EthxWeb Search Results

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Result=(("18.3".PC.) AND (@YD >= "20000000")) NOT (EDITORIAL OR LETTER)
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Documents: 1 - 325 of 1483

Document 1
Lidz, Charles W
Informed consent: a critical part of modern medical research.
Abstract: Informed consent is one of the great puzzles of modern medical research and practice. As Professor Henderson has argued in her article, there is ample reason to be concerned that many, and maybe all, of the goals announced for informed consent law and ethics have not been reached. In this article, I will review the goals that theorists and judges have assigned to the doctrine and discuss some of the evidence concerning the difficulties of meeting those goals. Finally, I will suggest some of the reasons that might account for our continued commitment to informed consent despite its difficulties.
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Document 2
Henderson, Gail E
Is informed consent broken?
The American journal of the medical sciences 2011 Oct; 342(4): 267-72
Abstract: For as long as the federal regulations governing human subjects research have existed, the practice of informed consent has been attacked as culturally biased, legalistic, ritualistic and unevenly enforced. Its focus on meeting the regulatory requirements is seen as undermining a truly ethical process that produces informed and voluntary participation in medical research. Recent changes in the clinical translational research enterprise, with large scale genomic and other data sharing made possible by advanced bioinformatic technologies, may further challenge this goal. Study participants are asked to consent to future studies with unspecified aims, broad data sharing policies and ongoing uncertainties regarding confidentiality protections and the potential benefit of incidental genomic research findings. Because more research is conducted under these new conditions, the very nature of the researcher-subject relationship is shifting and will require new governance mechanisms to promote the original goals of informed consent.
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Document 3
Chadwick, Ruth
The communitarian turn: myth or reality?
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Document 4
Desch, Karl; Li, Jun; Kim, Scott; Laventhal, Naomi; Metzger, Kristen; Siemieniak, David; Ginsburg, David

Analysis of informed consent document utilization in a minimal-risk genetic study.
Annals of internal medicine 2011 Sep 6; 155(5): 316-22

Abstract: The signed informed consent document certifies that the process of informed consent has taken place and provides research participants with comprehensive information about their role in the study. Despite efforts to optimize the informed consent document, only limited data are available about the actual use of consent documents by participants in biomedical research.

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Document 5
Miller, Franklin G; Wertheimer, Alan
The fair transaction model of informed consent: an alternative to autonomous authorization.
Kennedy Institute of Ethics journal 2011 Sep; 21(3): 201-18

Abstract: The doctrine of informed consent in bioethics has relied on the view that consent is valid when it represents a patient or research subject's autonomous authorization. In this article we challenge this reigning conception of the validity of informed consent in clinical research, focusing in particular on the problem of the therapeutic misconception. We argue that the autonomous authorization model of informed consent suffers from four defects: (1) it fails to do justice to the relevance of risk-benefit considerations in shaping the criteria for the validity of consent, (2) it compromises the interests of subjects by preventing them from consenting to research participation with less than substantial understanding when doing so would likely be consistent with their preferences and beneficial to them or at least be unlikely to cause them harm, (3) it jeopardizes the interests of investigators by denying them fair notice regarding when the consent of research subjects can be considered valid and thus make it permissible for them to be enrolled in research, and (4) it threatens the reasonable limits on the responsibility of investigators to assure the adequacy of subjects' understanding of what research participation involves. In place of the autonomous authorization model, we present and defend a fair transaction model of informed consent, which better reflects the values served by consent.

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Document 6
Barnhill, Anne
What it takes to defend deceptive placebo use.
Kennedy Institute of Ethics journal 2011 Sep; 21(3): 219-50

Abstract: A complete defense of deceptive placebo use must address this ethical objection: deceptive placebo use violates patient autonomy, because deceiving a patient about the placebo nature of a proposed treatment prevents her from giving informed consent to the treatment. Unfortunately, this objection isn't always recognized and clearly disambiguated from other ethical concerns. I consider how well several bioethicists who write about placebo use have responded to, or evaded, this objection. I conclude that defenders of deceptive placebo use should, following the lead of Onora O'Neill, argue that deceptive placebo use is compatible with informed consent.

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Document 7
Lipton, Lianna R; Santoro, Nanette; Taylor, Hugh; Kidwai, Neiha; Isaac, Barbara; Magnani, Maureen; Pal, Lubna
Assessing comprehension of clinical research.
Contemporary clinical trials 2011 Sep; 32(5): 608-13

Abstract: Comprehension and retention of study-related concepts by research subjects are understudied, particularly in certain areas of women's health such as menopausal hormone therapy (MHT).

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Document 8
Padhy, Biswa M; Gupta, Pooja; Gupta, Yogendra K
Analysis of the compliance of informed consent documents with good clinical practice guideline.
Contemporary clinical trials 2011 Sep; 32(5): 662-6
Abstract: Informed consent document plays an integral part in the process of obtaining informed consent. Although India is fast gaining repute as a preferred clinical trial destination, only few studies have evaluated the compliance of informed consent documents with the Indian Good Clinical Practice guideline.
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Document 9
Nelson, Robert M; Beauchamp, Tom L
Response to open peer commentaries on "the concept of voluntary consent".
Georgetown users check Georgetown Journal Finder for access to full text

Document 10
Nelson, Robert M; Beauchamp, Tom; Miller, Victoria A; Reynolds, William; Ittenbach, Richard F; Luce, Mary Frances
The concept of voluntary consent.
The American journal of bioethics: AJOB 2011 Aug; 11(8): 6-16
Abstract: Our primary focus is on analysis of the concept of voluntariness, with a secondary focus on the implications of our analysis for the concept and the requirements of voluntary informed consent. We propose that two necessary and jointly sufficient conditions must be satisfied for an action to be voluntary: intentionality, and substantial freedom from controlling influences. We reject authenticity as a necessary condition of voluntary action, and we note that constraining situations may or may not undermine voluntariness, depending on the circumstances and the psychological capacities of agents. We compare and evaluate several accounts of voluntariness and argue that our view, unlike other treatments in bioethics, is not a value-laden theory. We also discuss the empirical assessment of individuals' perceptions of the degrees of noncontrol and self-control. We propose use of a particular Decision Making Control Instrument. Empirical research using this instrument can provide data that will help establish appropriate policies and procedures for obtaining voluntary consent to research.
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Document 11
Appelbaum, Paul S
Can a theory of voluntariness be a priori and value-free?
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Document 12
Litton, Paul
The undue influence of causation.
Georgetown users check Georgetown Journal Finder for access to full text
The placebo phenomenon and medical ethics: rethinking the relationship between informed consent and risk-benefit assessment.

Abstract: It has been presumed within bioethics that the benefits and risks of treatments can be assessed independently of information disclosure to patients as part of the informed consent process. Research on placebo and nocebo effects indicates that this is not true for symptomatic treatments. The benefits and risks that patients experience from symptomatic treatments can be shaped powerfully by information about these treatments provided by clinicians. In this paper we discuss the implications of placebo and nocebo research for risk-benefit assessment and informed consent.

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Document 25
Epstein, Miran; Wilson, Mark
Consent in emergency care research.
Lancet 2011 Jul 2; 378(9785): 26; author reply 27
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Document 26
Catt, S; Langridge, C; Fallowfield, L; Talbot, D C; Jenkins, V
Reasons given by patients for participating, or not, in Phase 1 cancer trials.
Abstract: Communication with patients contemplating Phase 1 cancer trial participation can be challenging. Controversy exists as to whether they are provided with sufficient information to give genuinely informed consent. We present data examining the reasons patients gave for trial entry.
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Document 27
Aliyu, Gambo G
Informed consent of very sick subjects in Nigeria.
Abstract: This article highlights a number of ethical challenges I face in obtaining informed consent from very sick subjects with suspected pulmonary tuberculosis (TB). Some of the subjects with TB have an associated human immunodeficiency virus (HIV) infection. From my experience in administering informed consent and health surveys, I found the subjects to be generally mentally stable but physically exhausted. Many of the very sick subjects cough excessively and cannot tolerate a 45-minute conversation with the study staff in order for them to administer consent and conduct a survey after the routine clinical evaluation. In this situation, the administration of a qualitative consent that preserves the subject's right and autonomy becomes a challenge.
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Document 28
Cohn, Elizabeth Gross; Jia, Haomiao; Smith, Winifred Chapman; Erwin, Katherine; Larson, Elaine L
Measuring the process and quality of informed consent for clinical research: development and testing.
Oncology nursing forum 2011 Jul; 38(4): 417-22
Abstract: To develop and assess the reliability and validity of an observational instrument, the Process and Quality of Informed Consent (P-QIC).
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Document 29
Cyna, Allan M; Costi, David; Middleton, Philippa
Viewpoint: Randomised controlled trials using invasive 'placebo' controls are unethical and should be excluded from Cochrane Reviews.
Cochrane database of systematic reviews (Online) 2011 June 14(8): ED000029
Georgetown users check Georgetown Journal Finder for access to full text
Document 30
Ray, Brenda; Jackson, Colin; Ducat, Elizabeth; Ho, Ann; Hamon, Sara; Kreek, Mary Jeanne

Effect of ethnicity, gender and drug use history on achieving high rates of affirmative informed consent for genetics research: impact of sharing with a national repository.

Abstract: Genetic research representative of the population is crucial to understanding the underlying causes of many diseases. In a prospective evaluation of informed consent we assessed the willingness of individuals of different ethnicities, gender and drug dependence history to participate in genetic studies in which their genetic sample could be shared with a repository at the National Institutes of Health.

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Document 31
Goldberg, Daniel S

Eschewing definitions of the therapeutic misconception: a family resemblance analysis.
The Journal of medicine and philosophy 2011 Jun; 36(3): 296-320

Abstract: Twenty-five years after the term "therapeutic misconception' (TM) first entered the literature, most commentators agree that it remains widespread. However, the majority of scholarly attention has focused on the reasons why a patient cum human subject might confuse the goals of research with the goals of therapy. Although this paper addresses the social and cultural factors that seem to animate the TM among subjects, it also fills a niche in the literature by examining why investigators too might operate under a similar confusion. In framing these issues, the paper expressly adopts a Wittgensteinian approach to evaluating the TM, suggesting that interlocutors do not need any analytic definition of the TM to use the term meaningfully in thinking about the moral implications of the TM in practice.

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Document 32
Wendler, David

How to enroll participants in research ethically.
JAMA : the journal of the American Medical Association 2011 Apr 20; 305(15): 1587-8

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Document 33
Wolpe, Paul Root

The research subject as identified problem.

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Document 34
Schaefer, G Owen; Wertheimer, Alan

Reevaluating the right to withdraw from research without penalty.
The American journal of bioethics : AJOB 2011 Apr; 11(4): 14-6

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Document 35
Brown, Richard; Bylund, Carma L; Siminoff, Laura A; Slovin, Susan F
Seeking informed consent to Phase I cancer clinical trials: identifying oncologists' communication strategies.
Psycho-oncology 2011 Apr; 20(4): 361-8
Abstract: Phase I clinical trials are the gateway to effective new cancer treatments. Many physicians have difficulty when discussing Phase I clinical trials. Research demonstrates evidence of suboptimal communication. Little is known about communication strategies used by oncologists when recruiting patients for Phase I trials. We analyzed audio recorded Phase I consultations to identify oncologists' communication strategies.

Document 36
Maitland, Kathryn; Molyneux, Sassy; Boga, Mwamvua; Kiguli, Sarah; Lang, Trudie
Use of deferred consent for severely ill children in a multi-centre phase III trial.
Trials 2011 March 31; 12: 90
Abstract: Voluntary participation of a subject in research respects a subject's rights, strengthens its ethical conduct, and is formalized by the informed consent process. Clinical trials of life-saving interventions for medical emergencies often necessitate enrollment of patients where prior written individual informed consent is impossible. Although there are regulations and guidelines on protecting subjects in emergency research, these have been criticised for being limited and unnecessarily restrictive. Across Europe and the United States stringent regulations have resulted in a substantial decline of clinical trials involving emergency interventions.

Document 37
Roberts, Ian; Prieto-Merino, David; Shakur, Haleema; Chalmers, Iain; Nicholl, Jon
Effect of consent rituals on mortality in emergency care research.
Lancet 2011 Mar 26; 377(9771): 1071-2

Document 38
Kuehn, Bridget M
Patients' unrealistic hopes for cancer trial benefits may hinder consent.
JAMA : the journal of the American Medical Association 2011 Mar 23; 305(12): 1186-7

Document 39
Lee, Robin; Lampert, Samantha; Wilder, Lynn; Sowell, Anne L
Subjects agree to participate in environmental health studies without fully comprehending the associated risk.
International journal of environmental research and public health 2011 Mar; 8(3): 830-41
Abstract: Recent advances in environmental health research have greatly improved our ability to measure and quantify how individuals are exposed. These advances, however, bring bioethical uncertainties and potential risks that individuals should be aware of before consenting to participate. This study assessed how well participants from two environmental health studies comprehended consent form material. After signing the consent form, participants were asked to complete a comprehension assessment tool. The tool measured whether participants could recognize or recall six elements of the consent form they had just reviewed. Additional data were collected to look for differences
in comprehension by gender, age, race, and the time spent reading the original consent form. Seventy-three participants completed a comprehension assessment tool. Scores ranged from 1.91 to 6.00 (mean = 4.66); only three people had perfect comprehension scores. Among the least comprehended material were questions on study-related risks. Overall, 53% of participants were not aware of two or more study-related risks. As environmental public health studies pose uncertainties and potential risks, researchers need to do more to assess participants’ understanding before assuming that individuals have given their 'informed' consent.

**Document 40**

Berthelot, Jean-Marie

The placebo effect in rheumatology: new data.


**Abstract:** The placebo effect is often poorly understood or confused with evaluation bias or spontaneous improvement, particularly when study inclusion criteria select patients at the peak of their symptoms. Cerebral imaging studies have confirmed that the placebo effect exists, although it is now known to involve a combination of conditioned reflexes and reward anticipation. The magnitude of the placebo effect can be evaluated by randomly dividing patients into three groups, one of which receives no treatment at all; by crossover studies; or by the newly developed open-hidden study design. This last design has established that rebound effects can occur after placebo discontinuation, and other experiments have shown that anxiety is associated with a weaker placebo response. This anti-placebo effect of anxiety, similar to the nocebo effect, may involve the release of cholecystokinin. The strength of the placebo effect varies across procedures and joints. A marked placebo effect can be seen in rheumatology patients, as shown recently by two high-quality double-blind studies that found no difference between vertebroplasty and a sham procedure. Effective blinding is crucial both to obtain a strong placebo effect and to separate an intrinsic effect from a placebo effect. Beliefs of the patients and physicians regarding the active drug and the existence and strength of the placebo effect could also be usefully evaluated throughout clinical studies.

**Document 41**

McCaffery, Kirsten J; Turner, Robin; Macaskill, Petra; Walter, Stephen D; Chan, Siew Foong; Irwig, Les

Determining the impact of informed choice: separating treatment effects from the effects of choice and selection in randomized trials.

Medical decision making : an international journal of the Society for Medical Decision Making 2011 Mar-Apr; 31(2): 229-36

**Abstract:** The Rucker 2-stage randomized trial (RCT) design and method allows treatment, preference, and selection effects to be estimated separately in clinical trials.

**Document 42**

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

Informed consent and phase IV non-interventional drug research.

Current medical research and opinion 2011 Mar; 27(3): 513-8

**Abstract:** Most of the literature on informed consent in pharmaceutical drug research works on the assumption that informed consent is something that is homogeneous and thus can be rendered procedurally universal. This may be justifiable to a certain extent owing to the fact these are all drug trials anyway. Nevertheless, in spite of this general similarity, we also know that the clinical drug development phases are characteristically different, and that phase IV is very different from the other phases because, owing to its postmarketing nature, it is much more varied in scope and in type. Thus, it is worthwhile looking into the ethical nuances relevant to the informed consent process in phase IV non-interventional drug research. We shall deal with the issues on the necessity of informed consent for this type of research and then discuss the possibilities for an opt-out system. We conclude that informed consent is necessary for non-interventional studies, and thus any form of waiving of rights of participants to informed consent must have a valid substantial justification. The distinct character of phase IV accounts for the difference in content of the informed
consent document compared to that of earlier phases, and both opt-in and opt-out procedures are ethically justifiable as long as the participant's participation remains informed and voluntary.

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**Document 43**

Tait, Raymond C; Chibnall, John T; Iltis, Ana; Wall, Anji; Deshields, Teresa L

**Assessment of consent capability in psychiatric and medical studies.**


**Abstract:** In order to evaluate psychiatric factors that potentially influence assessment of consent capacity, 195 IRB members read summaries of hypothetical medical (cancer vs. neuropathic pain) and psychiatric trials. They then rated research participants' capacity for consent (capable or not capable), autonomy, and decisional abilities, as well as the legal risk to the institution of the study. Levels of depression information varied across the medical disorders. Significantly fewer IRB members judged participants in the depression trial to possess adequate capacity for consent relative to 4 of 6 medical conditions; legal risk to the institution also was rated higher in the psychiatric study. While IRB members judged participants in depression trials to have less capacity for consent and to pose higher levels of institutional risk than medical trial participants, the addition of increasing information regarding depressive co-morbidities had little or no effect on judgments of medical studies. Implications are discussed relative to the apparent overprotection of participants in psychiatric trials and underprotection of those in medical trials.

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**Document 44**

Van Der Veer, Nancy L; Drachman, David; Ahad, Sami; Silvers, George; Ramos, Gilbert

**Voluntariness to consent to research in a voluntarily and involuntarily hospitalized psychiatric population.**


**Abstract:** The purpose of our study was to examine rates of consent to participate in research in voluntarily and involuntarily hospitalized psychiatric patients in order to evaluate factors that may influence the decision to participate in research. We used logistic regression models to evaluate differences and found that involuntary patients were less likely to consent to participate. After adjustment for covariates, we found that consent rates did not differ between the involuntary and voluntary population, but that lower Global Assessment of Functioning (GAF) scores and psychosis negatively affected the decision to consent to research. We discuss the implications of our findings.

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**Document 45**

Brintnall-Karabelas, Julie; Sung, Susanna; Cadman, Mary Ellen; Squires, Carol; Whorton, Katherine; Pao, Maryland

**Improving recruitment in clinical trials: why eligible participants decline.**


**Abstract:** There is a need to explore why protocol-eligible subjects refuse participation in clinical trials. Without a clear understanding, participation by representative populations will be an ongoing obstacle to recruitment. This descriptive research study analyzes frequency data regarding a sample of 965 individuals who, despite being eligible for studies with the National Institute of Mental Health intramural program, declined research participation. Overall, responses regarding reasons for declining fell into the following five categories: a result of specific protocol issues; inconvenience; for other reasons not mentioned; financial reasons; and, lastly, decided to participate elsewhere. The results of this study identify common factors which suggest there are steps that investigators can take to better accommodate the needs of the public and, consequently, improve research participation.

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**Document 46**
Shafiq, Nusrat; Malhotra, Samir
Ethics in clinical research: need for assessing comprehension of informed consent form?
Contemporary clinical trials 2011 Mar; 32(2): 169-72
Abstract: Comprehension of informed consent form has not achieved the attention it deserves. We made a 24-item questionnaire to assess clinical research participants' comprehension of informed consent form (Contemp Clin Trials 2009;30:427-30). Due to repeated requests by clinical researchers in our country and abroad, we are publishing the questionnaire in this article.

Ubel, Peter A
The experimental imperative.
The Hastings Center report 2011 Mar-Apr; 41(2): 3

Rennie, Stuart
Viewing research participation as a moral obligation: in whose interests?
The Hastings Center report 2011 Mar-Apr; 41(2): 40-7
Abstract: A moral paradigm shift has been proposed for participation in health-related research. It's not just a praiseworthy option, some say; it's a social obligation. Recasting research participation in this way would have global ramifications, however. Who ultimately stands to gain the most from it, and who has the most to lose?

Caplan, Arthur L; Moreno, Jonathan D
The Havasu 'Baaja tribe and informed consent.
Lancet 2011 Feb 19; 377(9766): 621-2

Da Silva, Michael; Shaul, Randi Zlotnik; Kim, Celine C; d'Agincourt-Canning, Lori; Czoli, Christine; Schneider, Rayfel; Vanin, Sharon
Recruiting one's own patients for research: consent challenges for paediatric physician-researchers.
Health law in Canada 2011 Feb; 31(3): 72-80

Miller, Franklin G; Brody, Howard
Understanding and harnessing placebo effects: clearing away the underbrush.
The Journal of medicine and philosophy 2011 Feb; 36(1): 69-78
Abstract: Despite strong growth in scientific investigation of the placebo effect, understanding of this phenomenon remains deeply confused. We investigate critically seven common conceptual distinctions that impede clear understanding of the placebo effect: (1) verum/placebo, (2) active/inactive, (3) signal/noise, (4) specific/nonspecific,
(5) objective/subjective, (6) disease/illness, and (7) intervention/context. We argue that some of these should be eliminated entirely, whereas others must be used with caution to avoid bias. Clearing away the conceptual underbrush is needed to lay down a path to understanding and harnessing placebo effects in clinical medicine.

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**Document 52**

Labuzetta, Jamie N; Burnstein, Rowan; Pickard, John

**Ethical issues in consenting vulnerable patients for neuroscience research.**


**Abstract:** Many subjects cannot give fully informed consent to take part in research by virtue of age or mental capacity. However, it is unacceptable to deny these patients involvement in research by virtue of a lack of capacity to consent to such research. Further, this would hinder the advancement of medical science and technologies that might ultimately benefit these patients. Conversely, it is as unacceptable to discriminate against these patients and their condition as it is to exploit them or expose them to undue risk. Neuroscientific research raises a number of specific ethical issues in this patient population, in particular issues of consent, potential benefits of research, management of incidental findings and the assignment of appropriate controls. This paper examines the dilemmas that surround such ethical issues, and demonstrates that various procedures including informed consent, deferred consent and consent by proxy can be used to consent patients in both the standard medical and research arenas. Researchers, clinicians and regulatory authorities must work together to understand the benefits, limitations, risks and obligations of any research study involving these patients in order to advance medical care.

