis of risks and potential benefits in human subjects research: history, theory, and implications for U.S. regulation.


Call number: R853.H8 U548 2001 v.2

Document 682

Vanderpool, Harold Y.

Unfulfilled promise: how the Belmont Report can amend the Code of Federal Regulations Title 45 Part 46--Protection of Human Subjects.


Call number: R853.H8 U548 2001 v.2

Document 683

Moreno, Jonathan D.

Protectionism in research involving human subjects.


Call number: R853.H8 U548 2001 v.2

Document 684

Goldman, Janlori; Choy, Angela

Privacy and confidentiality in health research.


Call number: R853.H8 U548 2001 v.2

Document 685

McDonald, Michael

The governance of health care research involving human subjects: reflections on ethical policy for science research.


Call number: QH332.S3825 2001

Document 686

Dickens, Bernard M.

Can science or ethics compromise each other in human subject research?


Call number: QH332.S3825 2001
* **Chapter** Document 687
Dekkers, Wim J.M.
**Experimentation with human beings**
Call number: R724 .B48256 2001

**Chapter** Document 688
Alora, Angeles Tan
**Ethical issues in research.**
Call number: R725.5 .B49 2001

**Chapter** Document 689
Halpern, Sydney A.
**Constructing moral boundaries: public discourse on human experimentation in twentieth-century America.**
Call number: R724 .B4826 2001

**News** Document 691
Kolata, Gina
**Company Won't Get Access to Data of Famed Heart Study**

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

**Article** Document 692
Puetz, Linda
**Research ethics**
Bioethics Forum 2000 Winter; 16(4): 47-49

Georgetown users check Georgetown Journal Finder for access to full text

* **Article** Document 693
Koski, Greg
**Protecting human subjects in research -- Occasional views along a road less traveled**
* Document 694

Marshall, Mary Faith
**Taking the "I" out of IRB – and putting "community" in**
Bioethics Forum 2000 Winter; 16(4): 7-12

* Document 695

Genetics and human behavior [news]
Bulletin of Medical Ethics 2000 December-2001 January; (164): 7

* Document 696

Weijer, Charles
**The Ethical Analysis of Risk**

* Document 697

Pfeffer, Naomi; Hogg, Christine
**Research Subjects Need Independent Information and Advice**
CERES (Consumers for Ethics in Research) NEWS 2000 Winter; (29): 1

* Document 698

National Institutes of Health [NIH] (United States). Department of Clinical Bioethics
**Ethical and Regulatory Aspects of Human Subjects Research, November 1 - December 20, 2000**
Bethesda, MD: National Institutes of Health [NIH], 2000 November 1; [multiple pages; spiral bound volume]

Abstract: a collection of previously published papers gathered for the course held in seven weekly sessions at the Lipsett Amphitheater, November 1 - December 20, 2000. A syllabus of the course is included.

* Document 699

Gordon, B.; Prentice, E.
**Protection of human subjects in the United States: a short history**
Document 700
Association of American Medical Colleges [AAMC]. Office of Communications
Keeping Patients First: AAMC’s Strategic Response Guide to Controversies in Human Clinical Research
Washington, DC: The Association [KPFM], 2000 November; [multiple pages]
Abstract: This publication contains a number of internal communication documents related to the suspension of clinical research activities at Duke University in 1999. These documents are used to provide examples of appropriate ways to communicate when controversies arise in human clinical research.

http://www.aamc.org/publications/kpfm.htm (link may be outdated)

Document 701
King, Nancy M. P.
Patient or guinea pig?
Guinea Pig Zero 2000 November; (8): 18-21, 24
Georgetown users check Georgetown Journal Finder for access to full text

Document 702
Rettig, Richard A.
Are Patients a Scarc Resource for Academic Clinical Research?
Health Affairs 2000 November/December; 19(6): 195-205
Georgetown users check Georgetown Journal Finder for access to full text

Document 703
Hill, Joal M.
A New Era for Research Integrity
Park Ridge Center Bulletin 2000 November-December; (18): 3-4
Georgetown users check Georgetown Journal Finder for access to full text

Document 704
National Institutes of Health [NIH] (United States). Department of Clinical Bioethics
Ethical and Regulatory Aspects of Human Subjects Research, October 23 - December 11, 2002
Bethesda, MD: National Institutes of Health, 2000; [multiple pages] [3-ring binder]
Abstract: A syllabus and a collection of previously published papers gathered for the course held in weekly sessions at the National Institutes of Health, October 23 - December 11, 2002.