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**Document 53**

Mak, Donna B; Bulsara, Max; Goggin, Leigh S; Effler, Paul V

**Resending a consent form and information package to non-responders increases school-based consent return rate.**

*Australian and New Zealand journal of public health* 2011 Feb; 35(1): 89-90

**Document 54**

Momen-Heravi, Fatemeh; Khalilzadeh, Omid; Dorriz, Hassan

**Informed consent: dissimilar linguistic barriers in different societies.**


**Document 55**

McGuirk, S; Fahy, C; Costi, D; Cyna, A M

**Use of invasive placebos in research on local anaesthetic interventions.**

*Anaesthesia* 2011 Feb; 66(2): 84-91

**Abstract:** Placebos play a vital role in clinical research, but their invasive use in the context of local anaesthetic blocks is controversial. We assessed whether recently published randomised controlled trials of local anaesthetic blocks risked harming control group patients in contravention of the Declaration of Helsinki. We developed the 'SHAM' (Serious Harm and Morbidity) scale to assess risk: grade 0 = no risk (no intervention); grade 1 = minimal risk (for example, skin allergy to dressing); grade 2 = minor risk (for example, subcutaneous haematoma, infection); grade 3 = moderate risk (with or without placebo injection) (for example, neuropraxia); and grade 4 = major risk (such as blindness, pneumothorax, or liver laceration). Placebo interventions of the 59 included trials were given a SHAM
grade. Nine hundred and nineteen patients in 31 studies, including six studies with 183 children, received an invasive placebo assessed as SHAM grade >= 3. A high level of agreement (78%, χ² = 0.80, p < 0.001) for SHAM grades 0-4 increased to 100% following discussion between assessors. More than half of the randomised controlled study designs subjected patients in control groups to risks of serious or irreversible harm. A debate on whether it is justifiable to expose control group patients to risks of serious harm is overdue.

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**Document 56**

Behrendt, C; Gölz, T; Roesler, C; Bertz, H; Wünsch, A

*What do our patients understand about their trial participation? Assessing patients' understanding of their informed consent consultation about randomised clinical trials.*

Journal of medical ethics 2011 Feb; 37(2): 74-80

**Abstract:** Ethically, informed consent regarding randomised controlled trials (RCTs) should be understandable to patients. The patients can then give free consent or decline to participate in a RCT. Little is known about what patients really understand in consultations about RCTs.

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**Document 57**

Trinidad, S B; Fullerton, S M; Ludman, E J; Jarvik, G P; Larson, E B; Burke, W


Science (New York, N.Y.) 2011 Jan 21; 331(6015): 287-8

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**Document 58**

Palmour, Nicole; Affleck, William; Bell, Emily; Deslauriers, Constance; Pike, Bruce; Doyon, Julien; Racine, Eric

*Informed consent for MRI and fMRI research: analysis of a sample of Canadian consent documents.*

BMC medical ethics 2011 January 14; 12: 1

**Abstract:** Research ethics and the measures deployed to ensure ethical oversight of research (e.g., informed consent forms, ethics review) are vested with extremely important ethical and practical goals. Accordingly, these measures need to function effectively in real-world research and to follow high level standards.

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**Document 59**

Food and Drug Administration, HHS

*Informed consent elements. Final rule.*

Federal register 2011 Jan 4; 76(2): 256-70

**Abstract:** The Food and Drug Administration (FDA) is amending the current informed consent regulations to require that informed consent documents and processes for applicable drug (including biological products) and device clinical trials include a specific statement that clinical trial information will be entered into a databank. The databank referred to in this final rule is the clinical trial registry databank maintained by the National Institutes of Health/National Library of Medicine (NIH/NLM) which was created by statute. The submission of clinical trial information to this data bank also is required by statute. This amendment to the informed consent regulations is required by the Food and Drug Administration Amendments Act of 2007 (FDAAA) and is designed to promote transparency of clinical research to participants and patients.

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**Document 60**

Smith, William; Grady, Christine; Krohmal, Benjamin; Lazovski, Jaime; Wendler, David; INSIGHT ESPRIT Group

**Empirical evaluation of the need for 'on-going consent' in clinical research.**


**Abstract:** Some commentators argue that informed consent for clinical research should be an on-going process, which begins, rather than ends, with participants' initial consent. Lacking, however, are empirical data on whether there is a need for 'on-going consent'.

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**Document 61**

Apold, Victoria Smith; Downie, Jocelyn

**Bad news about bad news: the disclosure of risks to insurability in research consent processes.**

Accountability in research 2011 Jan; 18(1): 31-44

**Abstract:** One of the phenomena associated with research is "incidental findings," that is, unexpected findings made during the research, and outside the scope of the research, which have potential health importance. One underappreciated risk of incidental findings is the potential loss of the research subject's insurability; or if a research subject fails to disclose incidental findings when applying for insurance, the insurance contract may be voidable by the insurer. In this article, we seek to explain the insurability risks associated with incidental findings and to make recommendations for how researchers and research ethics committees should address the issue of disclosure of these risks.

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**Document 62**

Burns, Karen E A; Magyarody, Nora M; Duffett, Mark; Nisenbaum, Rosane; Cook, Deborah J

**Attitudes of the general public toward alternative consent models.**


**Abstract:** To assess the general public's attitudes toward various consent models and data management strategies for critically ill adults eligible to participate in a low-risk randomized trial.

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**Document 63**

Stiles, Paul G; Epstein, Monica K; Poythress, Norman G; Edens, John F

**Formal assessment of voluntariness with a three-part consent process.**


**Abstract:** Informed consent that is voluntary and made by an individual who is knowledgeable and competent is a foundational requirement for protecting human subjects from harm and exploitation that could result from research participation. In 1974 Miller and Willner proposed a two-part consent process that involved disclosure of information and assessment of comprehension. The authors propose a brief third component to the consent process: assessment of voluntariness. Three steps are involved: generate a list of potential coercive influences on the basis of the research population and the study context, develop a set of questions to assess the presence and intensity of the impact of these influences, and identify alternative courses of action should coercion be identified.

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Document 64
Stone, Kathlyn
NerveCenter: applying the lessons of HeLa cells to today's research.
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Document 65
Berger, Jeffrey T
Is best interests a relevant decision making standard for enrolling non-capacitated subjects into clinical research?
Abstract: The 'best interests' decision making standard is used in clinical care to make necessary health decisions for non-capacitated individuals for whom neither explicit nor inferred wishes are known. It has been also widely acknowledged as a basis for enrolling some non-capacitated adults into clinical research such as emergency, critical care, and dementia research. However, the best interests standard requires that choices provide the highest net benefit of available options, and clinical research rarely meets this criterion. In the context of modern norms of bioethics, the best interests standard rarely supports surrogate consent for research and should not be accepted as a routine provision.
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Document 66
Helgesson, Gert; Eriksson, Stefan
Does informed consent have an expiry date? A critical reappraisal of informed consent as a process.
Georgetown users check Georgetown Journal Finder for access to full text

Document 67
DeMaria, Anthony N
Problems with immortality.
Journal of the American College of Cardiology 2010 Dec 14; 56(25): 2140-2
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Document 68
Kottow, Miguel
The improper use of research placebos.
Journal of evaluation in clinical practice 2010 Dec; 16(6): 1041-4
Abstract: Reasons given for the routine use of placebos in Phase III clinical research are not convincing. Ethically inadequate strategies such as using placebos and recruiting the mentally incompetent for non-therapeutic research are allegedly permissible because research is purportedly aimed at benefiting the common weal.
Georgetown users check Georgetown Journal Finder for access to full text
Document 69
Shu Yu Chen,
**Informed consent practices of Chinese nurse researchers.**
Nursing ethics 2010 Nov; 17(6): 791

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Document 70
Tracey, Irene
**Getting the pain you expect: mechanisms of placebo, nocebo and reappraisal effects in humans.**
Nature medicine 2010 Nov; 16(11): 1277-83

*Abstract:* The perception of pain is subject to powerful influences. Understanding how these are mediated at a neuroanatomical and neurobiological level provides us with valuable information that has a direct impact on our ability to harness positive and minimize negative effects therapeutically, as well as optimize clinical trial designs when developing new analgesics. This is particularly relevant for placebo and nocebo effects. New research findings have directly contributed to an increased understanding of how placebo and nocebo effects are produced and what biological and psychological factors influence variances in the magnitude of the effect. The findings have relevance for chronic pain states and other disorders, where abnormal functioning of crucial brain regions might affect analgesic outcome even in the normal therapeutic setting.

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Document 71
Menikoff, Jerry
**Making research consent transparent.**
JAMA : the journal of the American Medical Association 2010 Oct 20; 304(15): 1713-4

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

Document 72
Golomb, Beatrice A; Erickson, Laura C; Koperski, Sabrina; Sack, Deanna; Enkin, Murray; Howick, Jeremy
**What's in placebos: who knows? Analysis of randomized, controlled trials.**

*Abstract:* No regulations govern placebo composition. The composition of placebos can influence trial outcomes and merits reporting.

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Document 73
Al Qadire, Mohammad M.; Hammami, Muhammad M.; Adubhameed, Hunida M.; Al Gaai, Eman A.
**Saudi views on consenting for research on medical records and leftover tissue samples**
BMC Medical Ethics 2010 October 18; 11.18: 7 p. [Online]. Accessed:

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

Document 74
Kaufmann, I M; Rühli, F J
Without 'informed consent'? Ethics and ancient mummy research.
Abstract: Ethical issues are of foremost importance in modern bio-medical science. Ethical guidelines and socio-cultural public awareness exist for modern samples, whereas for ancient mummy studies both are de facto lacking. This is particularly striking considering the fact that examinations are done without informed consent or that the investigations are invasive due to technological aspects and that it affects personality traits. The aim of this study is to show the pro and contra arguments of ancient mummy research from an ethical point of view with a particular focus on the various stakeholders involved in this research. Relevant stakeholders in addition to the examined individual are, for example, a particular researcher, and the science community in general, likely descendants of the mummy or any future generation. Our broad discussion of the moral dilemma of mummy research should help to extract relevant decision-making criteria for any such study in future. We specifically do not make any recommendations about how to rate these decision-factors, since this is highly dependent on temporal and cultural affiliations of the involved researcher. The sustainability of modern mummy research is dependent on ethical orientation, which can only be given and eventually settled in an interdisciplinary approach such as the one we attempt to present here.

Document 75
Paradis, Carmen; Phelan, Michael P; Brinich, Margaret
A pilot study to examine research subjects' perception of participating in research in the emergency department.
Abstract: The emergency department (ED) provides an arena for patient enrollment into a variety of research studies even for non-critically ill patients. Given the types of illness, time constraints and sense of urgency that exists in the ED environment, concern exists about whether research subjects in the ED can provide full consent for participation. We sought to identify enrolled research subjects' perspectives on the informed consent process for research conducted in the ED.

Document 76
Goldstein, Joshua N; Delaney, Kate E; Pelletier, Andrea J; Fisher, Jonathan; Blanc, Phillip G; Halsey, Mark; Pallin, Daniel J; Camargo, Carlos A Jr.
A brief educational intervention may increase public acceptance of emergency research without consent.
Abstract: We hypothesized that knowing the regulations regarding emergency research without consent would increase public support for this type of research.

Document 77
Griffith, Richard; Tengnah, Cassam
Safeguarding research subjects who lack decision-making capacity.
Abstract: In keeping with the Declaration of Helsinki, health-care research generally requires the informed consent of those who participate in the study. This approach upholds the autonomy of the participants but restricts research to subjects who have decision-making capacity. In order that people who lack decision making capacity can benefit from properly conducted research, the Mental Capacity Act 2005 introduced safeguards that enable researchers to investigate the care and treatment of people with incapacity while protecting this vulnerable patient group. This article
outlines the requirements that must be met when conducting research with subjects who lack decision-making capacity.

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**Document 78**

Krogstad, Donald J; Diop, Samba; Diallo, Amadou; Mzayek, Fawaz; Keating, Joseph; Koita, Ousmane A; Touré, Yéya T

**Informed consent in international research: the rationale for different approaches.**

The American journal of tropical medicine and hygiene 2010 Oct; 83(4): 743-7

**Abstract:** In developed countries, informed consent is based on the autonomy of the individual, a written description of the studies proposed, and previous experience of the participant with Western medicine. Consent is documented by the signature of the participant and supervised by institutional review boards (IRBs), which have conflicts of interest because they are also responsible for limiting institutional liability. In developing countries, the initial decision-making for informed consent is typically vested in the community rather than the individual, and illiteracy is common-limiting the value of written documents and signatures. The challenges in developing countries are exacerbated by the fact that persons at greatest risk of disease are often illiterate, have limited experience with Western medicine, and have limited understanding of the scientific rationale for the studies proposed. Given these differences, it is unrealistic to expect that consent strategies used in developed countries would be effective in such diverse settings.

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**Document 79**

Craven, Rebecca

**Protecting research participants with impaired decision-making capacity.**


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**Document 80**

Grassley, Chuck

**Americans should not be on a game show in U.S. emergency rooms and ambulances.**


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**Document 81**

Rosen, Clifford J; Khosla, Sundeep

**Placebo-controlled trials in osteoporosis—proceeding with caution.**

The New England journal of medicine 2010 Sep 30; 363(14): 1365-7; discussion e22

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**Document 82**

Stein, C Michael; Ray, Wayne A

**The ethics of placebo in studies with fracture end points in osteoporosis.**

The New England journal of medicine 2010 Sep 30; 363(14): 1367-70; discussion e21

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Negrini, Gabriella; la Pietra, Leonardo

[Clinical and epidemiological studies in the absence of specific consent of those concerned]. = Studi clinico-epidemiologici in assenza di specifico consenso degli interessati.


Hereu, Pilar; Pérez, Eulàlia; Fuentes, Inma; Vidal, Xavier; Suñé, Pilar; Arnau, Josep Maria

Consent in clinical trials: what do patients know?

Contemporary clinical trials 2010 Sep; 31(5): 443-6

Abstract: To assess participants' knowledge of key aspects about the clinical trials in which they are enrolled, describe the consent process, and assess the importance that investigators give to various aspects of trial information when verbally informing candidates.

Wilson, Eleanor; Pollock, Kristian; Aubeeluck, Aimee

Gaining and maintaining consent when capacity can be an issue: a research study with people with Huntington's disease

Clinical Ethics 2010 September; 5(3): 142-147

Meisel, Alan

When will we learn?

IRB 2010 Sep-Oct; 32(5): 9

Ludman, Evette J; Fullerton, Stephanie M; Spangler, Leslie; Trinidad, Susan Brown; Fujii, Monica M; Jarvik, Gail P; Larson, Eric B; Burke, Wylie

Glad you asked: participants' opinions of re-consent for dbGaP data submission.

Journal of empirical research on human research ethics : JERHRE 2010 Sep; 5(3): 9-16

Abstract: No consensus exists about when researchers need additional participant consent (reconsent) to submit existing data to the federal database of Genotypes and Phenotypes (dbGaP). Re-consent for submission of their data to dbGaP was sought from 1,340 study participants, 1,159 (86%) of whom agreed. We invited the first 400 of those who agreed to complete a telephone survey about their reasoning for their consent decision and their satisfaction with the reconsent process; 365 participants completed the survey. Respondents reported that it was very (69%) or somewhat (21%) important that they were asked for their permission. Many respondents considered alternatives to consent, such as notification-only or opt-out, to be unacceptable (67% and 40%, respectively). These results suggest that re-consent for dbGaP deposition may be advisable in certain cases to anticipate and honor participant preferences.
Document 88

Patients' information sheets and multicentre studies.

Document 89

Sulmasy, Daniel P; Astrow, Alan B; He, M Kai; Seils, Damon M; Meropol, Neal J; Micco, Ellyn; Weinfurt, Kevin P
The culture of faith and hope: patients' justifications for their high estimations of expected therapeutic benefit when enrolling in early phase oncology trials.
Cancer 2010 Aug 1; 116(15): 3702-11

Abstract: BACKGROUND: Patients' estimates of their chances of therapeutic benefit from participation in early phase trials greatly exceed historical data. Ethicists worry that this therapeutic misestimation undermines the validity of informed consent. METHODS: The authors interviewed 45 patients enrolled in phase 1 or 2 oncology trials about their expectations of therapeutic benefit and their reasons for those expectations. They used a phenomenological, qualitative approach with 1 primary coder to identify emergent themes, verified by 2 independent coders. RESULTS: Median expectations of therapeutic benefit varied from 50% to 80%, depending on how the question was asked. Justifications universally invoked hope and optimism, and 27 of 45 participants used 1 of these words. Three major themes emerged: 1) optimism as performative, that is, the notion that positive thoughts and expressions improve chances of benefit; 2) fighting cancer as a battle; and 3) faith in God, science, or both. Many participants described a culture in which optimism was encouraged and expected, such that trial enrollment became a way of reflecting this expectation. Many reported they had been told few patients would benefit and appeared to understand the uncertainties of clinical research, yet expressed high expected personal therapeutic benefit. More distressed participants were less likely to invoke performative justifications for their expectations (50% vs 84%; P=.04). CONCLUSIONS: Expressions of high expected therapeutic benefit had little to do with reporting knowledge and more to do with expressing optimism. These results have implications for understanding how to obtain valid consent from participants in early phase clinical trials.

Document 90

Sanossian, Nerses; Starkman, Sidney; Eckstein, Mark; Stratton, Samuel; Pratt, Frank; Conwit, Robin; Saver, Jeffrey L;
FAST-MAG Trial Investigators
Intercontinental elicitation of informed consent for enrollment in stroke research.
Cerebrovascular diseases (Basel, Switzerland) 2010 Aug; 30(3): 323-4

Document 91

George, Steven Z; Robinson, Michael E
Dynamic nature of the placebo response.
The Journal of orthopaedic and sports physical therapy 2010 Aug; 40(8): 452-4
Informed consent: revisiting the issues.

Abstract: Informed consent has been widely discussed in the ethics, legal, research, and clinical literature. Authors have addressed the ethical and legal bases for informed consent, its components, and its implementation both in research and in healthcare delivery. However, although there is considerable literature on the subject and the inclusion of this content within the curricula of the various schools of the health sciences, questions continue to arise regarding the process of informed consent and whether the person's right to self-determine was actually upheld. This article revisits issues of informed consent as related to research with human subjects and briefly defines informed consent, addresses selected issues, and offers some potential strategies to improve the process of obtaining informed consent when conducting research with human subjects.
kinds of concern one can have about such transactions - concerns about the nature of what is sold and concerns about the conditions in which the selling occurs. The former involves worries about degradation and the possible wrongness of selling a right of access to one's body. These worries, I argue, are not very serious. The latter involves worries about coercion, exploitation, and undue influence - about how, by virtue of their ignorance, impulsiveness, or desperation, guinea pigs can be taken advantage of by medical researchers. These worries are quite serious but I argue that, at least in cases where the exchange between guinea pigs and researchers is consensual and mutually beneficial, they do not raise insurmountable moral problems.

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**Document 97**

Stenson, Katherine; Chen, David; Tansey, Keith; Kerkhoff, Thomas R; Butt, Lester; Gallegos, Andrés J; Kirschner, Kristi L

**Informed consent and phase 1 research in spinal cord injury.**

PM & R: the journal of injury, function, and rehabilitation 2010 Jul; 2(7): 664-70

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**Document 98**

Schneider, Carl E

**The hydra.**


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**Document 99**

Jianping, Wang; Li, Lan; Xue, Di; Tang, Zhongjin; Jia, Xieyang; Wu, Rong; Xi, Yiqun; Wang, Tong; Zhou, Ping

**Analysis of the status of informed consent in medical research involving human subjects in public hospitals in Shanghai.**


**Abstract:** The objectives of the study are to understand the current practice of informed consent in medical research in public hospitals in Shanghai, and to share our views with other countries, especially developing countries.

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**Document 100**

Beebe, Lora Humphrey; Smith, Kathlene

**Informed consent to research in persons with schizophrenia spectrum disorders.**

Nursing ethics 2010 Jul; 17(4): 425-34

**Abstract:** This manuscript describes the responses and correlates of outpatients with schizophrenia spectrum disorders to a tool designed to measure comprehension before obtaining informed consent for research participation. We used the Evaluation to Sign Consent form to document comprehension in 100 outpatients as part of their consent to participate in an ongoing study of an exercise intervention. The findings suggest that using this form is a feasible and acceptable approach to documenting comprehension of research procedures prior to obtaining informed consent. Age 49 years and older and the receipt of intramuscular antipsychotic medication predicted the need for additional assistance to complete the Evaluation to Sign Consent form successfully (chi(2) = 8.29, P = 0.016). Nurse researchers should consider documenting comprehension with this tool owing to its availability, time efficiency and utility.