Document 705
Merz, Jon F.
Document 706
Costello, Anthony; Zumla, Alimuddin
Moving to Research Partnerships in Developing Countries
BMJ: British Medical Journal 2000 September 30; 321(7264): 827-829

Document 707
United States. Environmental Protection Agency [EPA]. Science Advisory Board
Comments on the use of Data from the Testing of Human Subjects: A Report by the Science Advisory Board and the FIFRA Scientific Advisory Panel

Document 708
Service, Robert S.
Tissue Engineers Build New Bone [news]
Science 2000 September 1; 289(5484): 1498-1500

Document 709
Kiberstis, Paula; Smith, Orla; Norman, Colin
Bone Health in the Balance
Science 2000 September 1; 289(5484): 1497

Document 710
Carpentier, Richard
Le Defi de la Recherche D'un Langage Commun dans la Redaction de Normes Pluridisciplinaires
Journal International de Bioethique: International Journal of Bioethics 2000 September-December; 11(3-4-5): 231-235

Document 711
Upton, Arthur C.
Time to Deal with the Legacy of Secrecy [review of UNDUE RISK: SECRET STATE EXPERIMENTS ON
HUMANS, by Jonathan D. Moreno
Nature 2000 August 31; 406(6799): 938
Georgetown users check Georgetown Journal Finder for access to full text

Document 712
Mayor, Susan
Lung Cancer Trial Has Problems in Recruitment [news]
BMJ: British Medical Journal 2000 July 22; 321(7255): 195
Georgetown users check Georgetown Journal Finder for access to full text

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

Document 713
Charatan, Fred
US Halts University of Oklahoma Clinical Research [news]
BMJ: British Medical Journal 2000 July 22; 321(7255): 195
Georgetown users check Georgetown Journal Finder for access to full text

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

* Document 714
Pollack, Andrew
Company Seeking Donors of DNA for a `Gene Trust'
New York Times 2000 August 1; p. A1, C10

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

Document 715
Kolata, Gina
Separating Research from News

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

Document 716
McAvoy, Leo; Winter, Patricia L.; Outley, Corliss Wilson; McDonald, Dan; Chavez, Deborah J.
Conducting research with communities of color
Society and Natural Resources 2000 July-August; 13(5): 479-488
Georgetown users check Georgetown Journal Finder for access to full text
Document 717
Jeffcoat, Marjorie K.
The World of Oral Research: How Do We Improve It?
Journal of Dental Research 2000 July; 79(7): 1448-1449
Georgetown users check Georgetown Journal Finder for access to full text

Document 718
Boman, Jeanette; Jevne, Ronna
Pearls, Pith, and Provocation: Ethical Evaluation in Qualitative Research
Qualitative Health Research 2000 July; 10(4): 547-554
Georgetown users check Georgetown Journal Finder for access to full text

Document 719
Hill, Jim
Sell yourself to science [news]
Psychology Today 2000 July-August; 32(4): 26
Georgetown users check Georgetown Journal Finder for access to full text

Document 720
Sutton, A. J.; Duval, S. J.; Tweedie, R. L.; Abrams, K. R.; Jones, D. R.
Empirical Assessment of Effect of Publication Bias on Meta-Analyses
BMJ: British Medical Journal 2000 June 10; 320(7249): 1574-1577
Georgetown users check Georgetown Journal Finder for access to full text

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

Document 721
Kahn, Jeffrey
Too old to benefit? Why are so few seniors in cancer research?
Bioethics Examiner 2000 Summer; 4(2): 1, 4
Georgetown users check Georgetown Journal Finder for access to full text

Document 722
McQuillen, Michael P.
Ethical lessons learned from the use of therapeutic plasma exchange in neurologic disease
Therapeutic Apheresis 2000 June; 4(3): 190-194
Georgetown users check Georgetown Journal Finder for access to full text
Rowland, April; Sirohi, Bhawna; Tait, Diana; Horton, Clive; Long, Simon; Singhal, Seema
Allogeneic Blood and Bone-Marrow Stem-Cell Transplantation in Haematological Malignant Diseases: A Randomised Trial
Lancet 2000 April 8; 355(9211): 1231-1237