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Document 101
Stunkel, Leanne; Benson, Meredith; McLellan, Louise; Sinaii, Ninet; Bedarida, Gabriella; Emanuel, Ezekiel; Grady, Christine
Comprehension and informed consent: assessing the effect of a short consent form.
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Document 102
Kithinji, Caroline; Kass, Nancy E
Assessing the readability of non-English-language consent forms: the case of Kiswahili for research conducted in Kenya.
Georgetown users check Georgetown Journal Finder for access to full text

Document 103
Risberg, Bo
[When the patient can't consent to participation in a trial: the Ethics Review Board should take over the decision responsibility from the relatives] = När patienten inte kan lämna sitt medgivande att ingå i en studie: Etikprövningsnämnden bör ta över beslutsansvaret från de anhöriga.
Läkartidningen 2010 Jul 21-Aug 10; 107(29-31): 1787
Georgetown users check Georgetown Journal Finder for access to full text

Document 104
Lee, Stacey B
Informed consent: Enforcing pharmaceutical companies' obligations abroad.
Abstract: The past several years have seen an evolution in the obligations of pharmaceutical companies conducting clinical trials abroad. Key players, such as international human rights organizations, multinational pharmaceutical companies, the United States government and courts, and the media, have played a significant role in defining these obligations. This article examines how such obligations have developed through the lens of past, present, and future recommendations for informed consent protections. In doing so, this article suggests that, no matter how robust obligations appear, they will continue to fall short of providing meaningful protection until they are accompanied by a substantive enforcement mechanism that holds multinational pharmaceutical companies accountable for their conduct. Issues of national sovereignty, particularly in the United States, will continue to prevent meaningful enforcement by an international tribunal or through one universally adopted code of ethics. This article argues that, rather than continuing to pursue an untenable international approach, the Alien Torts Statute (ATS) offers a viable enforcement mechanism, at least for US-based pharmaceutical companies. Recent federal appellate court precedent interpreting the ATS provides the mechanism for granting victims redress and enforcing accountability of sponsors (usually pharmaceutical companies and research and academic institutions) for informed consent misconduct. Substantive human rights protections are vital in order to ensure that every person can realize the "right to health." This article concludes that by building on the federal appellate court's ATS analysis, which grants foreign trial participants the right to pursue claims of human rights violations in US courts, a mechanism can be created for enforcing not only substantive informed consent, but also human rights protections.
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Document 105

Voeffray Favre, A C; Ruiz, J; Bodenmann, P; Gianinazzi, F; Izzo, F; Rossi, I
[The application of informed consent in medicine as social construction] = La quête du consentement éclairé en médecine comme construction sociale.
Revue médicale suisse 2010 Jun 9; 6(252): 1205-8

Abstract: The aim of this article is to propose an anthropological point of view about informed consent in medicine. This quest for legitimacy should be read as a relational and social construction. In the heart of clinical complexity we find on one side various techniques employed by the medical community to validate research and to obtain the consent of patients. On the other side patients offer plural and subjective answers due to the doctor patient hierarchical and long relationship. Between constraints and freedoms, informed consent brings to light social relation.

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Document 106

Nussinovitch, Udi; Eidelman, Leonid; Shoenfeld, Yehuda
[Placebo use in clinical studies].
Harefuah 2010 Jun; 149(6): 365-9, 403

Abstract: Placebo use in clinical settings was first reported in the 1930's. Placebo-controlled randomized trials are conducted in order to explore the efficacy of new treatments. Nevertheless, the ethical aspects of placebo use remain controversial. It is usually accepted that placebo should be used only in circumstances where it causes no significant discomfort. Yet, the term "significant discomfort" may be interpreted in different ways. There is evidence that the placebo may be effective in some settings, and in other circumstances may be associated with side effects. Herein, we discuss the ethical dilemmas of placebo use, the evidence for its benefit or lack of benefit, and the current guidelines for conducting placebo-controlled trials.

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Document 107

Ziegenfuss, Jeanette Y
Embedded authorization form also reduces respondent burden.

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Document 108

Lecouturier, Jan; Stobart, Lynne; Murtagh, Madeleine J.; Ford, Gary A.; Rapley, Tim; Louw, Stephen J.; Rodgers, Helen
The challenges of seeking consent from adults to participate in acute research studies
Clinical Ethics 2010 June; 5(2): 73-76

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Document 109

Fovargue, Sara; Miola, José
Research and adults without capacity
Clinical Ethics 2010 June; 5(2): 63-66

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De Vries, Raymond; Stanczyk, Aimee; Wall, Ian F; Uhlmann, Rebecca; Damschroder, Laura J; Kim, Scott Y
Assessing the quality of democratic deliberation: a case study of public deliberation on the ethics of surrogate consent for research.

Abstract: "Deliberative democracy" is an increasingly popular method for soliciting public input on health care policies. There are a number of ways of organizing deliberative democracy (DD) sessions, but they generally involve gathering a group of citizens, supplying them with information relevant to the policy in question, giving them time to interact with each other and with experts in the policy area, and collecting their informed and considered opinions. As the method has become more widely used, some have questioned the quality of the public input it generates. Although theorists of DD agree that "good" input - i.e., input that is the product of careful and thorough reflection - is an essential aspect of useful and effective deliberation, few have actually measured the quality of deliberative sessions. As part of a DD project organized to help guide policies on the morally complex question of allowing surrogate permission to enroll persons with dementia in medical research, we developed and tested measures of "quality of deliberation." After a brief discussion of the substantive results of our research - survey data from participants in the DD sessions and control groups showed a significant change in participants' attitudes toward surrogate consent - we examine the process by which this change occurred, describing and assessing the characteristics of our DD sessions. We use both quantitative and qualitative data from our DD sessions, conducted in southeastern Michigan, United States, to examine four dimensions of the quality of deliberation: 1) equal participation by all members of the session, 2) respect for the opinions of others, 3) a willingness to adopt a societal perspective on the issue in question (rather than a focus on what is best for participants as individuals), and 4) reasoned justification of one's positions. We demonstrate that DD can be reliably used to elicit opinions of the public and show how analysis of the quality of deliberations can offer insight into the ways opinions about ethical dilemmas are formed and changed.

Ménoni, Véronique; Lucas, Noël; Leforestier, Jean François; Dimet, Jérôme; Doz, François; Chatellier, Gilles; Tréluyer, Jean-Marc; Chappuy, Hélène
The readability of information and consent forms in clinical research in France.
PloS one 2010 May 11; 5(5): e10576

Abstract: BACKGROUND: Quantitative tools have been developed to evaluate the readability of written documents and have been used in several studies to evaluate information and consent forms. These studies all showed that such documents had a low level of readability. Our objective is to evaluate the readability of Information and Consent Forms (ICFs) used in clinical research. METHODS AND FINDINGS: Clinical research protocols were collected from four public clinical research centers in France. Readability was evaluated based on three criteria: the presence of an illustration, the length of the text and its Flesch score. Potential effects of protocol characteristics on the length and readability of the ICFs were determined. Medical and statutory parts of the ICF form were analyzed separately. The readability of these documents was compared with that of everyday contracts, press articles, literary extracts and political speeches. We included 209 protocols and the corresponding 275 ICFs. The median length was 1304 words. Their Flesch readability scores were low (median: 24), and only about half that of selected press articles. ICFs for industrially sponsored and randomized protocols were the longest and had the highest readability scores. More than half (52%) of the text in ICFs concerned medical information, and this information was statistically (p<0.05) more readable (Flesch: 28) than statutory information (Flesch: 21). CONCLUSION: Regardless of the field of research, the ICFs for protocols included had poor readability scores. However, a prospective analysis of this test in French should be carried out before it is put into general use.

Albala, Ilene; Doyle, Margaret; Appelbaum, Paul S
The evolution of consent forms for research: a quarter century of changes.
IRB 2010 May-Jun; 32(3): 7-11
Document 113

Brehaut, Jamie C; Fergusson, Dean A; Kimmelman, Jonathan; Shojania, Kaveh G; Saginur, Raphael; Elwyn, Glyn

Using decision aids may improve informed consent for research.
Contemporary clinical trials 2010 May; 31(3): 218-20

Abstract: This commentary argues that the existing approach towards obtaining informed consent for clinical research may be improved by using decision aids. Problems with the current approach include i) an emphasis on documentation to the detriment of good quality decision-making; ii) ad hoc rather than theory-based research studying how to improve informed consent; and iii) a lack of clarity around what is meant by 'comprehension' and how to measure it. Decision aids, which clearly improve patient treatment decisions but are new to decisions surrounding study participation, have strengths in precisely the areas where the informed consent literature is weak. Decision aids facilitate a process of decision-making, combining clear documentation, exercises to facilitate decision-making, and consultation. They are increasingly informed by theory and clear, empirically-derived standards. Furthermore, decision aid research has clearly defined and operationalized three indicators of good quality decision-making in situations where there is no objectively correct answer: demonstrable knowledge of key aspects of the decision, accurate perceptions of the probabilities of various outcomes, and a match between preferred outcomes and the choice made. We identify outstanding issues and propose a research approach that will determine whether the use of decision aids can improve the informed consent process.

Document 114

Noel-Weiss, Joy; Woodend, A Kirsten; Kujawa-Myles, Sonya

Lactation and breastfeeding research studies: who should provide consent for the neonate?

Abstract: Research ethics guidelines do not provide sufficient direction for breastfeeding and human lactation studies. This article presents the principles of consent for research studies and discusses rationales for who should consent for infants in lactation and breastfeeding research studies.

Document 115

Largent, Emily A.; Wendler, David; Emanuel, Ezekiel; Miller, Franklin G.

Is emergency research without initial consent justified?: the consent substitute model.
Archives of Internal Medicine 2010 April 26; 170(8): 668-674

Abstract: Emergency research poses a fundamental ethical dilemma: prohibit valuable research because informed consent is not possible or enroll individuals in clinical trials without informed consent. Although emergency research without initial consent is allowable in the United States, its regulatory status remains uncertain internationally. More important, no ethical justification for emergency research without consent has been widely accepted. Whether emergency research without initial consent can be justified depends on whether the values that are secured by informed consent-respect for autonomy and protection of well-being-can be secured by other means. Analysis suggests that these values can be secured by the satisfaction of 5 conditions: (1) responsiveness (the experimental intervention must be responsive to an urgent medical need of the patients), (2) comparable risk-benefit ratio (the risk-benefit ratio of the experimental intervention is favorable, and at least as favorable as that of available alternatives and the control, if any), (3) no conflicting preferences (there is no compelling reason to think that participation in the research conflicts with enrolled patients' values or interests), (4) minimal net risks (nonbeneficial procedures included in the study cumulatively pose no greater than minimal risk), and (5) prompt consent (consent for ongoing and additional emergency research interventions is obtained as soon as possible). Together, these conditions constitute an ethical substitute for informed consent in emergency research-forming the consent substitute model.
Waiver of informed consent in prehospital emergency health research in Australia.

Monash bioethics review 2010 Mar; 29(1): 07.1-16

Abstract: Informed consent is a vital part of ethical research. In emergency health care research environments such as ambulance services and emergency departments, it is sometimes necessary to conduct trial interventions or observations without patient consent. At times where treatment is time critical, it may be impossible or inappropriate to seek consent from next of kin. Emergency medicine is one of the few areas where the process of informed consent can be waived to allow research to proceed without patient consent. This article will explore the ethics of informed consent in the prehospital emergency research context. This will include an overview of current Australian guidelines for ethical research, and recent changes in law internationally which have affected the conduct of international emergency health research. An overview of the ethical reasoning behind the waiver of informed consent in emergency research is presented, also addressing issues relating to emergency health research such as proxy consent, unconscious patients, and patient decision making capacity. The unusual circumstances encountered in the prehospital ambulance environment will also be discussed, including the dependent and coercive relationship between patients and ambulance professionals, and a lack of alternatives for care and transport for patients who refuse consent. The conflict arising from differences in medical culture and values between patients and health care professionals will also briefly be discussed. It will be argued that, while emergency care research should not require informed consent due to the restrictions of time and dependent nature of the relationship between patient and health professional, emergency health researchers still have a responsibility to consider the patients' perspective when considering the ethical issues of an emergency research project, particularly in the prehospital environment.

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Parental consent for neuroimaging in paediatric research.

Child: care, health and development 2010 Mar; 36(2): 241-8

Abstract: Functional magnetic resonance imaging (fMRI) is increasingly applied in paediatric research. Parents typically provide research consent for their children; yet, no study has examined the rates of consent, nor factors influencing parental decision making for consent. The present study aimed to determine the proportion of parents that would consent to their child undergoing an fMRI study, and to elicit the reasons, motivators and detractors affecting their decision.

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Evaluation of informed consent in health research: a questionnaire survey.

Scandinavian journal of caring sciences 2010 Mar; 24(1): 56-64

Abstract: Informed consent is ethically and legally required for all biomedical and health research involving human participants. This study analyses the realization of informed consent in health research from the point of view of healthy, voluntary adult participants. Empirical studies from this point of view are still rare.

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Informed consent issues in traumatic brain injury research: current status of capacity assessment and recommendations for safeguards.

Document 120
Paris, Adeline; Brandt, Christian; Cornu, Catherine; Maison, Patrick; Thalamas, Claire; Cracowski, Jean-Luc
Informed consent document improvement does not increase patients' comprehension in biomedical research.
British journal of clinical pharmacology 2010 Mar; 69(3): 231-7
Abstract: AIMS: International guidelines on ethics in biomedical research require that the informed consent of all enrolled participants is obtained. A written document describing the research, the informed consent (IC) document, must be given to all participants by the investigator. Most IC documents are long, containing much information. The aim of the present study was to determine whether the modification of the IC document by a working group or systematic improvement in its lexicosyntactic readability can improve comprehension of the written information given to patients participating in biomedical research. METHODS: One hundred and fifty-nine patients were randomized to read one of the three versions of the IC document: unchanged document, document modified using systematic improvement of lexicosyntactic readability and document modified by a working group. RESULTS: Neither the improvement in the lexicosyntactic readability, nor the intervention of the working group significantly improved the score of objective comprehension for the subjects included in this study: it was 66.6 (95% confidence interval 64.0, 69.2) for the control group, 68.8 (66.2, 71.4) for the group with the document improved for lexicosyntactic readability and 69.2 (66.0, 72.4) for the group who read the document improved by the working group (P= 0.38). CONCLUSIONS: We failed to show that improving IC document comprehension through a lexicosyntactic approach or by a working group leads to better comprehension.

Document 121
Marshall, Jennifer
Disclosure of unknown harms in magnetic resonance imaging research.
Accountability in research 2010 Mar ; 17(2): 67-78
Abstract: Unknown harms are by their nature difficult to communicate. While magnetic resonance imaging (MRI) has known risks (e.g., metal projectiles, dislodgement of medical implants), this imaging modality also has potential unknown long-term negative health effects associated with its static magnetic fields. We carried out a research ethics board (REB) file review of previously approved MRI research studies and found that unknown risks were either left undisclosed or were inadequately disclosed to research participants and REBs. This article outlines issues raised by our REB file review and suggests steps that should be taken in order to satisfactorily communicate information about potential unknown harms of MRI.

Document 122
Menikoff, Jerry
Void for vagueness: a problem in research consent?
Circulation. Cardiovascular quality and outcomes 2010 Mar ; 3(2): 116-7

Document 123
Fortune-Greeley, Alice K; Hardy, N Chantelle; Lin, Li; Friedman, Joëlle Y; Lawlor, Janice S; Muhlbaier, Lawrence H; Hall, Mark A; Schulman, Kevin A; Sugarman, Jeremy; Weinfurt, Kevin P
Patient reactions to confidentiality, liability, and financial aspects of informed consent in cardiology research.
Circulation. Cardiovascular quality and outcomes 2010 Mar ; 3(2): 151-8
Abstract: BACKGROUND: Although the informed consent process is supposed to help potential research participants
make informed and voluntary decisions about participating in research, little is known about how participants react to language in the informed consent document and whether their reactions are related to their willingness to enroll in clinical trials. We examined the relationship between patients’ reactions to standard informed consent language and their willingness to participate in a hypothetical clinical trial. METHODS AND RESULTS: We simulated the consent process for a hypothetical cardiology clinical trial with 470 patients in an outpatient cardiovascular medicine clinic at a large academic medical center. We analyzed the spontaneous comments and questions that participants made during the interviews about each section of the informed consent document. Few participants made positive comments. Participants made the most negative comments about the sections on risks, study purpose or protocol, and payment for injury. Having a negative reaction to any section was associated with a lower likelihood of participating in the clinical trial. Using a multivariable model, we found that negative reactions in the patient rights, financial disclosure, and confidentiality sections predicted willingness to participate (P<0.001). CONCLUSIONS: Recognizing elements of informed consent that elicit questions and concerns from potential research participants may help investigators design clinical research trials and model language in a way that reduces concerns or increases participant understanding, thereby enhancing informed consent for research.

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**Document 124**

Menikoff, Jerry

**Void for vagueness: a problem in research consent?**

Circulation. Cardiovascular quality and outcomes 2010 Mar; 3(2): 116-7

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**Document 125**

Fortune-Greeley, Alice K; Hardy, N Chantelle; Lin, Li; Friedman, Joëlle Y; Lawlor, Janice S; Muhlbaier, Lawrence H; Hall, Mark A; Schulman, Kevin A; Sugarman, Jeremy Weinfurt, Kevin P

**Patient reactions to confidentiality, liability, and financial aspects of informed consent in cardiology research.**

Circulation. Cardiovascular quality and outcomes 2010 Mar; 3(2): 151-8

**Abstract:** BACKGROUND: Although the informed consent process is supposed to help potential research participants make informed and voluntary decisions about participating in research, little is known about how participants react to language in the informed consent document and whether their reactions are related to their willingness to enroll in clinical trials. We examined the relationship between patients’ reactions to standard informed consent language and their willingness to participate in a hypothetical clinical trial. METHODS AND RESULTS: We simulated the consent process for a hypothetical cardiology clinical trial with 470 patients in an outpatient cardiovascular medicine clinic at a large academic medical center. We analyzed the spontaneous comments and questions that participants made during the interviews about each section of the informed consent document. Few participants made positive comments. Participants made the most negative comments about the sections on risks, study purpose or protocol, and payment for injury. Having a negative reaction to any section was associated with a lower likelihood of participating in the clinical trial. Using a multivariable model, we found that negative reactions in the patient rights, financial disclosure, and confidentiality sections predicted willingness to participate (P<0.001). CONCLUSIONS: Recognizing elements of informed consent that elicit questions and concerns from potential research participants may help investigators design clinical research trials and model language in a way that reduces concerns or increases participant understanding, thereby enhancing informed consent for research.

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**Document 126**

Olsen, Douglas P; Honghong Wang, ; Pang, Samantha

**Informed consent practices of Chinese nurse researchers.**

Nursing ethics 2010 Mar; 17(2): 179-87

**Abstract:** Nursing research in China is at an early stage of development and little is known about the practices of Chinese nurse researchers. This interview study carried out at a university in central China explores the informed consent practices of Chinese nurse researchers and the cultural considerations of using a western technique. Nine
Semistructured interviews were conducted in English with assistance and simultaneous translation from a Chinese nurse with research experience. The interviews were analyzed by one western and two Chinese researchers and major themes were identified. All participants endorsed informed consent as ethically required. Differences were noted between some of the informed consent practices typically recommended in the USA and those identified in this study, such as: recruitment using local and government officials, recruiting directly from medical records without special permission, family consultation in consent and consent control, and not revealing randomization to intervention groups receiving different treatments.

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Document 127
Maloney, Dennis M.
Agency says new consent element has many benefits

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Document 128
Olsen, Douglas P; Honghong Wang, ; Pang, Samantha
Informed consent practices of Chinese nurse researchers.
Nursing Ethics 2010 March; 17(2): 179-187

Abstract: Nursing research in China is at an early stage of development and little is known about the practices of Chinese nurse researchers. This interview study carried out at a university in central China explores the informed consent practices of Chinese nurse researchers and the cultural considerations of using a western technique. Nine semistructured interviews were conducted in English with assistance and simultaneous translation from a Chinese nurse with research experience. The interviews were analyzed by one western and two Chinese researchers and major themes were identified. All participants endorsed informed consent as ethically required. Differences were noted between some of the informed consent practices typically recommended in the USA and those identified in this study, such as: recruitment using local and government officials, recruiting directly from medical records without special permission, family consultation in consent and consent control, and not revealing randomization to intervention groups receiving different treatments.

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Document 129
Fadare, Joseph O.; Porteri, Corinna
Informed consent in human subject research: a comparison of current international and nigerian guidelines.

Abstract: Informed consent is a basic requirement for the conduct of ethical research involving human subjects. Currently, the Helsinki Declaration of the World Medical Association and the International Ethical Guidelines for Biomedical Research of the Council for International Organizations of Medical Sciences (CIOMS) are widely accepted as international codes regulating human subject research and the informed consent sections of these documents are quite important. Debates on the applicability of these guidelines in different socio-cultural settings are ongoing and many workers have advocated the need for national or regional guidelines. Nigeria, a developing country, has recently adopted its national guideline regulating human subject research: the National Health Research Ethics Committee (NHREC) code. A content analysis of the three guidelines was done to see if the Nigerian guidelines confer any additional protection for research subjects. The concept of a Community Advisory Committee in the Nigerian guideline is a novel one that emphasizes research as a community burden and should promote a form of "research friendship" to foster the welfare of research participants. There is also the need for a regular update of the NHREC code so as to address some issues that were not considered in its current version.

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Document 130
Dugosh, Karen Leggett; Festinger, David S.; Croft, Jason R.; Marlowe, Douglas B.
Measuring coercion to participate in research within a doubly vulnerable population: initial development of the coercion assessment scale.
Abstract: Despite many efforts aimed to ensure that research participation is autonomous and not coerced, there exists no reliable and valid measure of perceived coercion for the doubly vulnerable population of substance-abusing offenders. The current study describes the development and initial validation of an instrument measuring perceived coercion to participate in research among substance-abusing offenders. The results indicated that a substantial number of individuals report feeling coerced to participate in the study. In addition, the instrument has adequate levels of internal consistency, a one-dimensional factor structure, and evidence of discriminative validity. This study provides initial support for the instrument's validity and clinical utility.

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Document 131
Finniss, Damien G.; Kaptchuk, Ted J.; Miller, Franklin; Benedetti, Fabrizio
Biological, clinical, and ethical advances of placebo effects.
Lancet 2010 February 20; 375(9715): 686-695
Abstract: For many years, placebos have been defined by their inert content and their use as controls in clinical trials and treatments in clinical practice. Recent research shows that placebo effects are genuine psychobiological events attributable to the overall therapeutic context, and that these effects can be robust in both laboratory and clinical settings. There is also evidence that placebo effects can exist in clinical practice, even if no placebo is given. Further promotion and integration of laboratory and clinical research will allow advances in the ethical use of placebo mechanisms that are inherent in routine clinical care, and encourage the use of treatments that stimulate placebo effects.

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Document 132
Nathan, Aruna T.; Hoehn, K. Sarah; Ittenbach, Richard F.; Gaynor, J. William; Nicolson, Susan; Wernovsky, Gil; Nelson, Robert M.
Assessment of parental decision-making in neonatal cardiac research: a pilot study.
Journal of Medical Ethics 2010 February; 36(2): 106-10
Abstract: OBJECTIVE: To assess parental permission for a neonate's research participation using the MacArthur competence assessment tool for clinical research (MacCAT-CR), specifically testing the components of understanding, appreciation, reasoning and choice. STUDY DESIGN: Quantitative interviews using study-specific MacCAT-CR tools. HYPOTHESIS: Parents of critically ill newborns would produce comparable MacCAT-CR scores to healthy adult controls without the emotional stress of an infant with critical heart disease or the urgency of surgery. Parents of infants diagnosed prenatally would have higher MacCAT-CR scores than parents of infants diagnosed postnatally. There would be no difference in MacCAT-CR scores between parents with respect to gender or whether they did or did not permit research participation. PARTICIPANTS: Parents of neonates undergoing cardiac surgery who had made decisions about research participation before their neonate's surgery. METHODS: The MacCAT-CR. RESULTS: 35 parents (18 mothers; 17 fathers) of 24 neonates completed 55 interviews for one or more of three studies. Total scores: magnetic resonance imaging (mean 36.6, SD 7.71), genetics (mean 38.8, SD 3.44), heart rate variability (mean 37.7, SD 3.30). Parents generally scored higher than published subject populations and were comparable to published control populations with some exceptions. CONCLUSIONS: The MacCAT-CR can be used to assess parental permission for neonatal research participation. Despite the stress of a critically ill neonate requiring surgery, parents were able to understand study-specific information and make informed decisions to permit their neonate's participation.

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**Document 133**

Kitua, Andrew; Folb, Peter; Warsame, Marian; Binka, Fred; Faiz, Abul; Ribeiro, Isabel; Peto, Tom; Gyapong, John; Yunus, Emran Bin; Rahman, Ridwan; Baiden, Frank; Clerk, Christine; Mrango, Zakayo; Makasi, Charles; Kimbute, Omar; Hossain, Amir; Samad, Rasheda; Gomes, Melba

**The use of placebo in a trial of rectal artesunate as initial treatment for severe malaria patients en route to referral clinics: ethical issues.**

Journal of Medical Ethics 2010 February; 36(2): 116-20

**Abstract:** Placebo-controlled trials are controversial when individuals might be denied existing beneficial medical interventions. In the case of malaria, most patients die in rural villages without healthcare facilities. An artesunate suppository that can be given by minimally skilled persons might be of value when patients suddenly become too ill for oral treatment but are several hours from a facility that can give injectable treatment for severe disease. In such situations, by default, no treatment is (or can be) given until the patient reaches a facility, making the placebo control design clinically relevant; alternative bioequivalence designs at the facility would misrepresent reality and risk incorrect conclusions. We describe the ethical issues underpinning a placebo-controlled trial in severe malaria. To protect patients and minimise risk, all patients were referred immediately to hospital so that each had a higher chance of prompt treatment through participation. There was no difference between artesunate and placebo in patients who reached clinic rapidly; among those who could not, a single artesunate suppository significantly reduced death or permanent disability, a finding of direct and indirect benefit to patients in participating villages and elsewhere.

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**Document 134**

Maloney, Dennis M.

**In court: Research subject claims consent form was faulty**


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**Document 135**

Maloney, Dennis M.

**New guidance on IRB continuing reviews**


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**Document 136**

Maloney, Dennis M.

**Agency proposes new informed consent element**


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**Document 137**

Tarini, Beth A.; Goldenberg, A.; Singer, D.; Clark, S.J.; Butchart, A.; Davis, M.M.

**Not without my permission: parents' willingness to permit use of newborn screening samples for research.**

Public Health Genomics 2010 February; 13(3): 125-130

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The use of placebo in a trial of rectal artesunate as initial treatment for severe malaria patients en route to referral clinics: ethical issues.

Journal of Medical Ethics 2010 February; 36(2): 116-120

Abstract: Placebo-controlled trials are controversial when individuals might be denied existing beneficial medical interventions. In the case of malaria, most patients die in rural villages without healthcare facilities. An artesunate suppository that can be given by minimally skilled persons might be of value when patients suddenly become too ill for oral treatment but are several hours from a facility that can give injectable treatment for severe disease. In such situations, by default, no treatment is (or can be) given until the patient reaches a facility, making the placebo control design clinically relevant; alternative bioequivalence designs at the facility would misrepresent reality and risk incorrect conclusions. We describe the ethical issues underpinning a placebo-controlled trial in severe malaria. To protect patients and minimise risk, all patients were referred immediately to hospital so that each had a higher chance of prompt treatment through participation. There was no difference between artesunate and placebo in patients who reached clinic rapidly; among those who could not, a single artesunate suppository significantly reduced death or permanent disability, a finding of direct and indirect benefit to patients in participating villages and elsewhere.

Gulbrandsen, Pål; Jensen, Bård Fossli

Post-recruitment confirmation of informed consent by SMS.

Journal of Medical Ethics 2010 February; 36(2): 126-128

Abstract: BACKGROUND: To allow patients to reflect about a decision to participate in a clinical trial, guidelines suggest a 24-h delay from when they are informed about the trial to when they give consent. In certain clinical settings, this is likely to hamper recruitment. METHOD: After oral and written information about the trial has been given in person, the patient signs the declaration of consent knowing that they will be asked again after 24 h whether they confirm or regret the decision. This procedure can be done by SMS. The investigators must document the response. The procedure was tried in a study in which the doctors were randomly assigned to receive a clinical communication skills course, and encounters with patients were videotaped before and after the course. RESULTS: 553 patients were approached, 530 (95.8%) gave initial consent, eight of these later regretted their consent. DISCUSSION: The low level of regrets suggests this is an acceptable procedure for patients. TRIAL REGISTRATION: The RCT was registered before initiation - registration # ISRCTN22153332.

Romain, Paul L.

Ethics: Investigators' interests: what should trial participants be told?


Abstract: Minimizing the potential adverse effects of clinical investigators' financial conflicts of interest involves, in part, determining how much of an investigator's "business" should be disclosed to participants in research studies. What should be disclosed and why? How will we know if disclosure matters?
**Document 141**

Markman, Maurie

**Therapeutic intent and misconception in early-phase clinical trials in the gynecologic malignancies.**


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**Document 142**

Roston, Eric

**She changed medicine, but her family can’t afford care [review of The immortal life of Henrietta Lacks, by Rebecca Skloot]**


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

**Document 143**

Sáenz de Tejada López, M; Valle Mansilla, J I; Ruiz-Canela, M

**[Deficiencies in consent forms for genomic research].** = Deficiencias en las Hojas de Información de Estudios Genómicos.

Cuadernos de bioética : revista oficial de la Asociación Española de Bioética y Ética Médica 2010 Jan-Apr; 21(71): 95-108

**Abstract:** whenever biological samples are requested for genomic research consent from donors is always needed. in this process, appropriate information offered to participants is essential. the aim of this study is to assess the information included in consent forms from genomic studies.

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**Document 144**

Resnik, David B.; Patrone, Daniel; Peddada, Shyamal

**Evaluating the quality of information about alternatives to research participation in oncology consent forms.**

Contemporary Clinical Trials 2010 January; 31(1): 18-21

**Abstract:** A careful consideration of the alternatives to research participation is an essential element of making an informed choice to enroll in a biomedical research study. While there is general agreement on the importance of informing prospective subjects about alternatives to research participation, little is known about how investigators communicate this information. The purpose of this study was to attempt to assess the quality of information about alternatives contained in informed consent documents in oncology randomized controlled trials. Our study indicates that there is room for improvement concerning the discussion of alternatives to research participation in informed consent documents. Though most of the documents in our study met the minimal disclosure standard found in the U.S. federal regulations, less than a third met the reasonable person standard, a widely accepted principle endorsed by the common law and various ethics guidelines and documents. There was a statistically significant difference between the alternative discussions in local and model forms (P<0.0014). The alternatives discussions in local informed consent documents were more likely to receive higher scores than those in model consent documents, with an odds-ratio of 3.5 to 1.

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**Document 145**

Bhan, Anant
Use of blanket consent for retrospective research in academic institutions: need for scrutiny and integrating safeguards.
Georgetown users check Georgetown Journal Finder for access to full text

Document 146
Ravina, Bernad; Swearingen, Christopher; Elm, Jordan; Kamp, Comelia; Kieburtz, Karl; Kim, Scott Y.H.
Long term understanding of study information in research participants with Parkinson's disease.
Parkinsonism & Related Disorders 2010 January; 16(1): 60-63

Abstract: CONTEXT: Little is known about research participants' understanding of consent information over the course of a clinical study and the relationship of this information with participant behavior. METHODS: We conducted a cross sectional patient completed questionnaire of comprehension and satisfaction administered at the end of a Parkinson's disease clinical trial. MAIN OUTCOME: Scores on 9 comprehension items in a 30 item questionnaire covering the key elements of informed consent. RESULTS: 78% of eligible trial participants completed this substudy. Greater than 90% of respondents showed good comprehension of the study purpose, method of treatment assignment, experimental nature of drugs, voluntary participation, and expected effect of the trial on their PD. However, 42.3% of subjects incorrectly endorsed that participating in the study was part of the "usual treatment" for their PD. We found no relationship between comprehension, compliance, and satisfaction with whether or not one's own neurologist was also the study doctor. Years of education and cognitive function at baseline were correlated with comprehension of study information. CONCLUSIONS: Overall comprehension of key study information presented in the consent was high after 12 months of trial participation, although there were inconsistencies in responses that need further study.
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Document 147
Singh, Ilina
Cryptic coercion.

http://muse.jhu.edu/journals/hastings_center_report/toc/hcr.40.1.html (link may be outdated)

Document 148
Skloot, Rebecca
THE IMMORTAL LIFE OF HENRIETTA LACKS
Call number: RC265.6 .L24 S55 2010

Document 149
Buccini, Laura D.; Iverson, Donald; Caputi, Peter; Jones, Caroline
An Australian based study on the readability of HIV/AIDS and Type 2 diabetes clinical trial informed consent documents
Georgetown users check Georgetown Journal Finder for access to full text
Document 150

Yazici, Yusuf; Yazici, Hasan

Informed consent: time for more transparency.
Arthritis research & therapy 2010; 12(3): 121

Abstract: Informed consent is not only for documenting a patient's acceptance of enrolling in a clinical trial. It currently is the patient's and, we propose, should also be the public's main source of information regarding the reasons for the planned study, what is known in the field about the proposed trial, and what to expect as far as efficacy and harm. Informed consent is not currently part of the clinical trial registries. For purposes of full disclosure to the patients and the public, the informed consent should be part of the required documents for such registries.

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Document 151

Yazici, Yusuf

Informed consent–practical considerations.
Bulletin of the NYU hospital for joint diseases 2010; 68(2): 127-9

Abstract: Informed consent is a legal document that summarizes what will take place in a study in a language the study subjects can understand and is the process by which a person decides whether or not to participate in a study. The document is not limited to explaining the intervention or potential risks and benefits but is also the source of understanding why the study is being done and what the particular study will add to what is already known. Overall, informed consent is a document providing important transparency and clarity about the study. While consent forms are mandatory prior to study approval by internal review boards, they are not published as part of study results and are not part of clinical trial registries. The central role of an informed consent document in any study could be vitally expanded and enhanced with inclusion and full disclosure of its content through clinical trial registries and published reports in the literature, bringing improved transparency to the entire clinical trial process. Transparency is important for the maintenance of high standards in clinical research and for public trust of the process, a sometimes underrecognized factor in healthcare initiatives.

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Document 152

Sansone, Randy A; Lam, Charlene; Wiederman, Michael W

Survey cover pages: to take or not to take.
International journal of psychiatry in medicine 2010; 40(2): 229-31

Abstract: In survey research, the elements of informed consent, including contact information for the researchers and the Institutional Review Board, may be located on a cover page, which participants are advised that they may take. To date, we are not aware of any studies examining the percentage of research participants that actually take these cover pages, which was the purpose of this study. Among a consecutive sample of 419 patients in an internal medicine setting, 16% removed the cover page. There were no demographic predictors regarding who took versus did not take the cover page.

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Document 153

Festinger, David S.; Dugosh, Karen L.; Croft, Jason R.; Arabia, Patricia L.; Marlowe, Douglas B.

Corrected feedback: a procedure to enhance recall of informed consent to research among substance abusing offenders
Ethics & Behavior 2010; 20(5): 387-399

Georgetown users check Georgetown Journal Finder for access to full text
Document 154

Miller, Franklin G.

* Consent to clinical research*


Call number: KZ1262 .C65 E86 2010

Document 155

United States. Food and Drug Administration [FDA]

* Informed consent elements: proposed rule*

Federal Register 2009 December 29; 74(248): 68750-68756

Georgetown users check Georgetown Journal Finder for access to full text

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

Document 156

Harder, Ben

* Should you join a research study?*

U.S. News and World Report 2009 December; 146(11): 68, 71

Georgetown users check Georgetown Journal Finder for access to full text

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

Document 157

Foglia, Mary Beth; Salas, Halle Showalter; Diekema, Douglas S

* A quality improvement approach to improving informed consent practices in pediatric research.*


Georgetown users check Georgetown Journal Finder for access to full text

Document 158

Appelbaum, Paul S.; Lidz, Charles W.; Klitzman, Robert

* Voluntariness of consent to research: a preliminary empirical investigation.*

IRB: Ethics and Human Research 2009 November-December; 31(6): 10-14

Georgetown users check Georgetown Journal Finder for access to full text

Document 159

Resnik, D.B.

* Re-consenting human subjects: ethical, legal and practical issues.*

Journal of Medical Ethics 2009 November; 35(11): 656-657

Georgetown users check Georgetown Journal Finder for access to full text

http://jme.bmj.com (link may be outdated)
* Document 160
Chenaud, C; Merlani, P; Verdon, M; Ricou, B
Who should consent for research in adult intensive care? Preferences of patients and their relatives: a pilot study.
Journal of Medical Ethics 2009 November; 35(11): 709-712
Abstract: INTRODUCTION: Research in intensive care is necessary for the continuing advancement of patient care. In research, informed consent is considered essential for patient protection. In intensive care, the modalities of informed consent are currently being debated by both lawyers and the medical community. The preferences of patients and their relatives regarding informed consent for research in intensive care have never been assessed. The aim of this study was to investigate these preferences. METHODS: A pilot study conducted via a questionnaire mailed to patients and relatives who had experienced intensive care. RESULTS: 52/400 patient-relative pairs completed the questionnaire fully. If the patient was imagined to be conscious, 75% of patients and 77% of relatives believed the patient should be the person who should consent. If the patient was imagined to be unconscious, 72% of patients and 67% of relatives thought that a relative should be asked to consent. The majority of responders thought that at least two persons should consent. Their answers were concordant in 61-80% of cases, depending on the question. Patients (25%) and relatives (30%) did not feel free in their decision to participate in a study. The majority of patients and relatives wanted to consent by writing, indifferently with or without a witness. CONCLUSION: Patients are willing to decide on their own participation in a study. If they lose their capacity to decide for themselves, in the great majority of cases, they would agree to delegate the decision to a relative. Georgetown users check Georgetown Journal Finder for access to full text
http://jme.bmj.com (link may be outdated)

Document 161
Bavdekar, S B
Informed Consent Documents submitted for initial review: what do they state about compensation for injured research participants?
Indian journal of medical sciences 2009 Oct; 63(10): 455-60
Abstract: Research carries a small but definite risk of injury to participants. However, there is no unanimity amongst the stakeholders regarding the nature and extent of compensation to be provided to an injured participant. Georgetown users check Georgetown Journal Finder for access to full text

Document 162
Osrin, David; Azad, Kishwar; Fernandez, Armida; Manandhar, Dharma S.; Mwansambo, Charles W.; Tripathy, Prasanta; Costello, Anthony M.
Ethical challenges in cluster randomized controlled trials: experiences from public health interventions in Africa and Asia
Georgetown users check Georgetown Journal Finder for access to full text
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2755306/pdf/08 (link may be outdated)

Document 163
Lombardo, Paul A.
Tracking chromosomes, castrating dwarves: uniformed consent and eugenic research
Ethics & Medicine 2009 Fall; 25(3): 149-164
Bhansali, S; Shafiq, N; Malhotra, S; Pandhi, P; Singh, Inderjeet; Venkateshan, S P; Siddhu, S; Sharma, Y P; Talwar, K K

Evaluation of the ability of clinical research participants to comprehend informed consent form.
Contemporary clinical trials 2009 Sep; 30(5): 427-30

Abstract: The comprehension of informed consent is an integral part of clinical trials. Though India is rapidly becoming a hub of clinical trials very few studies have dealt with the issue of comprehension of informed consent by the patients participating in these trials.

Brehaut, Jamie C; Saginur, Raphael; Elwyn, Glyn

Informed consent documentation necessary but not sufficient.
Contemporary clinical trials 2009 Sep; 30(5): 388-9

Goldner, Jesse

Emergency research without informed consent
Medical Ethics Newsletter [Lahey Clinic] 2009 Fall; 16(3): 4, 7

Napier, Stephen

Rethinking Informed Consent in Bioethics, by Neil C. Manson and Onora O'Neill [book review]
National Catholic Bioethics Quarterly 2009 Autumn; 9(3): 610-613

Howick, Jeremy

Questioning the methodologic superiority of 'placebo' over 'active' controlled trials.
American Journal of Bioethics 2009 September; 9(9): 34-48

Abstract: A resilient issue in research ethics is whether and when a placebo-controlled trial (PCT) is justified if it deprives research subjects of a recognized treatment. The clinicians' moral duty to provide the best available care seems to require the use of 'active' controlled trials (ACTs) that use an established treatment as a control whenever such a therapy is available. In another regard, ACTs are supposedly methodologically inferior to PCTs. Hence, the moral duty of the clinical researcher to use the best methods will favor PCTs. In this target article, I analyze the three reasons for believing that ACTs are inferior to PCTs namely: 1) ACTs lack 'assay sensitivity'; 2) ACTs do not measure absolute effect size; and 3) ACTs require more participants; and I contend that none are acceptable. Consequently the tension between clinical and research ethics dissolves: the moral duty of the clinician to avoid PCTs is unopposed by methodological considerations.
Document 169

Miller, Franklin G.
The rationale for placebo-controlled trials: methodology and policy considerations.
American Journal of Bioethics 2009 September; 9(9): 49-50

Document 170

Nunn, Robin
Preparing for a post-placebo paradigm: ethics and choice of control in clinical trials.
American Journal of Bioethics 2009 September; 9(9): 51-52

Document 171

Senn, Stephen
Placebo misconceptions.
American Journal of Bioethics 2009 September; 9(9): 53-54

Document 172

Dworkin, Ronald W.
A clinical perspective on placebo research: looking back, looking forward.
American Journal of Bioethics 2009 September; 9(9): 54-55

Document 173

Petrini, Carlo
Ethical issues in the difference between placebo-controlled and active-controlled trials.
American Journal of Bioethics 2009 September; 9(9): 56-58
Document 174
van der Graaf, Rieke; van Delden, Johannes J.M.
Conflating scientific with clinical considerations.
American Journal of Bioethics 2009 September; 9(9): 58-59
Georgetown users check Georgetown Journal Finder for access to full text

Document 175
Anderson, James A.
Who's in control of the choice of control?
American Journal of Bioethics 2009 September; 9(9): 60-62
Georgetown users check Georgetown Journal Finder for access to full text

Document 176
Rennie, Stuart; Stürmer, Til
Strengthening Howick's argument against the alleged superiority of placebo-controlled trials.
American Journal of Bioethics 2009 September; 9(9): 62-64
Georgetown users check Georgetown Journal Finder for access to full text

Document 177
Moerman, Daniel E.
Research, medicine, and "placebos".
American Journal of Bioethics 2009 September; 9(9): 64-65
Georgetown users check Georgetown Journal Finder for access to full text

Document 178
Enkin, Murray W.
Questioning the methodological superiority of 'placebo' over 'active' controlled trials.
American Journal of Bioethics 2009 September; 9(9): 66-67
Georgetown users check Georgetown Journal Finder for access to full text
Golomb, Beatrice Alexandra
Control theory: placebo-controlled drug trials have problems. Active-controlled drug trials are not always the solution.
American Journal of Bioethics 2009 September; 9(9): 67-69
Georgetown users check Georgetown Journal Finder for access to full text
http://www.bioethics.net/journal/issues.php (link may be outdated)

Kim, Scott Y.H.; Schrock, Lauren; Wilson, Renee M.; Frank, Samuel A.; Holloway, Robert G.; Kieburtz, Karl; de Vries, Raymond G.
An approach to evaluating the therapeutic misconception.
IRB: Ethics and Human Research 2009 September-October; 31(5): 7-14
Georgetown users check Georgetown Journal Finder for access to full text

Miller, Franklin G.; Colloca, Luana; Kaptchuk, Ted J.
The placebo effect: illness and interpersonal healing.
Perspectives in Biology and Medicine 2009 Autumn; 52(4): 518-539
Georgetown users check Georgetown Journal Finder for access to full text
http://muse.jhu.edu/journals/pbm/ (link may be outdated)

Agency for Healthcare Research and Quality [AHRQ]
Informed Consent and Authorization Toolkit for Minimal Risk Research
http://www.ahrq.gov/fund/informedconsent/ictoolkit.pdf (link may be outdated)

Miller, Victoria A.; Reynolds, William W.; Ittenbach, Richard F.; Luce, Mary Frances; Beauchamp, Tom L.; Nelson, Robert M.
Challenges in measuring a new construct: perception of voluntariness for research and treatment decision making.
Abstract: RELIABLE AND VALID MEASURES OF RELEVANT constructs are critical in the developing field of the empirical study of research ethics. The early phases of scale development for such constructs can be complex. We describe the methodological challenges of construct definition and operationalization and how we addressed them in our study to develop a measure of perception of voluntariness. We also briefly present our conceptual approach to the construct of voluntariness, which we defined as the perception of control over decision making. Our multifaceted approach to scale development ensured that we would develop a construct definition of sufficient breadth and depth, that our new measure of voluntariness would be applicable across disciplines, and that there was a clear link between our construct definition and items. The strategies discussed here can be adapted by other researchers who are considering a scale development study related to the empirical study of ethics.
Document 184
Beskow, Laura M.; Smolek, Sondra J.