Georgetown users check Georgetown Journal Finder for access to full text

* Document 730
Russell, Margaret L.; Moralejo, Donna G.; Burgess, Ellen D.
Paying Research Subjects: Participants' Perspectives
Journal of Medical Ethics 2000 April; 26(2): 126-130

Georgetown users check Georgetown Journal Finder for access to full text

Document 731
Womack, Christopher; Gray, Neil; Aikens, Julie; Jack, Alison
The Peterborough Hospital Human Tissue Bank
ATLA: Alternatives to Laboratory Animals 2000 March-April; 28(2): 259-270

Georgetown users check Georgetown Journal Finder for access to full text

Document 732
Tierney, Jayne F.; Clarke, Mike; Stewart, Lesley A.
Is There Bias in the Publication of Individual Patient Data Meta-Analyses?
International Journal of Technology Assesment in Health Care 2000 Spring; 16(2): 657-667

Georgetown users check Georgetown Journal Finder for access to full text

Document 733
Comiti, Vincent-Pierre
Quand la Pratique Medicale Etait un Risque Biologique [When Medical Practice was a Biological Risk]

Georgetown users check Georgetown Journal Finder for access to full text

Document 734
van der Koy, Derek; Weiss, Samuel
Why Stem Cells?
Science 2000 February 25; 287(5457): 1439-1441

Georgetown users check Georgetown Journal Finder for access to full text

Document 735
Gage, Fred H.
Mammalian Neural Stem Cells
Science 2000 February 25; 287(5457): 1433-1438
Document 736
Slack, J. M. W.
**Stem Cells in Epithelial Tissues**
Science 2000 February 25; 287(5457): 1431-1433

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

Document 737
Vogel, Gretchen
**Can Old Cells Learn New Tricks? [news]**
Science 2000 February 25; 287(5457): 1418-1419

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

Document 738
Hines, Pamela J.; Purnell, Beverly A.; Marx, Jean
**Stem Cells Branch Out [introduction to special section on Stem Cell Research and Ethics]**
Science 2000 February 25; 287(5457): 1417

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

Document 739
Eston, Roger G.; Rowlands, Ann V.
**Stages in the Development of a Research Project: Putting the Idea Together**

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

Document 740
Lindee, M. Susan
**Knowledge to Heal, Knowledge to Injure [review of UNDUE RISK: SECRET STATE EXPERIMENTS ON HUMANS, by Jonathan Moreno]**
Science 2000 January 28; 287(5453): 598-599

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

Document 741
**Ted Kaczinski: guinea pig**
Guinea Pig Zero 2000 January; (7): 38

Georgetown users check [Georgetown Journal Finder](#) for access to full text
Abstract: With Robert Lawrence Kuhn "Leading scientists and scholars explore new controversies about microbes, drug testing, and the volatile world of alternative medicine. In each episode: how does science advance and its philosophical implications affect us?" [description taken from back cover] Includes shows: Microbes - Friend or Foe?, Testing New Drugs: Are People Guinea Pigs?, Who Gets to Validate Alternative Medicine?

http://www.pbs.org/closertotruth and http://www.scitedaily.com (link may be outdated)
Mini-hearings on issues in human tissue storage.
Call number: R856.4 .R47 I999 v.2

Chapter Document 749
Iglesias, Teresa
Biomedical research in Ireland: ethical and legal framework.
Call number: KJC6227 .R46 2000 v.2

Chapter Document 750
Kopelman, Loretta M.
Changing views of paternalism in research: AIDS activists demand change.
Call number: R723 .P445 2000

* Article Document 751
Mazza, Alberto J.
The promotion of scientific medical research at the service of man from the point of view of cultural effectiveness
Georgetown users check Georgetown Journal Finder for access to full text

* Article Document 752
Rosner, Fred
Human Experimentation in Judaism
Cancer Investigation 2000; 18(7): 689-691
Georgetown users check Georgetown Journal Finder for access to full text

Article Document 753
Eby, Maureen A.
ETHICS IN MEDICAL RESEARCH: A HANDBOOK OF GOOD PRACTICE, by T. Smith [book review]
Nursing Ethics 2000 September; 7(5): 457-458
Georgetown users check Georgetown Journal Finder for access to full text