**Prospective biorepository participants' perspectives on access to research results.**

**Abstract:** DISCLOSURE OF INDIVIDUAL RESEARCH results to research participants has been the subject of professional guidelines as well as scholarly commentary, yet controversy remains. To gather data on participant perspectives, we interviewed 40 individuals from the Durham, North Carolina area about a biorepository consent form and conducted an in-depth analysis of responses to a series of questions concerning access to research results. Cross-cutting themes emerged about (1) the nature of research; (2) the nature of research results; (3) expectations concerning access to research results; and (4) practical issues in providing access to research results. Our findings highlight the importance for sound policy development of soliciting stakeholder input, and exploring the complexities behind their evaluations.

Document 185
Knapp, Peter; Raynor, D.K.; Silcock, J.; Parkinson, B.

**Performance-based readability testing of participant materials for a phase I trial: TGN1412.**
Journal of Medical Ethics 2009 September; 35(9): 573-578

**Abstract:** BACKGROUND: Concern has been expressed about the process of consent to clinical trials, particularly in phase I "first-in-man" trials. Trial participant information sheets are often lengthy and technical. Content-based readability testing of sheets, which is often required to obtain research ethics approval for trials in the USA, is limited and cannot indicate how information will perform. METHODS: An independent-groups design was used to study the user-testing performance of the participant information sheet from the phase I TGN1412 trial. Members of the public were asked to read it, then find and demonstrate understanding of 21 key aspects of the trial. The participant information sheet was then rewritten, redesigned and tested on 20 members of the public, using the same 21-item questionnaire. RESULTS: On the original TGN1412 participant information sheet, participants could not find answers and some of the found information was not understood. Six of 21 questions, including those relating to placebo, follow-up visits and the emergency phone number, were found by eight or fewer of 10 participants. The revised information sheet performed better, with the answers to 17 of 21 questions found and understood by all 20 participants. CONCLUSIONS: Tests showed that the TGN1412 participant information sheet may not inform participants adequately for consent. Revising its content and design led to significant improvements. Writers of materials for trial participants should take account of good practice in information design. Performance-based user testing may be a useful method to indicate strengths and weaknesses in trial materials.

Document 186
Liao, S. Matthew; Sheehan, Mark; Clarke, Steve

**The duty to disclose adverse clinical trial results.**
American Journal of Bioethics 2009 August; 9(8): 24-32

**Abstract:** Participants in some clinical trials are at risk of being harmed and sometimes are seriously harmed as a result of not being provided with available, relevant risk information. We argue that this situation is unacceptable and that there is a moral duty to disclose all adverse clinical trial results to participants in clinical trials. This duty is grounded in the human right not to be placed at risk of harm without informed consent. We consider objections to
disclosure grounded in considerations of commercial interest, and we argue that these concerns are insufficient to
override the moral duty to disclose adverse clinical trial results. However, we also develop a proposal that enables
commercial interests to be protected, while promoting the duty to disclose adverse clinical trial results.

* Document 187
Hassoun, Nicole
The duty to disclose (even more) adverse clinical trial results.
American Journal of Bioethics 2009 August; 9(8): 33-34

* Document 188
McGoey, Linsey
Compounding risks to patients: selective disclosure is not an option.
American Journal of Bioethics 2009 August; 9(8): 35-36

* Document 189
Shah, Kavita R.; Batzer, Frances R.
Improving subject recruitment by maintaining truly informed consent: a practical benefit of disclosing
adverse clinical trial results.
American Journal of Bioethics 2009 August; 9(8): 36-37

* Document 190
Oakley, Justin
Respecting participant autonomy and the disclosure of clinical trial results.
American Journal of Bioethics 2009 August; 9(8): 38

* Document 191
Banja, John D.; Dunlop, Boadie
Enhancing informed consent in clinical trials and exploring resistances to disclosing adverse clinical trial
results.
Document 192

Wu, Kevin Chien-Chang

Precautionary harm disclosure in clinical trials.
American Journal of Bioethics 2009 August; 9(8): 43-45

Disclosure of adverse clinical trial results -- should legal immunity be granted to drug companies?
American Journal of Bioethics 2009 August; 9(8): 45-47

Panoyan, Lucy; Lee, Shuko; Arar, Rawan; Abboud, Hanna E.; Arar, Nedal

The informed consent process in genetic family studies

Abstract: The informed consent process provides protection by ensuring that potential research subjects understand the goals of the research project they are being asked to voluntarily partake in as well as the risks associated with the study. We examined subjects’ comprehension and ability to identify issues explicitly raised during the consent process that was conducted as part of their participation in a genetic family study (GFS). We employed cross-sectional design by providing a short, self-administrative questionnaire to 246 participants recruited from families enrolled in the Extended Family Investigation of Nephropathy and Diabetes (EFIND) study conducted at the University of Texas Health Science Center. Participants responded to the questionnaire directly after their enrollment in the EFIND study. The questionnaire consisted of multiple-choice questions and focused on the understanding of the purposes, procedures, and risks associated with their participation in the EFIND study. These questions were formulated to reflect basic information presented to subjects through the consent process. Responses to questions were expressed as percentages, placing equal weight on each response. Participants were Mexican-American, 62.3% female and averaged 35.2 ±12.7 years old (range: 18-76). Our findings showed that the average comprehension score was 58. About 30% of the participants did not know the name of the study, and 70% did not identify all elements related to the study procedures. The most striking finding was the lack of understanding concerning the social risks associated with participation in EFIND. While 35.1% of participants identified all potential physical risks, only 1.3% could identify all of the social risks. Our findings showed that participants comprehension score was significantly associated with their level of education and income. We conclude that using the informed consent process to communicate research social risks to subjects participating in GFS has some limitations. Future research directed at improving risk communications to subjects of low socioeconomic levels participating in genetic research is justified.

http://www.gspjournal.com (link may be outdated)
Document 195

Jansen, Lynn A.
The ethics of altruism in clinical research

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Document 196

Koyman, Shlomo A.; McCabe, Mary S.; Emanuel, Ezekiel J.; Grady, Christine
A consent form template for phase 1 oncology trials

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Document 197

Wazaify, Mayyada; Khalil, Susan S.; Silverman, Henry J.
Expression of therapeutic misconception amongst Egyptians: a qualitative pilot study.
BMC Medical Ethics [electronic] 2009 June 30; 10: 7

Abstract: BACKGROUND: Studies have shown that research participants fail to appreciate the difference between research and medical care, labeling such phenomenon as a "therapeutic misconception" (TM). Since research activity involving human participants is increasing in the Middle East, qualitative research investigating aspects of TM is warranted. Our objective was to assess for the existence of therapeutic misconception amongst Egyptians.

METHODS: Study Tool: We developed a semi-structured interview guide to elicit the knowledge, attitudes, and perspectives of Egyptians regarding medical research. SETTING: We recruited individuals from the outpatient settings (public and private) at Ain Shams University in Cairo, Egypt. ANALYSIS: Interviews were taped, transcribed, and translated. We analyzed the content of the transcribed text to identify the presence of a TM, defined in one of two ways: TM1 = inaccurate beliefs about how individualized care can be compromised by the procedures in the research and TM2 = inaccurate appraisal of benefit obtained from the research study. RESULTS: Our findings showed that a majority of participants (11/15) expressed inaccurate beliefs regarding the degree with which individualized care will be maintained in the research setting (TM1) and a smaller number of participants (5/15) manifested an unreasonable belief in the likelihood of benefits to be obtained from a research study (TM2). A total of 12 of the 15 participants were judged to have expressed a TM on either one of these bases. CONCLUSION: The presence of TM is not uncommon amongst Egyptian individuals. We recommend further qualitative studies investigating aspects of TM involving a larger sample size distinguished by different types of illnesses and socio-economic variables, as well as those who have and have not participated in clinical research.

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http://www.biomedcentral.com/1472-6939/10/7 (link may be outdated)

Document 198

Sammons, H.
Ethical issues of clinical trials in children: a European perspective.
Archives of Disease in Childhood 2009 June; 94(6): 474-477

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Document 199

Moore, Peter K.; Moore, Ernest E.; Moore, Frederick A.
Exception from informed consent requirements for emergency research.
Surgery 2009 June; 145(6): 630-635

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* Document 200
Walkup, James; Bock, Elinor
What do prospective research participants want to know? What do they assume they know already?
Abstract: USING A FRAMEWORK BASED ON conversational pragmatics, data were collected on spontaneous information requests by people who were invited to participate in a simple research study. Subjects requested information on some standard elements of consent (e.g., scientific purpose, time required, investigator), but not others (e.g., voluntariness, freedom to quit, data maintenance, risks). Using post hoc fixed response queries, we investigated factors responsible for absence of queries on elements of consent. We found that participants sometimes did not ask because they assumed they already knew the answer; other times they did not care about the answer. This small pilot study suggests that inclusion of elements considered inappropriate by respondents may be redundant and, in at least some circumstances, potentially confusing.

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http://www.ucpressjournals.com/journal.asp?j=jer (link may be outdated)

* Document 201
Dunlop, Boadie W.; Banja, J.
A renewed, ethical defense of placebo-controlled trials of new treatments for major depression and anxiety disorders
Abstract: The use of placebo as a control condition in clinical trials of major depressive disorder and anxiety disorders continues to be an area of ethical concern. Typically, opponents of placebo controls argue that they violate the beneficent-based, "best proven diagnostic and therapeutic method" that the original Helsinki Declaration of 1964 famously asserted participants are owed. A more consequentialist, oppositional argument is that participants receiving placebo might suffer enormously by being deprived of their usual medication(s). Nevertheless, recent findings of potential for suicidality in young people treated with antidepressants, along with meta-analyses suggesting that antidepressants add no significant clinical benefit over placebos, warrant a re-evaluation of the arguments against placebo. Furthermore, the nature of placebo treatment in short-term clinical trials is often not well understood, and lack of understanding can foster opposition to it. This paper will show how scientific justifications for placebo use are morally relevant. The fundamental ethical importance of placebo controls is discussed in relation to several aspects of clinical trials, including detection of adverse events, accurate assessment of clinical benefit, advancing understanding of the heterogeneity of depression and anxiety disorders and respecting informed consent requirements. Prohibiting the use of placebo controls is morally concerning in that such prohibitions allow for the possibility of serious adverse public health consequences. Moral worries that research participants receiving placebo are being unduly jeopardised will be shown to be exaggerated, especially in relation to the net benefits for end-users to be gained from the quality of data resulting from using placebo controls.

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

* Document 202
Annas, George J.
Globalized clinical trials and informed consent [commentary]
Chen, Xiao-yuan

[Exploration of the placebo control issue in clinical trials of anti-cancer drugs].

Bath, Philip M.W.; Watson, Alan R.

Need for ethics approval and patient consent in clinical research.
Stroke 2009 May; 40(5): 1555-1556

Freer, Yvonne; McIntosh, Neil; Teunisse, Saskia; Anand, Kanwaljeet J.S.; Boyle, Elaine M.

More information, less understanding: a randomized study on consent issues in neonatal research.
Pediatrics 2009 May; 123(5): 1301-1305

Muir, Kelly W.; Lee, Paul P.

Literacy and informed consent: a case for literacy screening in glaucoma research.
Archives of Ophthalmology 2009 May; 127(5): 698-699

Anderson, James R.; Schonfeld, Toby L.

Data-sharing dilemmas: allowing pharmaceutical company access to research data
IRB: Ethics and Human Research 2009 May-June; 31(3): 17-19

Kass, Nancy E.; Sugarman, Jeremy; Medley, Amy M.; Fogarty, Linda A.; Taylor, Holly A.; Daugherty, Christopher K.; Emerson, Mark R.; Goodman, Steven N.; Hlubocky, Fay J.; Hurwitz, Herbert I.; Carducci, Michael; Goodwin-Landher, Annallys

An intervention to improve cancer patients' understanding of early-phase clinical trials
IRB: Ethics and Human Research 2009 May-June; 31(3): 1-10
Document 209
Maloney, Dennis M.
**Researcher claims that knowledge of study phases constitutes informed consent**
Human Research Report 2009 April; 24(4): 6
Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 210
Woodcock, Thomas Edward
**Surgical research in the UK.**
Annals of the Royal College of Surgeons of England 2009 April; 91(3): 188-191
Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 211
Festinger, David S.; Marlowe, Douglas B.; Croft, Jason R.; Dugosh, Karen L.; Arabia, Patricia L.; Benasutti, Kathleen M.
**Monetary incentives improve recall of research consent information: it pays to remember.**
Experimental and Clinical Psychopharmacology 2009 April; 17(2): 99-104
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Document 212
Luce, John M.
**Informed consent for clinical research involving patients with chest disease in the United States.**
Chest 2009 April; 135(4): 1061-1068
Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 213
Angeles-Llerenas, Angélica R; Wirtz, Veronika; Lara-Alvarez, César Francisco
**The role and responsibilities of witnesses in the informed consent process.**
Developing World Bioethics 2009 April; 9(1): 18-25
*Abstract:*
Various mechanisms to ensure the protection of subjects in human research have been suggested, including the presence of witnesses during the informed consent process. For our commentary on the use of witnesses and their potential role and responsibility during the consent process, we start by addressing current guidelines for human subjects research in four Latin American countries. By using examples from public health research, we highlight some of the practical difficulties of using witnessed consent, from becoming a meaningless ritual at one end of the spectrum to the research subject feeling intimidated or coerced to participate at the other. Apart from these practical difficulties, it is unclear what responsibility the witness could and should have. We argue that there are important ethical questions about the role of witnesses that have not been adequately addressed in national and international regulations. This work addresses these gaps and argues that more debate is required to define the role and responsibilities of witnesses in the consent process, their training requirements and whether a universal legal requirement for witnessed consent, regardless of the type of research, is desirable.
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**Document 214**

Stein, Rob

*Part of study testing trauma treatments is shut down*

Washington Post 2009 March 27; p. A5

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

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**Document 215**

Ruyter, Knut W.

*When is a consent voluntary? = Når er et samtykke frivillig?*

[Tidsskrift for den Norske lægeforening: tidsskrift for praktisk medicin, ny række 2009 March 26; 129(7): 617](#)

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**Document 216**

Maloney, Dennis M.

*Parental consent remains the key issue*

[Human Research Report 2009 March; 24(3): 8](#)

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**Document 217**

Adiogo, Dieudonne Desire

*La notion de consentement éclairé: mythe ou réalité pour les pays africains. = The notion of informed consent: a myth or reality for African countries*


**Abstract:** The question of informed consent in Africa is an issue of great debate between the defenders of the respect of personal independence and the defenders of community organization. These two theses need to be complementary in order to reconcile: the respect of personal independence participating in research and the preservation of all diversity which are one of the guarantors of progress. Due to the weak capacity of groups to be determined and due to the weak interest of the different research players, it is important that a step towards the preservation of the rights of subjects participating in research and communities be implemented. For this, it is important to give a sense of responsibility to both sponsors and researchers and the ethics committees that regulate this process.

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**Document 218**

Perrey, Christophe; Ymba, Awa

*De l'information à la décision: les motifs du consentement à un essai vaccinal contre l'hépatite B en Côte d'Ivoire. = From information to the decision: the motives of consent to a vaccine trial for hepatitis B in the Ivory Coast*


**Abstract:** Consent represents a key element in any biomedical research on humans. Ideally conceived as free from any constraints, informed by well-understood information and attested to by signature, its authorization in the context of clinical trials conducted in Southern hemisphere countries raises a certain number of difficulties. For this presentation, we studied the motivations of a group of Abidjan women (n=127) to participate or not, with their newborn, in a vaccine protocol trial against Hepatitis B called HEPACI. Consent seemed to stem from various decision-making factors. Firstly, it demonstrated a pragmatic strategy aimed at improving the care of the mother and
child regarding healthcare institutions. This was followed by other factors, but according to levels of importance and variable intrications. Trust in the healthcare staff or in the clinical trial managers, the point of view of the spouse, the comprehension of information, the fears regarding the trial (fed or not by rumor phenomena) and the socio-political context also influenced the agreement of the participants.

**Document 219**

Derme, Assétou Ismaëla; Sirima, Sodiomon Bienvenu

*Le consentement individuel, libre et éclairé dans le cadre des essais de vaccin en milieu rural Africain.* = *Free and informed consent in context of vaccine trials in rural Africa*


**Abstract:** In biomedical research, the necessity to obtain free and informed consent of any participants taking part in a medical trial, recognized in the 1980s, has now become a universal principle. However, depending on the context, this principle comes up against many obstacles which can even question the objectivity intended by obtaining consent. In fact, in African societies, perception schemes and social organization reproduce the social hierarchies corresponding to the different decision-making spheres. In these societies, the opinion of elders, family and the whole community takes precedent over the individual. Consent brings up the issue of conciliation between general opinion and that of the individual, cultural and universal values, and the individual and the community. Free and informed consent is still a process in progress which needs to take into account the socio-cultural factors of the community. It is an essential issue which needs to resolved within the African context.

**Document 220**

Bulger, Eileen M.; Schmidt, Terri A.; Cook, Andrea J.; Brasel, Karen J.; Griffiths, Denise E.; Kudenchuk, Peter J.; Davis, Daniel; Bardarson, Berit; Idris, Ahamed H.; Aufderheide, Tom P.

*The random dialing survey as a tool for community consultation for research involving the emergency medicine exception from informed consent.*


**Document 221**

Buccini, Laura D.; Caputi, Peter; Iverson, Don; Jones, Caroline

*Toward a construct definition of informed consent comprehension.*


**Abstract:** VARIATION IN HOW INFORMED CONSENT comprehension tests have been developed may be largely due to the absence of a standardized construct definition. Developing a construct definition would provide a standardized framework for determining how an instrument should be constructed, implemented, interpreted, and applied. Therefore, we utilized the Delphi consensus approach with an international expert panel (N = 19) to gather knowledge, opinions and eventually consensus for a construct definition. Expert consensus was achieved after three revision cycles. While acknowledging that there are limitations to this study, it nonetheless should be considered as a step toward standardization of a construct definition of informed consent comprehension.

**Document 222**

Henry, James; Palmer, Barton W.; Palinkas, Lawrence; Glorioso, Danielle Kukene; Caligiuri, Michael P.; Jeste, Dilip V.

*Reformed consent: adapting to new media and research participant preferences.*
Document 223
Ursin, Lars Oystein

**Personal autonomy and informed consent**

Medicine, Health Care, and Philosophy 2009 February; 12(1): 17-24

*Abstract*: Two ways of understanding the notion of autonomy are outlined and discussed in this article, in order to clarify how and if informed consent requirements in biotechnological research are to be justified by the promotion of personal autonomy: A proceduralist conception linking autonomy with authenticity, and a substantivist conception linking autonomy with control. The importance of distinguishing autonomy from liberty is emphasised, which opens for a possible conflict between respecting the freedom and the autonomy of research participants. It is argued that this has implications for how consent requirements based on different criteria of specificity and understanding should be viewed and justified.

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

Document 224
Wendler, David

**Must research participants understand randomization?**

American Journal of Bioethics 2009 February; 9(2): 3-8

*Abstract*: In standard medical care, physicians select treatments for patients based on clinical judgment, considering which treatment is best for the individual patient, given the patient's history and circumstances. In contrast, investigators conducting randomized clinical trials select treatments for participants based on a random selection process. Because this process represents a significant departure from the norms of standard medical care, it is widely assumed that potential research participants must understand randomization to give valid informed consent. This assumption, together with data that many research participants do not understand randomization, implies that randomized clinical trials often fail to obtain adequately informed consent. Before accepting this conclusion, and before initiating extensive efforts to improve research participants' understanding of randomization, we should assess the plausible, but rarely analyzed assumption that participants need to understand randomization to give valid informed consent for randomized clinical trials.

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

Document 225
Morreim, Haavi

**The dirty little truth: we want them to understand, but not really . . .**

American Journal of Bioethics 2009 February; 9(2): 9-11; reply by David Wendler, W1-W2

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

Document 226
Trachman, Howard

**To study, perchance to treat**
American Journal of Bioethics 2009 February; 9(2): 11-12; reply by David Wendler, W1- W2

* Document 227
Fox, Mark D.; Hellman, Chan M.; Jelley, Martina R.
**Equipoise trumps randomization**
American Journal of Bioethics 2009 February; 9(2): 13-14; reply by David Wendler, W1- W2

* Document 228
Brody, Howard; Childress, Andrew M.
**Understanding randomization: helpful strategies**

* Document 229
Reynolds, Don; Fleming, David A.
**Randomization and the transactional framework for informed consent**
American Journal of Bioethics 2009 February; 9(2): 16-17; reply by David Wendler, W1- W2

* Document 230
Howick, Jeremy
**If children understand drawing straws and flipping coins, research participants can understand randomization**
American Journal of Bioethics 2009 February; 9(2): 19-20; reply by David Wendler, W1- W2

* Document 231
Moyer, Anne; Floyd, Anna H.L.
**Equipoise may be in the eye of the beholder**
American Journal of Bioethics 2009 February; 9(2): 21-22; reply by David Wendler, W1- W2
Document 232
Dyer, Clare
**Researchers denied access to records without consent** [news]
*BMJ: British Medical Journal* 2009 January 31; 338(7689): 256

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Document 233
Hewitt, Robert; Watson, Peter H.; Dhir, Rajiv; Aamodt, Roger; Thomas, Gerry; Mercola, Dan; Grizzle, William E.; Morente, Manuel M.
**Timing of consent for the research use of surgically removed tissue: is postoperative consenting acceptable?**
*Cancer* 2009 January 1; 115(1): 4-9

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Ciaranello, Andrea L.; Walensky, Rochelle P.; Sax, Paul E.; Chang, Yuchiao; Freedberg, Kenneth A.; Weissman, Joel S.
**Access to medications and medical care after participation in HIV clinical trials: a systematic review of trial protocols and informed consent documents.**
*HIV Clinical Trials* 2009 January-February; 10(1): 13-24

Document 235
Felt, Ulrike; Bister, Milena D.; Strassnig, Michael; Wagner, Ursula
**Refusing the information paradigm: informed consent, medical research, and patient participation.**
*Health* 2009 January; 13(1): 87-106

Document 236
Brink, Monique; Deunk, Jaap; van Tongeren, Paul; Blickman, Johan G.
**Observational research in trauma radiology: should patients be informed?**
*Journal of the American College of Radiology* 2009 January; 6(1): 51-57

Document 237
Zanchetti, Alberto; Mancia, Giuseppe
**The dilemma of placebo controlled studies: scientific evidence, guidelines, ethics and regulatory
recommendations.

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* Document 238
Jansen, Tim C; Kompanje, Erwin J O; Bakker, Jan
Deferred proxy consent in emergency critical care research: ethically valid and practically feasible.
Critical Care Medicine 2009 January; 37(1 Suppl): S65-68

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Document 239
Nelson, Maria J.; Warden, Craig; Griffiths, Denise; Zive, Dana; Schmidt, Terri; Hedges, Jerris R.; Daya, Mohamud; Newgard, Craig D.
A geospatial analysis of persons opting out of an exception from informed consent out-of-hospital clinical trial.
Resuscitation 2009 January; 80(1): 89-95

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* Document 240
Boccia, Maria L.; Campbell, Frances A.; Goldman, Barbara D.; Skinner, Martie
Differential recall of consent information and parental decisions about enrolling children in research studies.

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* Document 241
Anderson, James R.; Schonfeld, Toby
Research, not quality assurance.
Anesthesia and Analgesia 2009 January; 108(1): 376; author reply 376-377

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* Document 242
Wasan, Ajay D.; Taubenberger, Simone P.; Robinson, Walter M.
Reasons for participation in pain research: can they indicate a lack of informed consent?

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* Document 243
Kimmelman, Jonathan
Battling a thousand points of might.
**Document 244**
Appelbaum, Paul S.; Lidz, Charles W.; Klitzman, Robert

**Voluntariness of consent to research: a conceptual model.**

**Abstract:** A good deal of policy and practice in human subjects research aims to ensure that when subjects consent to research, they do so voluntarily. To date, however, voluntariness and its impairment have been poorly conceptualized and studied. The legal doctrine of informed consent could provide a useful model.

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**Document 245**
Mangset, Margrete; Berge, E.; Frde, R.; Nessa, J.; Wyller, T.B.

**“Two per cent isn’t a lot, but when it comes to death it seems quite a lot anyway”: patients’ perception of risk and willingness to accept risks associated with thrombolytic drug treatment for acute stroke.**
Journal of Medical Ethics 2009 January; 35(1): 42-46

**Abstract:** BACKGROUND: Thrombolytic drugs to treat an acute ischaemic stroke reduce the risk of death or major disability. The treatment is, however, also associated with an increased risk of potentially fatal intracranial bleeding. This confronts the patient with the dilemma of whether or not to take a risk of a serious side effect in order to increase the likelihood of a favourable outcome. OBJECTIVE: To explore acute stroke patients' perception of risk and willingness to accept risks associated with thrombolytic drug treatment. DESIGN: Eleven patients who had been informed about thrombolytic drug treatment and had been through the process of deciding whether or not to participate in a thrombolytic drug trial went through repeated qualitative, semistructured interviews. RESULTS: Many patients showed a limited perception of the risks connected with thrombolytic drug treatment. Some perceived the risk as not relevant to them and were reluctant to accept that treatment could cause harm. Others seemed to be aware that treatment would mean exposure to risk. The patients' willingness to take a risk also varied substantially. Several statements revealed ambiguity and confusion about being involved in a decision about treatment. The patients’ reasoning about risk was put into the context of their health-related experiences and life histories. Several patients wanted the doctor to be responsible for the decisions. CONCLUSION: Acute stroke patients’ difficulties in perceiving and processing information about risk may reduce their ability to be involved in clinical decisions where risks are involved.

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**Document 246**
Corrigan, Oonagh; McMillan, John; Liddell, Kathleen; Richards, Martin; and Weijer, Charles, eds.

**THE LIMITS OF CONSENT: A SOCIO-ETHICAL APPROACH TO HUMAN SUBJECT RESEARCH IN MEDICINE**

Call number: K3611.I5 L558 2009

**Document 247**
Sampson, Heather; Weijer, Charles; Pullman, Daryl

**Research governance lessons from the National Placebo Initiative**

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Document 248
Kovács, Maria Julia
Pesquisa com pacientes gravemente enfermos: autonomia, riscos, benefícios e dignidade
Revista Bioética 2009; 17(2): 309-318
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Document 249
Patra, Prasanna Kumar; Sleeboom-Faulkner, Margaret
Informed consent in genetic research and biobanking in India: some common impediments
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Ness, David E.; Kiesling, Scott F.; Lidz, Charles W.
Why does informed consent fail? A discourse analytic approach
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Tolich, Martin; Hapuku, Jonas
Number-8-wire ethics: a New Zealand ethics committee's response to lengthy international clinical trial information sheets.
New Zealand Medical Journal 2009; 122(1293): 3567
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Document 252
Miller, Victoria A.; Reynolds, William W.; Nelson, Robert M.
Children in research: linking assent and parental permission
Call number: QH332 .P46 2009

Document 253
Ellenberg, Susan S.
The use of placebo-control groups in clinical trials
Call number: QH332 .P46 2009
Document 254
Baren, Jill M.
Unique aspects of informed consent in emergency research
Call number: QH332 .P46 2009

Document 255
Abadie, Roberto
A guinea pig’s wage: risk and commoditization in pharmaceutical research in America
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Document 256
Beauchamp, Tom L
The exploitation of the economically disadvantaged in pharmaceutical research
Call number: R724 .E821115 2009

Document 257
Ponder, Margaret; Statham, Helen; Hallowell, Nina; Richards, Martin
Is consent sufficient? A case study of qualitative research with men with intellectual disabilities
Call number: K3611 .I5 L558 2009

Document 258
Bielby, Philip
Towards supported decision-making in biomedical research with cognitively vulnerable adults
Call number: K3611 .I5 L558 2009

Document 259
Hughes, Julian C.; Haines, Erica; Summerville, Lorraine; Davies, Karen; Collerton, Joanna; Kirkwood, Thomas B.L.
Consenting older adults: research as a virtuous relationship
In: Corrigan, Oonagh; McMillan, John; Liddell, Kathleen; Richards, Martin; Weijer, Charles, eds. The Limits of Consent: A Socio-Ethical Approach to Human Subject Research in Medicine. Oxford; New York: Oxford University Press, 2009: 133-149
Call number: K3611 .I5 L558 2009

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Dawson, Angus
The normative status of the requirement to gain an informed consent in clinical trials: comprehension, obligations, and empirical evidence
In: Corrigan, Oonagh; McMillan, John; Liddell, Kathleen; Richards, Martin; Weijer, Charles, eds. The Limits of Consent: A Socio-Ethical Approach to Human Subject Research in Medicine. Oxford; New York: Oxford University Press, 2009: 99-113
Call number: K3611 .I5 L558 2009

Liddell, Kathleen
Beyond a rebarbative commitment to consent
Call number: K3611 .I5 L558 2009

Snowdon, Claire; Elbourne, Diana; Garcia, Jo
The decision to decline to enrol in a clinical trial: a blind spot in the literature on decision-making for research participation
In: Corrigan, Oonagh; McMillan, John; Liddell, Kathleen; Richards, Martin; Weijer, Charles, eds. The Limits of Consent: A Socio-Ethical Approach to Human Subject Research in Medicine. Oxford; New York: Oxford University Press, 2009: 57-77
Call number: K3611 .I5 L558 2009

Miller, Paul B.; Johnston, Josephine
Consent and private liability in clinical research
Call number: K3611 .I5 L558 2009

Miller, Paul B.; Weijer, Charles
Trust and exploitation in clinical research
Call number: K3611 .I5 L558 2009

Holm, Søren; Madsen, Søren
Informed consent in medical research—a procedure stretched beyond breaking point?
Call number: K3611 .I5 L558 2009
Document 266
Chenaud, C.; Gigon, F.; Ricou, B; Merlani, P.
Le consentement éclairé pour la recherche aux soins intensifs en Suisse: quelle solution? [Informed consent for intensive care research in Switzerland: any solution?]
Revue Médicale Suisse 2008 December 10; 4(183): 2691-2695
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Document 267
Lemaire, François
Informed consent for and regulation of critical care research.
Georgetown users check Georgetown Journal Finder for access to full text

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Maloney, Dennis M.
Court emphasizes that informed consent is not enough in research
Human Research Report 2008 December; 23(12): 8
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Maloney, Dennis M.
When informed consent forms must be revised
Human Research Report 2008 December; 23(12): 4
Georgetown users check Georgetown Journal Finder for access to full text

Document 270
Waring, Duff R.
The antidepressant debate and the balanced placebo trial design: an ethical analysis
Georgetown users check Georgetown Journal Finder for access to full text

Document 271
Cooper, Matthew
Sharing data and results with study participants: report on a survey of cultural anthropologists
Abstract: A first-ever survey of cultural anthropologists was conducted concerning the sharing of data, interpretations, and results with study participants. Briefly summarized, the study showed that almost all of the survey respondents had shared data or results with participants and almost all found this to be a positive experience. They had carried out research in many countries, some over long periods of time, and many had completed several field projects. Most believe that researchers, either alone or in consultation with participants and their groups, should decide whether, when, and what to share. Anthropologists find that sharing produces many benefits, for themselves as individuals and as researchers, for individual participants, and for the communities, groups, or institutions to which
the latter belong. The perceived harms that might result from sharing have to do particularly with potential threats to privacy, confidentiality or anonymity, as well as the possibilities of social conflict and oppression. Thus, researchers have serious concerns about the sharing of certain kinds of data that might lead to such consequences. While many or most respondents think that sharing is the ethically proper course of action, they are very aware of the complexities of particular situations and the need for nuanced decision making. Most think that the researcher should play a major role in deciding whether sharing should take place and what should be shared. Hence, for these cultural anthropologists, in the end, sharing requires trying to balance the good of sharing with the good of doing no harm to those with whom they have done research.

**Document 272**

**Bento, Silvana Ferreira; Hardy, Ellen; Osis, Maria José Duarte**

**Process for obtaining informed consent: women's opinions.**

Developing World Bioethics 2008 December; 8(3): 197-206

**Abstract:** In Brazil, every study involving human beings is required to produce an informed consent form that must be signed by study participants: this is stated in Resolution 196/96. (1) Consent must be obtained through a specific structured process. OBJECTIVE: To present the opinions of women regarding how the process of obtaining informed consent should be conducted when women are invited to participate in studies on contraceptive methods.

**SUBJECTS AND METHODS:** Eight focus groups were conducted, involving a total of 51 women living in the metropolitan region of Campinas. The women involved in the study were either participating in a clinical trial in the area of women's health or had participated in such a trial in the previous 12 months. A thematic guide was used to conduct the focus group discussions; the discussions were recorded, transcribed and a thematic analysis performed.

**RESULTS:** In general, the person who invites a woman to participate in a study should be a member of the research team but not the principal investigator. Information relating to the study should be given orally and in writing, both individually and in the group setting. Study volunteers should be informed about, among other things, the risks, possible side effects and discomforts, including long-term effects. The use of audiovisual aids to provide information was suggested. CONCLUSION: The process for obtaining informed consent was seen as a means of establishing a relationship between the volunteers and the investigator/research team. The information that the study participants expected to be given coincides with the requirements established under Resolution 196/96. The use of audiovisual aids would improve understanding of the information provided.

**Document 273**

**Willison, Donald J.; Swinton, Marilyn; Schwartz, Lisa; Abelson, Julia; Charles, Cathy; Northrup, David; Cheng, Ji; Thabane, Lehana**

**Alternatives to project-specific consent for access to personal information for health research: insights from a public dialogue.**

BMC Medical Ethics 2008 November 18; 9: 18

**Abstract:** BACKGROUND: The role of consent for research use of health information is contentious. Most discussion has focused on when project-specific consent may be waived but, recently, a broader range of consent options has been entertained, including broad opt-in for multiple studies with restrictions and notification with opt-out. We sought to elicit public values in this matter and to work toward an agreement about a common approach to consent for use of personal information for health research through deliberative public dialogues. METHODS: We conducted seven day-long public dialogues, involving 98 participants across Canada. Immediately before and after each dialogue, participants completed a fixed-response questionnaire rating individuals' support for 3 approaches to consent in the abstract and their consent choices for 5 health research scenarios using personal information. They also rated how confident different safeguards made them feel that their information was being used responsibly. RESULTS: Broad opt-in consent for use of personal information garnered the greatest support in the abstract. When presented with specific research scenarios, no one approach to consent predominated. When profit was introduced into the scenarios, consent choices shifted toward greater control over use. Despite lively and constructive dialogues, and considerable shifting in opinion at the individual level, at the end of the day, there was no substantive aggregate movement in opinion. Personal controls were among the most commonly cited approaches to improving people's confidence in the responsible use of their information for research. CONCLUSION: Because no one approach to consent satisfied even a simple majority of dialogue participants and the importance placed on personal controls, a
A mechanism should be developed for documenting consent choice for different types of research, including ways for individuals to check who has accessed their medical record for purposes other than clinical care. This could be done, for example, through a web-based patient portal to their electronic health record. Researchers and policy makers should continue to engage the public to promote greater public understanding of the research process and to look for feasible alternatives to existing approaches to project-specific consent for observational research.

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Cahana, Alex; Hurst, Samia A.
Voluntary informed consent in research and clinical care: an update.
Pain Practice 2008 November-December; 8(6): 446-451

* Document 275
Sand, Kari; Loge, Jon Håvard; Berger, Ola; Grønberg, Bjørn Henning; Kaasa, Stein
Lung cancer patients' perceptions of informed consent documents.
Patient Education and Counseling 2008 November; 73(2): 313-317

* Document 276
Bergenmar, Mia; Molin, Clementine; Wilking, Nils; Brandberg, Yvonne
Knowledge and understanding among cancer patients consenting to participate in clinical trials.
European Journal of Cancer 2008 November; 44(17): 2627-2633

* Document 277
Suwanpakdee, Detchvijitr; Chamnanvanakij, Sangkae; Panichkul, Suthee
Perception of medical personnel on informed consent for research participation in Phramongkutklao Hospital and Phramongkutklao College of Medicine.
Journal of the Medical Association of Thailand = Chotmaihet thangphaet 2008 November; 91(11): 1754-1759

* Document 278
Resnick, David B.; Peddada, Shyamal; Altilio, Jason; Wang, Nancy; Menikoff, Jerry
Oncology consent forms: failure to disclose off-site treatment availability
Document 279
Instone, Susan L.; Mueller, Mary-Rose; Gilbert, Tari L.
**Therapeutic discourse among nurses and physicians in controlled clinical trials**
Nursing Ethics 2008 November; 15(6): 803-812

**Abstract:** An ethnographic field study about the informed consent process in investigational drug trials for seriously ill persons with hepatitis C suggests that nurses and physicians referred to these trials as giving treatment, even though they involved placebos. Interview data and informed consent documents contained frequent references to the term 'treatment trial' or 'treatment'. Although these findings were unexpected and not the original focus of our study, we consider them in the light of an extensive literature on the 'therapeutic misconception' that has been described among physicians and patients with AIDS and other serious illnesses. We also suggest that certain organizational and professional characteristics of nursing and medicine reinforce this tendency to refer to the trials as treatment. Implications for further research are provided.

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Document 280
Fernandez, Conrad
**Public expectations for return of results – time to stop being paternalistic?**

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

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

Document 281
Fisher, Rebecca
**A closer look: are we subjects or are we donors?**

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

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

Document 282
Maloney, Dennis M.
**Court objects to role of researchers and says parental consent not enough**
Human Research Report 2008 October; 23(10): 8

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

Document 283
Neff, Margaret J.
**Informed consent: what is it? who can give it? how do we improve it?**
Respiratory Care 2008 October; 53(10): 1337-1341

Georgetown users check [Georgetown Journal Finder](#) for access to full text
* Parker, Lisa S.; Kienholz, Michelle L.

**Disclosure issues in neuroscience research**
Accountability in Research 2008 October-December; 15(4): 226-241

**Abstract:** Issues of disclosure arise in neuroscientific research during the informed consent process, whenever incidental findings are identified, and when study results are generated. The possibility of disclosure of incidental findings and/or research results may raise informational expectations on the part of subjects and may alter a study's risk:benefit ratio. We recommend that the informed consent process address this potential consequence of research participation, and specify the conditions under which particular types of information will be offered, the conditions under which information may not be disclosed, and any provisions for helping subjects make sense of the information to be disclosed.

Georgetown users check [Georgetown Journal Finder](https://library.georgetown.edu/journalfinder) for access to full text

* Carter, Adrian; Hall, Wayne

**The issue of consent in research that administers drugs of addiction to addicted persons**
Accountability in Research 2008 October-December; 15(4): 209-225

**Abstract:** In addiction, impaired control over drug use raises questions about the capacity of addicted persons to consent to participate in research studies in which they are given their drug of addiction. We review the case for doing such research, and the arguments that addiction does, and does not, prevent addicted persons from consenting to such research. We argue for a more nuanced view that acknowledges that while in some situations addiction impairs decision-making capacity, it does not eliminate such capacity. We conclude with some suggestions for recruiting addicted subjects and designing experiments in ways to obtain free and informed consent.

Georgetown users check [Georgetown Journal Finder](https://library.georgetown.edu/journalfinder) for access to full text

* Stocking, Carol B.; Hougham, Gavin W.; Danner, Deborah D.; Patterson, Marion B.; Whitehouse, Peter J.; Sachs, Greg A.

**Variable judgments of decisional capacity in cognitively impaired research subjects.**
Journal of the American Geriatrics Society 2008 October; 56(10): 1893-1897

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* Bogardus, Tomas

**Should we be alarmed by medical research? [review of A Review Essay of What the Doctor Didn't Say: The Hidden Truth About Medical Research, by Jerry Menikoff and Edward P. Richards]**
Journal of Medicine and Philosophy 2008 October; 33(5): 524-532

Georgetown users check [Georgetown Journal Finder](https://library.georgetown.edu/journalfinder) for access to full text

* Mangset, M.; Førde, R.; Nessa, J.; Berge, E.; Bruun Wyller, T.

**"I don't like that, it's tricking people too much...": acute informed consent to participation in a trial of thrombolysis for stroke**
Abstract: BACKGROUND: Informed consent is regarded as a contract between autonomous and equal parties and requires the elements of information disclosure, understanding, voluntariness and consent. The validity of informed consent for critically ill patients has been questioned. Little is known about how these patients experience the process of consent. OBJECTIVE: The aim of this study was to explore critically ill patients' experience with the principle of informed consent in a clinical trial and their ability to give valid informed consent. DESIGN: 11 stroke patients who had been informed about thrombolytic treatment and had been through the process of deciding whether or not to participate in a thrombolysis trial went through repeated qualitative semistructured interviews. RESULTS: None of the patients had any clear understanding of the purpose of the trial. Neither did they understand the principles of randomisation and voluntariness. Reasons for giving or not giving consent were trust, conceptions of benefits and risks and altruism. Several patients found it immoral to involve patients in the consent procedure and argued that this was the doctors' responsibility. Others argued that it is a duty to question patients and perceived it as a sign of being treated with respect and dignity. A majority of the patients found the consent process vague and ambiguous. CONCLUSIONS: The results indicate that the principle of informed consent from critically ill patients cannot be seen as a contract between equal and autonomous parties. Further studies are needed to explore critically ill patients' experiences with the process of informed consent.

http://www.jmedethics.com (link may be outdated)
Caon, Martin
Radiation information and informed consent for clinical trials.
Journal of Radiological Protection 2008 September; 28(3): 415-422

Bravo, Gina; Duguet, Anne-Marie; Dubois, Marie-France; Delpierre, Cyrille; Vellas, Bruno
Substitute consent for research involving the elderly: a comparison between Quebec and France.
Journal of Cross-Cultural Gerontology 2008 September; 23(3): 239-253

Henderson, Alex; Bushby, K.; Shakespeare, T.; Woods, S.
Consent, choice and children in genetic research [abstract; poster 1.54]
Journal of Medical Genetics 2008 September; 45(Supplement 1): S58

van Deventer, M. Oskar
Meta-placebo: do doctors have to lie about giving a fake treatment?
Medical Hypotheses 2008 September; 71(3): 335-339

Kass, Nancy; Taylor, Holly; Fogarty, Linda; Sugarman, Jeremy; Goodman, Steven N.; Goodwin-Lander, Annallys; Carducci, Michael; Huwitz, Herbert
Purpose and benefits of early phase cancer trials: what do oncologists say? What do patients hear?
Abstract: Cancer patients overestimate benefits of early phase trials but studies have not reported what oncologists say to patients about trials. We audiotaped oncologists talking to cancer patients about Phase I or II trials and interviewed patients about the purpose and expected outcomes of trials presented to them. Oncologists gave mixed messages, saying Phase I trials measure safety and dosing, yet referring to trials as treatment with uncertain therapeutic effects. Seventeen percent of Phase I respondents said the trial's purpose related to safety/dosing (p = 0.017); 17% of Phase I respondents said the purpose was "to cure my cancer." Patients may find it important to believe trials offer significant benefit. Oncologists, while respecting patients' hopes, should be precise in their language, particularly regarding Phase I trials, distinguishing early stages of research from treatment.

Anderson, Emily E.; Ilis, Ana S.
Assessing and improving research participants' understanding of risk: potential lessons from the literature on
physician-patient risk communication
Abstract: Evidence that lay people frequently misinterpret risk raises concerns for the ethical conduct of human research, which requires adequate disclosure, understanding, and appreciation of risk information. Review of the risk communication research literature suggests new directions for empirical research on human research ethics: Investigation is needed on how to best assess and improve potential and enrolled subjects' understanding of risk information. Preferences regarding the presentation of risk information and the effects of alternative presentation formats and decision aids on knowledge, trust, satisfaction, risk/benefit analysis, and perceptions of respectful treatment should be studied. Research is also needed on the effects of payment for research participation, the order in which study information is presented, and having one's own physician present risk information.

Schwartz, Victor; Appelbaum, Paul S.
Improving the quality of informed consent to research

Nelson, Erin; Mykitiuk, Roxanne; Nisker, Jeff; Christilaw, Jan; Corey, Julie Anne; Heaman, Maureen; Lippman, Abby; Rodgers, Sandra; Shapiro, Jodi; Sherwin, Susan
Informed consent to donate embryos for research purposes.
Journal of Obstetrics and Gynaecology Canada = Journal d'obstétrique et gynécologie du Canada 2008 September; 30(9): 824-836

Zaleski-Durand; I.S.; Alberti, C.; Duval, X.; Gottot, S.; Ravaud, Ph.; Gainotti, S.; Genod-Vincent, C.; Moreau, D.; Amiel, D.
Informed consent in clinical research in France: assessment and factors associated with therapeutic misconception
Abstract: Background: Informed consent in clinical research is mandated throughout the world. Both patient subjects and investigators are required to understand and accept the distinction between research and treatment. Aim: To document the extent and to identify factors associated with therapeutic misconception in a population of patient subjects or parent proxies recruited from a variety of multicentre trials (parent studies). Patients and methods: The study comprised two phases: the development of a questionnaire to assess the quality of informed consent and a survey of patient subjects based on this questionnaire. Results: A total of 303 patient subjects or parent proxies were contacted and 279 questionnaires were analysed. The median age was 49.5 years, sex ratio was 1 and 61% of respondents were professionally active. Overall memorisation of the oral or written communication of informed consent was good (69–97%), and satisfaction with the process was around 70%. Therapeutic misconception was present in 70% of respondents, who expected to receive better care and ignored the consequence of randomisation and treatment comparisons. This was positively associated with the acuteness and severity of the disease. Conclusion: The authors suggest that the risk of therapeutic misconception be specifically addressed in consent forms as an educational tool for both patients and institut...
**Document 301**

Chwang, Eric

**Against the inalienable right to withdraw from research**

Bioethics 2008 September; 22(7): 370-378

**Abstract:** In this paper I argue, against the current consensus, that the right to withdraw from research is sometimes alienable. In other words, research subjects are sometimes morally permitted to waive their right to withdraw. The argument proceeds in three major steps. In the first step, I argue that rights typically should be presumed alienable, both because that is not illegitimately coercive and because the general paternalistic motivation for keeping them inalienable is untenable. In the second step of the argument, I consider three special characteristics of the right to withdraw, first that its waiver might be exploitative, second that research involves intimate bodily access, and third that it is irreversible. I argue that none of these characteristics justify an inalienable right to withdraw. In the third step, I examine four considerations often taken to justify various other allegedly inalienable rights: concerns about treating yourself merely as a means as might be the case in suicide, concerns about revoking all your future freedoms in slavery contracts, the resolution of coordination problems, and public interest. I argue that the motivations involved in these four types of situations do not apply to the right to withdraw from research.

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**Document 302**

Adshead, Gwen

**Studying the mind: ethical issues and guidance in mental health research**

Clinical Ethics 2008 September; 3(3): 141-144

**Abstract:** Freely given informed consent to participation is the ethical cornerstone of research in health care. However, in mental health settings, there are many patients who lack the capacity to give such consent to participate in research. There is an abundance of guidance now available on how researchers might think about this issue and the Royal College of Psychiatrists has also recently reviewed its guidance to members about the ethics of research. In this piece, I will discuss some of the issues that were raised during the revision process, and add some reflections of my own.

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**Document 303**

Heslop, P.; Jepson, M.

**Negotiating consent to include people with intellectual disabilities in research [abstract]**

Journal of Intellectual Disability Research 2008 August; 52(8-9): 698

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**Document 304**

Healy, D.

**Ethics and science of placebo-controlled trials.**


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Document 305
Capps, B.
Balancing ethical research and placebo administration.
Georgetown users check Georgetown Journal Finder for access to full text

Document 306
Maloney, Dennis M.
OHRP investigation: informed consent documents missing many key elements
Human Research Report 2008 August; 23(8): 7
Georgetown users check Georgetown Journal Finder for access to full text

Document 307
Fortun, P.; West, J.; Chalkley, L.; Shonde, A.; Hawkey, C.
Recall of informed consent information by healthy volunteers in clinical trials
QJM : monthly journal of the Association of Physicians 2008 August; 101(8): 625-629
Georgetown users check Georgetown Journal Finder for access to full text

Document 308
La Caze, Adam
A problem for achieving informed choice
Theoretical Medicine and Bioethics 2008 August; 29(4): 255-265
Abstract: Most agree that, if all else is equal, patients should be provided with enough information about proposed medical therapies to allow them to make an informed decision about what, if anything, they wish to receive. This is the principle of informed choice; it is closely related to the notion of informed consent. Contemporary clinical trials are analysed according to classical statistics. This paper puts forward the argument that classical statistics does not provide the right sort of information for informing choice. The notion of probability used by classical statistics is complex and difficult to communicate. Therapeutic decisions are best informed by statistical approaches that assign probabilities to hypotheses about the benefits and harms of therapies. Bayesian approaches to statistical inference provide such probabilities.
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Document 309
Frimpong-Mansoh, Augustine
Culture and voluntary informed consent in African health care systems
Developing World Bioethics 2008 August; 8(2): 104-114
Abstract: This paper discusses how to apply a collective decision model of the principle of voluntary informed consent in African communitarian culture, in a culturally sensitive way, in order to protect research candidates from potential exploitations and abuses. Dismissing cultural and ethical skepticism surrounding the global application of the principle of voluntary informed consent, the paper ultimately concludes that international collaboration on diagnostic and therapeutic medical research in Africa, especially HIV vaccine trials, is a moral imperative.
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Giving consent in dementia research
Warner, James; Nomani, Erum
Georgetown users check Georgetown Journal Finder for access to full text
http://www.thelancet.com/journals/lancet (link may be outdated)

Court victory for subject of experimental therapy [news brief]
Nature 2008 July 17; 454(7202): 265
Georgetown users check Georgetown Journal Finder for access to full text
http://www.nature.com (link may be outdated)

Giving addicts their drug of choice: the problem of consent.
Walker, Tom
Bioethics 2008 July; 22(6): 314-320
Abstract: Researchers working on drug addiction may, for a variety of reasons, want to carry out research which involves giving addicts their drug of choice. In carrying out this research consent needs to be obtained from those addicts recruited to participate in it. Concerns have been raised about whether or not such addicts are able to give this consent. Despite their differences, however, both sides in this debate appear to be agreed that the way to resolve this issue is to determine whether or not addicts have irresistible cravings for drugs - if they do, then they cannot consent to this type of research; if they do not, then they can. This I will argue is a mistake. Determining whether or not addicts can say 'No' to offers of drugs will not help us to make much progress here. Instead we need to look at the various ways in which different types of research may undermine an addict's competence to give consent. What we will find is that the details of the research make a big difference here and that, as such, we need to steer a course between, on the one hand, painting all addicts as being unable to consent to research which involves providing them with drugs, and, on the other, maintaining that there are no problems in obtaining consent from addicts to take part in such research.
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In court: researchers have duty to protect extending beyond informed consent
Maloney, Dennis M.
Human Research Report 2008 July; 23(7): 8
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Determination of required content of the informed consent process for human participants in biomedical research conducted in the U.S. a practical tool to assist clinical investigators.
Chanaud, Cheryl M.
Contemporary Clinical Trials 2008 July; 29(4): 501-506
Document 315
Misra, Sahana; Socherman, Robert; Hauser, Peter; Ganzini, Linda
Appreciation of research information in patients with bipolar disorder.
Bipolar Disorders 2008 July; 10(5): 635-646

Document 316
Glass, Kathleen Cranley
Ethical obligations and the use of placebo controls.

Document 317
Weinfurt, Kevin P.; Seils, Damon M.; Tzeng, Janice P.; Compton, Kate L.; Sulmasy, Daniel P.; Astrow, Alan B.; Solarino, Nicholas A.; Schulman, Kevin A.; Meropol, Neal J.
Expectations of benefit in early-phase clinical trials: implications for assessing the adequacy of informed consent
Medical Decision Making 2008 July-August; 28(4): 575-581

Document 318
Sugarman, Jeremy; Bingham, Clifton O., 3rd.
Ethical issues in rheumatology clinical trials.

Document 319
Hadskis, Michael; Kenny, Nuala; Downie, Jocelyn; Schmidt, Matthias; D'Arcy, Ryan
The therapeutic misconception: a threat to valid parental consent for pediatric neuroimaging research
Accountability in Research 2008 July-September; 15(3): 133-151

Abstract: Neuroimaging research has brought major advances to child health and wellbeing. However, because of the vulnerabilities associated with neurological and developmental conditions, the parental need for hope, and the expectation of parents that new medical advances can benefit their child, pediatric neuroimaging research presents significant challenges to the general problem of consent in the context of research involving children. A particular challenge in this domain is created by the presence of therapeutic misconception on the part of parents and other key research stakeholders. This article reviews the concept of therapeutic misconception and its role in pediatric neuroimaging research. It argues that this misconception can compromise consent given by parents for the involvement of their children in research as healthy controls or as persons with neurological and developmental conditions. The article further contends that therapeutic misconception can undermine the research ethics review process for proposed and ongoing neuroimaging studies. Against this backdrop, the article concludes with recommendations for mitigating the effects of therapeutic misconception in pediatric neuroimaging research.
**Document 320**

Swartling, U.; Helgesson, G.

**Self-assessed understanding as a tool for evaluating consent: reflections on a longitudinal study**

*Journal of Medical Ethics* 2008 July; 34(7): 557-562

**Abstract:** Based on extensive clinical questionnaire data, this paper explores the relation between research subjects' self-assessed understanding and actual knowledge of a large-scale predictive screening study, and its implications for the proper handling of information and consent routines in longitudinal studies. The initial data show that low self-assessed understanding among participants was correlated with limited knowledge, concern over participation and collected samples, less satisfaction with information, and feeling passive or negative towards the study. Among those reporting high understanding, a non-negligible number displayed a lack of knowledge regarding central aspects of the study. Regarding high assessed understanding, the multivariate analysis identified the main predictor variables to be knowledge, having a positive attitude towards participation and the study itself, being satisfied with information, having a stable psychosocial background and feeling calm regarding the handling of samples. These findings indicate that to evaluate participants' understanding through self-assessment may not be a reliable method. Self-assessed understanding may rather be a good indicator of general attitudes than a tool for analysing content. The data also show that actual understanding varies considerably among participants, suggesting that more effort needs to be put into adjusting the information to the needs of different subgroups. It is argued that when doing this, researchers in longitudinal studies must be careful not to exhaust participants with excessive information that they do not want and that may cause them to drop out. The ethical relevance of obtaining repeated consents in longitudinal research is discussed.

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**Document 321**

Rector, Thomas S.

**How should we communicate the likelihood of risks to inform decisions about consent?**


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**Document 322**

Salas, Halle Showalter; Aziz, Zuraya; Villareale, Nanci; Diekema, Douglas S.

**The research and family liaison: enhancing informed consent**


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**Document 323**

Jefferson, Angela L.; Lambe, Susan; Moser, David J.; Byerly, Laura K.; Ozonoff, Al; Karlawish, Jason H.

**Decisional capacity for research participation in individuals with mild cognitive impairment**

*Journal of the American Geriatrics Society* 2008 July; 56(7): 1236-1243

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**Document 324**

Oduro, Abraham R.; Aborigo, Raymond A.; Amugsi, Dickson; Anto, Francis; Anyorigiya, Thomas; Atuguba, Frank; Hodgson, Abraham; Koram, Kwadwo A.
Understanding and retention of the informed consent process among parents in rural northern Ghana

[7 August 2008]

Abstract: Background The individual informed consent model remains critical to the ethical conduct and regulation of research involving human beings. Parental informed consent process in a rural setting of northern Ghana was studied to describe comprehension and retention among parents as part of the evaluation of the existing informed consent process. Methods The study involved 270 female parents who gave consent for their children to participate in a prospective cohort study that evaluated immune correlates of protection against childhood malaria in northern Ghana. A semi-structured interview with questions based on the informed consent themes was administered. Parents were interviewed on their comprehension and retention of the process and also on ways to improve upon the existing process. Results The average parental age was 33.3 years (range 18-62), married women constituted a majority (91.9%), Christians (71.9%), farmers (62.2%) and those with no formal education (53.7%). Only 3% had ever taken part in a research and 54% had at least one relation ever participate in a research. About 90% of parents knew their children were involved in a research study that was not related to medical care, and 66% said the study procedures were thoroughly explained to them. Approximately, 70% recalled the study involved direct benefits compared with 20% for direct risks. The majority (95%) understood study participation was completely voluntary but only 21% recalled they could withdraw from the study without giving reasons. Younger parents had more consistent comprehension than older ones. Maternal reasons for allowing their children to take part in the research were free medical care (36.5%), better medical care (18.8%), general benefits (29.4%), contribution to research in the area (8.8%) and benefit to the community (1.8%). Parental suggestions for improving the consent process included devoting more time for explanations (46.9%), use of the local languages (15.9%) and obtaining consent at home (10.3%). Conclusion Significant but varied comprehension of the informed consent process exists among parents who participate in research activities in northern Ghana and it appears the existing practices are fairly effective in informing research participants in the study area.

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Malawi Medical Journal 2008 June; 20(2): 37-41

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Clinical research: the patients' perspectives.
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Knifed, Eva; Lipsman, Nir; Mason, Warren; Bernstein, Mark

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Neuro-oncology 2008 June; 10(3): 348-354

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Gonzalez, Stephanie K.; Helling, Thomas S.

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Journal of Trauma 2008 June; 64(6): 1665-1672

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Trommelmans, Leen; Selling, Joseph; Dierickx, Kris

**Informing participants in clinical trials with ex vivo human tissue-engineered products: what to tell and how to tell it?**


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Sumathipala, Athula; Siribaddana, Sisira; Hewage, Suwin; Lekamwattage, Manura; Athukorale, Manjula; Siriwardhana, Chesmal; Murray, Joanna; Prince, Martin

**Informed consent in Sri Lanka: a survey among ethics committee members**


**Abstract:** Background: Approval of the research proposal by an ethical review committee from both sponsoring and host countries is a generally agreed requirement in externally sponsored research. However, capacity for ethics review is not universal. Aim of this study was to identify opinions and views of the members serving in ethical review and ethics committees in Sri Lanka on informed consent, essential components in the information leaflet and the consent form. Methods: We obtained ethical approval from UK and Sri Lanka. A series of consensus generation meetings on the protocol were conducted. A task oriented interview guide was developed. The interview was based on open-ended questionnaire. Then the participants were given a WHO checklist on informed consent and requested to rate the items on a three point scale ranging from extremely important to not important. Results: Twenty-nine members from ethics committees participated. Majority of participants (23), believed a copy of the information leaflet and consent form, should accompany research proposal. Opinions about the items that should be included in the information leaflets varied. Participants identified 18 criteria as requirements in the information leaflet and 19 for the consent form. The majority, 20 (69%), believed that all research need ethical approval but identified limited human resource, time and inadequate capacity as constraints. Fifteen (52%) believed that written consent is not required for all research. Verbal consent emerged as an alternative to written consent. The majority of participants rated all components of the WHO checklist as important. Conclusion: The number of themes generated for the consent form (N = 18) is as many as for the information leaflet (N = 19) and had several overlaps. This suggests that the consent form should be itemized to reflect the contents covered in the information leaflet. The participants’ opinion on components of the information leaflets and consent forms proved to be similar with WHO checklist on informed consent.

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Ethical review and informed consent in cardiovascular research reports in Argentina.
Arquivos Brasileiros de Cardiologia 2008 May; 90(5): 290-293

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Children's consent and paediatric research: is it appropriate for healthy children to be the decision-makers in clinical research?
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Resnik, David B.; Zeldin, Darryl C.
Environmental health research on hazards in the home and the duty to warn.
Bioethics 2008 May ; 22(4): 209-217
Abstract: When environmental health researchers study hazards in the home, they often discover information that may be relevant to protecting the health and safety of the research subjects and occupants. This article describes the ethical and legal basis for a duty to warn research subjects and occupants about hazards in the home and explores the extent of this duty. Investigators should inform research subjects and occupants about the results of tests conducted as part of the research protocol only if the information is likely to be accurate, reliable, and medically useful. Investigators should warn subjects and occupants about hazards they happen to discover while they are in the home, if a reasonable person would warn the subjects and occupants about those hazards. Investigators should not report illegal hazards discovered in the home to the authorities, unless those hazards constitute abuse or neglect of children or mentally disabled people living in the home. When investigators decide to warn research subjects and occupants about hazards in the home, they should take some steps to help them make effective use of this information, such as providing additional counselling or making a referral for remediation or medical treatment. Investigators should discuss these issues with research subjects during the informed consent process.
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Wertheimer, A.; Miller, Franklin G.
Payment for research participation: a coercive offer?
Journal of Medical Ethics 2008 May; 34(5): 389-392
Abstract: Payment for research participation has raised ethical concerns, especially with respect to its potential for coercion. We argue that characterising payment for research participation as coercive is misguided, because offers of benefit cannot constitute coercion. In this article we analyse the concept of coercion, refute mistaken conceptions of coercion and explain why the offer of payment for research participation is never coercive but in some cases may produce undue inducement.
Georgetown users check Georgetown Journal Finder for access to full text
http://www.jmedethics.com (link may be outdated)
Abstract: Background: In emergency research, obtaining informed consent can be problematic. Research to develop and improve treatments for patients admitted to hospital with life-threatening and debilitating conditions is much needed yet the issue of research without consent (RWC) raises concerns about unethical practices and the loss of individual autonomy. Consistent with the policy and practice turn towards greater patient and public involvement in health care decisions, in the US, Canada and EU, guidelines and legislation implemented to protect patients and facilitate acute research with adults who are unable to give consent have been developed with little involvement of the lay public. This paper reviews research examining public opinion regarding RWC for research in emergency situations, and whether the rules and regulations permitting research of this kind are in accordance with the views of those who ultimately may be the most affected. Methods: Seven electronic databases were searched: Medline, Embase, CINAHL, Cochrane Database of Systematic Reviews, Philosopher's Index, Age Info, PsychInfo, Sociological Abstracts and Web of Science. Only those articles pertaining to the views of the public in the US, Canada and EU member states were included. Opinion pieces and those not published in English were excluded. Results: Considering the wealth of literature on the perspectives of professionals, there was relatively little information about public attitudes. Twelve studies employing a range of research methods were identified. In five of the six questionnaire surveys around half the sample did not agree generally with RWC, though paradoxically, a higher percentage would personally take part in such a study. Unfortunately most of the studies were not designed to investigate individuals' views in any depth. There also appears to be a level of mistrust of medical research and some patients were more likely to accept an experimental treatment 'outside' of a research protocol. Conclusion: There are too few data to evaluate whether the rules and regulations permitting RWC protects – or is acceptable to – the public. However, any attempts to engage the public should take place in the context of findings from further basic research to attend to the apparently paradoxical findings of some of the current surveys.

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Impediments to obtaining informed consent for clinical research in trauma patients.
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A proposal for a model of informed consent for the collection, storage and use of biological materials for research purposes.
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Mtunthama, N.; Malamba, R.; French, N.; Molyneux, M.E.; Zijlstra, E.E.; Gordon, S.B.

**Malawians permit research bronchoscopy due to perceived need for healthcare**

*Journal of Medical Ethics* 2008 April; 34(4): 303-307

**Abstract:** Objectives: Bronchoalveolar lavage obtained at bronchoscopy is useful for research on pulmonary defence mechanisms. Bronchoscopy involves some discomfort and risk to subjects. We audited the process of consent, experienced adverse effects and reasons for participation among research bronchoscopy volunteers. Design: 100 consecutive volunteer research subjects attending for bronchoscopy, repeat bronchoscopy or routine recruitment clinic were interviewed. Information was gathered about volunteer motivation, perception of the consent process and adverse effects of bronchoscopy. Suggestions for improvement were requested. Responses were themed by a second investigator prior to data analysis. Results: 81 bronchoscopy-experienced subjects (total of 263 procedures) and 19 new volunteers were interviewed. 19 subjects (21%) reported adverse symptoms during or after bronchoscopy, but no symptoms were of sufficient severity that they would not repeat the procedure. The frequency of symptoms was not related to gender, the quality of the lavage or the HIV status of the subject. 76 subjects (94%) reported that the information given pre-procedure was useful and adequate but 43 (56%) had further questions mostly relating to their own results. The reasons given for research participation were access to health assessment (75 subjects), access to treatment when ill (61 subjects), desire to participate in research (15 subjects) and remuneration (6 subjects). 7 subjects complained that the remuneration was inadequate. Conclusions: The main incentive to participation in research bronchoscopy was access to healthcare. Informed consent and procedure technique were adequate but subjects would value more feedback about individual and project results.

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**Ethics of placebo-controlled clinical trials in multiple sclerosis: a reassessment.**

*Neurology* 2008 March 25; 70(13 Pt 2): 1134-1140

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In court: informed consent relationship constitutes a binding contract
Human Research Report 2008 March; 23(3): 8
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Rowland, Mia
Case two: experimental blood substitute on first response vehicles.
Clinical Laboratory Science 2008 Spring; 21(2): 118-119
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*Systematic bias introduced by the informed consent process in a diagnostic research study.*


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Karlawish, Jason; Kim, Scott Y.H.; Knopman, David; van Dyck, Christopher H.; James, Bryan D.; Marson, Daniel

*The views of Alzheimer disease patients and their study partners on proxy consent for clinical trial enrollment.*

American Journal of Geriatric Psychiatry 2008 March; 16(3): 240-247

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Marshall, Patricia A.

"Cultural competence" and informed consent in international health research


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Simon, Christian; Mosavel, Maghboeba  
**Key conceptual issues in the forging of “culturally competent” community health initiatives: a South African example**  

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McNutt, Louise-Anne; Waltermaurer, Eve; Bednarczyk, Robert A.; Carlson, Bonnie E.; Kotval, Jeroo; McCauley, Jeanne; Campbell, Jacquelyn C.; Ford, Daniel E.  
**Are we misjudging how well informed consent forms are read?**  
**Abstract:** UNDERSTANDING THAT INFORMED CONSENT forms are provided to be read and comprehended, this study compares the research assistant's perception of comprehension with the actual time potential participants spend reading their consent form. After providing information verbally to two samples of women, research assistants observed as the women reviewed and signed the consent form recording the time spent reading and the assistant's impression of reading behavior. Over half of the women "read" their consent forms in thirty seconds or less before signing. Despite the brief time participants actually read, research assistants reported that 38%–74% (depending on the sample) appeared to have completely read the forms. Research to determine if timing aids will improve research assistants' assessment of participant reading behaviors should be considered.

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Jacoby, Liva H.; Young, Barry; Watt, James  
**Public disclosure in research with exception from informed consent: the use of survey methods to assess its effectiveness**  
**Abstract:** IN CLINICAL TRIALS WITH EXCEPTION from informed consent, the Final Rule stipulates that investigators inform and consult with the community. A random-digit-dialing survey of 200 individuals assessed the effectiveness of public disclosure via press releases, notices in local newspapers, local radio and television stations and the host hospital's website, as well as a series of community meetings regarding a pending clinical trial of this kind. Results showed a 10% awareness level of the public trial, which is higher than surveys using convenience samples. Understanding of the nature of the trial was generally poor, while opinions about participating in this type of research were more favorable among individuals aware of the trial. Our findings suggest that adherence to the intent of the Final Rule is dependent on uniform guidelines for what constitute effective public disclosure methods and adequate community awareness and understanding and the use of rigorous sampling methods for evaluation.

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**Motivations of mothers to enroll their newborn infants in general clinical research on well-infant care and development**  
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Assessment of informed consent understanding: HIV vaccine trials in Port-au-Prince [abstract]
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Clinical research in low-literacy populations: using teach-back to assess comprehension of informed consent and privacy information

Effective use of consent forms and interactive questions in the consent process
IRB: Ethics and Human Research 2008 March-April; 30(2): 8-12

Beyond informed consent: the therapeutic misconception and trust
Journal of Medical Ethics 2008 March; 34(3): 202-205

Unconscious emotional reasoning and the therapeutic misconception
Journal of Medical Ethics 2008 March; 34(3): 193-197
the doctor-patient relationship may unavoidably interfere with the process of obtaining informed consent. Following this argument we suggest new ways to prevent or at least mitigate the therapeutic misconception.

**Document 380**

**Participation in dementia research: rates and correlates of capacity to give informed consent**  
Journal of Medical Ethics 2008 March; 34(3): 167-170  
**Abstract:** BACKGROUND: Many people participating in dementia research may lack capacity to give informed consent and the relationship between cognitive function and capacity remains unclear. Recent changes in the law reinforce the need for robust and reproducible methods of assessing capacity when recruiting people for research.  
AIMS: To identify numbers of capacitous participants in a pragmatic randomised trial of dementia treatment; to assess characteristics associated with capacity; to describe a legally acceptable consent process for research.  
METHODS: As part of a pragmatic randomised controlled trial of Ginkgo biloba for mild-moderate dementia, we used a consenting algorithm that met the requirements of existing case law and the exigencies of the new Mental Capacity Act. We decided who had capacity to give informed consent for participation in the trial using this algorithm and sought predictors of capacity. RESULTS: Most participants (76%) with mild-moderate dementia in this trial were unable to give informed consent according to the legal criteria. When adjusted for confounding, the Mini Mental State examination did not predict the presence of capacity. CONCLUSION: Cognitive testing alone is insufficient to assess the presence of capacity. Researchers and clinicians need to be aware of the challenging processes regarding capacity assessment. We outline a procedure which we believe meets the ethical and legal requirements.

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**Quality-improvement research and informed consent**  

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Tarini, Beth A.; Burke, Wylie; Scott, C. Ronald; Wilfond, Benjamin S.  
**Waiving informed consent in newborn screening research: balancing social value and respect**  

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Saks, Elyn R.; Dunn, Laura B.; Wimer, Jessica; Gonzales, Michael; Kim, Scott
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American Journal of Geriatric Psychiatry 2008 January; 16(1): 83-91

Disclosure of information to potential subjects on research recruitment web sites
Klitzman, Robert; Albala, Ilene; Siragusa, Joseph; Patel, Jignasha; Appelbaum, Paul S.

Impact of clinical trials information handbook on patient knowledge, perceptions, and likelihood of participation
Campbell, Heather M.; Raisch, Dennis W.; Sather, Mike R.; Segal, Alissa R.; Warren, Stuart R.; Naik, Rupali

Informed consent in Ghana: what do participants really understand?
Hill, Zelee; Tawiah-Agyemang, C.; Odei-Danso, S.; Kirkwood, B.
Journal of Medical Ethics 2008 January; 34(1): 48-53

Abstract: OBJECTIVES: To explore how subjects in a placebo-controlled vitamin A supplementation trial among Ghanaian women aged 15-45 years perceive the trial and whether they know that not all trial capsules are the same,
and to identify factors associated with this knowledge. METHODS: 60 semistructured interviews and 12 focus groups were conducted to explore subjects' perceptions of the trial. Steps were taken to address areas of low comprehension, including retraining fieldworkers. 1971 trial subjects were randomly selected for a survey measuring their knowledge that not all trial capsules are the same. The subjects' fieldworkers were also interviewed about their characteristics and trial knowledge. Factors associated with knowledge were explored using multi-level modeling.

RESULTS: Although subjects knew they were taking part in research, most thought they were receiving an active and beneficial medication. Variables associated with knowledge were education and district of residence. Radio broadcasts benefited those with some schooling. Fieldworkers' characteristics were not associated with subjects' knowledge. CONCLUSIONS: Research and debate on new or improved consent procedures are urgently required, particularly for subjects with little education.

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Clinical Trials 2008; 5(6): 617-623
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Varieties of uncertainty and the validity of informed consent.
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**When regulations conflict with our moral sense**
Protecting Human Subjects 2008; (16): 13

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**Does complex consent hinder beneficial research?**
Protecting Human Subjects 2008; (16): 12-13

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**Is it coercive to offer incentives to subjects?**
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Rounsaville, Daniel B.; Hunkele, Karen; Easton, Caroline J.; Nich, Charla; Carroll, Kathleen M.
Making consent more informed: preliminary results from a multiple-choice test among probation-referred marijuana users entering a randomized clinical trial

Document 413
Minnies, Deon; Hawkridge, Tony; Hanekom, Willem; Ehrlich, Rodney; London, Leslie; Hussey, Greg
Evaluation of the quality of informed consent in a vaccine field trial in a developing country setting
Abstract: Background: Informed consent is an ethical and legal requirement for research involving human participants. However, few studies have evaluated the process, particularly in Africa. Participants in a case control study designed to identify correlates of immune protection against tuberculosis (TB) in South Africa. This study was in turn nested in a large TB vaccine efficacy trial. The aim of the study was to evaluate the quality of consent in the case control study, and to identify factors that may influence the quality of consent. Cross-sectional study conducted over a 4 month period. Methods: Consent was obtained from parents of trial participants. These parents were asked to complete a questionnaire that contained questions about the key elements of informed consent (voluntary participation, confidentiality, the main risks and benefits, etc.). The recall (success in selecting the correct answers) and understanding (correctness of interpretation of statements presented) were measured. Results: The majority of the 192 subjects interviewed obtained scores greater than 75% for both the recall and understanding sections. The median score for recall was 66%; interquartile range (IQR) = 55%–77% and for understanding 75% (IQR = 50%–87%). Most (79%) were aware of the risks and 64% knew that they participated voluntarily. Participants who had completed Grade 7 at school and higher were more likely (OR = 4.94; 95% CI = 1.57 – 15.55) to obtain scores greater than 75% for recall than those who did not. Participants who were consented by professional nurses who had worked for more than two years in research were also more likely (OR = 2.62; 95% CI = 1.35–5.07) to obtain such scores for recall than those who were not. Conclusion: Notwithstanding the constraints in a developing country, in a population with low levels of literacy and education, the quality of informed consent found in this study could be considered as building blocks for establishing acceptable standards for public health research. Education level of respondents and experience of research staff taking the consent were associated with good quality informed consent.

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Empirical issues in informed consent for research
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A history of informed consent in clinical research
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Research involving those at risk for impaired decision-making capacity
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Miller, Franklin G.; Rosenstein, Donald L.
Challenge experiments
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Delfosse, Marie-Luce
Réflexions sur l'utilisation du placebo dans la recherche internationale. L'exemple des essais relatifs à la transmission verticale périnatale du virus HIV. = Reflections on the use of a placebo in international research. The example of trials relative to the vertical perinatal transmission of the HIV virus
Abstract: This article offers a reflection on certain arguments (for and against) advanced regarding clinical trials against a placebo sponsored by the North to be conducted in the South. The aim is to show the strength and the ethical implications of these arguments. The example chosen is that of trials relative to the vertical perinatal transmission of the HIV virus. It is particularly interesting. In fact, it has stemmed much controversy and the questions it raises have evolved, though, they are still being developed. Whereas the ethical requirements to be respected in international research promoted by a Northern country to be conducted in the South are becoming more specific. Even if these trials are not the latest conducted concerning this issue, the arguments which have developed in their regard stand true, in my opinion, for other experiments. The examination of the arguments retained shows the close interweaving of the different constitutive ethics of the ethics of trials, as well as the evolution from a deontological perspective to a contractualist perspective. It also brings forward some particularly sensitive points which warrant in-depth reflection.

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Informed consent: interpretations and practice on social surveys.
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Changing constructions of informed consent: qualitative research and complex social worlds.
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Informed consent in cross-cultural perspective: clinical research in the Tibetan Autonomous Region, PRC

Using mystery clients to assess condom negotiation in Malawi: some ethical concerns

Declining enrolment in a clinical trial and injurious misconceptions: is there a flipside to the therapeutic misconception?
Clinical Ethics 2007 December; 2(4): 193-200

Abstract: The term 'therapeutic misconception' (TM) was introduced in 1982 to conceptualize how some psychiatry trial participants perceived and interpreted their involvement in research. TM has since been identified in many settings and is a major component in research ethics discussions. A qualitative study included a subgroup of interviews with five parents (two couples, one mother) who declined to enrol their baby in a neonatal trial. Analysis suggested the possibility of a counterpart to TM which, given the original terminology, we term the 'injurious misconception' (IM). While TM is closely linked to the elision of care and research, and involves an over-stated sense of benefit and protection, IM may be a product of a particularly keen and discomforting sense of distinctions between care and research and a correspondingly over-stated sense of risk and threat.
Breese, Peter E.; Burman, William J.; Goldberg, Stefan; Weis, Stephen E.

Education level, primary language, and comprehension of the informed consent process

Abstract: TO OBTAIN INFORMATION ON HOW PERSONS from diverse backgrounds experience the informed consent process, we surveyed adults with a wide variety of educational levels and different primary languages (English, Spanish, or Vietnamese) who had recently enrolled in a study requiring written informed consent. Of the 100 participants, 62 were non-White, 43 had less than a high school education, and 60 had a primary language other than English. The median score for comprehension was 62% (IQR 50–76%); the median satisfaction score was 86% (IQR 71–100%). In multivariate analysis, only educational level was significantly associated with comprehension and satisfaction with the informed consent process (p < 0.001). Comprehension and satisfaction with the informed consent process were markedly lower among persons with lower educational levels.

Catania, Joseph A.; Wolf, Leslie E.; Wertleib, Stacey; Lo, Bernard; Henne, Jeff

Research participants' perceptions of the Certificate of Confidentiality's assurances and limitations

Abstract: THE CERTIFICATE OF CONFIDENTIALITY (COC) provides additional protections to personal and sensitive research data. COC guarantees are not absolute and investigators are obligated to inform potential participants of COC limitations. The present study utilized qualitative and partnership methodology to examine participants' (N = 24) perceptions of COC assurances and limitations in the context of a hypothetical study on depression. Although some participants were comforted by COC assurances, a majority of participants had confidentiality/privacy concerns specifically with COC passages concerning federal audits and legal reporting requirements. As one respondent noted, "Why is it that you guys don't have to turn the records over to the court unless I say so . . . but you have to give them over to the government? . . . I don't know about what is goin' on." Our findings underscore the need for larger quantitative investigations to examine the negative and positive impact of COCs on research participation and response bias.

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The impact of HIPAA authorization on willingness to participate in clinical research.
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Risk perception and decision processes underlying informed consent to research participation.
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Goldim, José Roberto; Clotet, Joaquim; Ribeiro, Jorge Pinto
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Resnik, David B.
Questionable research practices compel subjects to join studies [review of What the Doctor Didn't Say: The Hidden Truth About Medical Research, by Jerry Menikoff (with Edward P. Richards)]
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IRB: Ethics and Human Research 2007 November-December; 29(6): 7-14
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An analysis of factors that predict patient consent to take part in a randomized controlled trial
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'No time to be lost!' Ethical considerations on consent for inclusion in emergency pharmacological research in severe traumatic brain injury in the European Union
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Feuchtbaum, Lisa; Cunningham, George; Sciortino, Stan
Questioning the need for informed consent: a case study of California's experience with a pilot newborn screening research project
Abstract: California provides mandatory newborn screening for disorders that cause irreversible, severe disabilities if not identified and treated early in life. Parental consent is not required. In 2001, the Genetic Disease Branch was mandated to pilot test a new technology that could identify many additional disorders using the same blood specimen already collected. Study participation required informed consent, which was obtained for 47% of births during the study timeframe. The inability of hospitals to carry out the consent procedure for all newborns resulted in denial of testing and missed cases. If informed consent were waived, all newborns could have been tested. Several empirical questions are posed and each is examined from the perspective of society, the parents and the newborn. It is concluded that the legitimate needs of society and the interests of newborns should not be sacrificed to respond to the autonomy interests of the few parents who did not wish their infant to participate in the study, and that in the future, parental consent should be waived for projects evaluating new screening technologies.
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Are you looking at me? Medical researchers keen to scour patients' data for insights into disease should get
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The role of the consent document in informed consent for pediatric leukemia trials
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Ethicists balk at new emergency trials that skip informed consent [news]
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**Evaluation of informed consent: a pilot study**

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Shaibu, Sheila
**Ethical and cultural considerations in informed consent in Botswana**
Nursing Ethics 2007 July; 14(4): 503-509
**Abstract:** Reflections on my experience of conducting research in Botswana are used to highlight tensions and conflicts that arise from adhering to the western conceptualization of bioethics and the need to be culturally sensitive when carrying out research in one's own culture. Cultural practices required the need to exercise discretionary judgement guided by respect for the culture and decision-making protocols of the research participants. Ethical challenges that arose are discussed. The brokerage role of nurse educators and leaders in contextualizing western bioethics is emphasized.

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**Compact versus contract: industry sponsors’ obligations to their research subjects**

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**The role of the clinical trial nurse in the informed consent process**
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**Ethical approval of clinical studies, informed consent, and the Declaration of Helsinki: what you need to know**


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Molter, Nancy C.

**Exemption of informed consent (final rule): procedures for critical trauma studies**

Journal of Trauma 2007 June; 62(6, Supplement): S78-S79

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Dickert, Neal W.; Sugarman, Jeremy

**Getting the ethics right regarding research in the emergency setting: lessons from the PolyHeme Study**


*Abstract:* Research in emergency settings (RES) has become a major public issue with urgent policy implications. Significant attention has focused recently on RES in response to the trial of PolyHeme, a synthetic blood substitute, in trauma victims in hemorrhagic shock. Unfortunately, the discussion of the PolyHeme trial in the popular and scholarly press leaves important questions unanswered. This paper articulates three important lessons from the PolyHeme trial that have significant policy implications. First, the RES regulations should be re-visited, particularly the requirement that existing treatments be unproven or unsatisfactory in order for research to be acceptable without consent. Second, further conceptual and empirical scholarship is needed to accomplish the goal of effectively involving communities. Third, a more subtle analysis is needed regarding how to balance the needs of maintaining public trust and protecting confidential trade information in the context of RES.

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May, William E.

**Proxy consent for nontherapeutic experimentation**

National Catholic Bioethics Quarterly 2007 Summer; 7(2): 239-247

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Stein, Rob

**Critical care without consent; ethicists disagree on experimenting during crises**

Washington Post 2007 May 27; p. A1, A16

[http://www.washingtonpost.com](http://www.washingtonpost.com) (link may be outdated)
Medical Guinea Pig (2007)

Abstract: "Is it possible that you might have been used as a medical guinea pig without your knowledge? ABC News reports on a medical experiment on unsuspecting accident patients brought into hospital ERs that has been happening in more than 20 cities across the country. What is being tested is an experimental, artificial blood substitute known as Polyheme, developed by a company called Northfield Labs. The sponsors of the study say using accident victims for the experiment without their consent is necessary for the greater good to save lives of severely injured patients in the future. But critics call the test an unconscionable breach of medical ethics and a violation of the fundamental notion of informed consent." [description is from the Amazon site] The correspondent is Brian Ross.

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

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Dew, Rachel E.

Informed consent for research in borderline personality disorder [debate]


Abstract: Background: Previous research on informed consent for research in psychiatric patients has centered on disorders that affect comprehension and appreciation of risks. Little has been written about consent to research in those subjects with Borderline Personality Disorder, a prevalent and disabling condition. Discussion: Despite apparently intact cognition and comprehension of risks, a borderline subject may deliberately choose self-harm in order to fulfill abnormal psychological needs, or due to suicidality. Alternatively, such a subject may refuse enrollment due to transference or the desire to harm him or herself. Such phenomena could be precipitated or prevented by the interpersonal dynamics of the informed consent encounter. Summary: Caution should be exercised in obtaining informed consent for research from subjects with Borderline Personality Disorder. A literature review and recommendations for future research are discussed.

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Smith-Tyler, June

Informed consent, confidentiality, and subject rights in clinical trials.


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Intensive Care Medicine 2007 May; 33(5): 807-813

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**Subjective evaluations of research participation by persons with mental illness**

Journal of Nervous and Mental Disease 2007 May; 195(5): 430-435

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Journal of Minimally Invasive Gynecology 2007 May-June; 14(3): 278-283

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Maloney, Dennis M.

**Informed consent issues raised by emerging field**

Human Research Report 2007 May; 22(5): 4

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**The many ways of saying yes and no: reflections on the research coordinator’s role in recruiting research participants and obtaining informed consent**

IRB: Ethics and Human Research 2007 May-June; 29(3): 6-10

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Ethical issues surrounding studies with vulnerable populations: a case study of South African street children
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Neuropsychological functioning and recall of research consent information among drug court clients
Ethics and Behavior 2007 April; 17(2): 163-186
Abstract: Evidence suggests that research participants often fail to recall much of the information provided during the informed consent process. This study was conducted to determine the proportion of consent information recalled by drug court participants following a structured informed consent procedure and the neuropsychological factors that were related to recall. Eighty-five participants completed a standard informed consent procedure to participate in an ongoing research study, followed by a 17-item consent quiz and a brief neuropsychological battery 2 weeks later. Participants performed within the normal range on most of the neuropsychological measures, although roughly one third showed deficits on measures of executive functioning. Participants failed to recall over 65% of the consent information within 2 weeks of entering the study, and their recall was significantly correlated with verbal IQ, drug problem severity, reading ability, memory, and attention. These factors may be useful in determining whether research participants require enhanced consent procedures.
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**Emergency research: only possible if consent is waived?**
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Biros, Michelle
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Reporting of informed consent and approval by institutional review board (IRB) in randomized controlled drug trials conducted in nursing homes (NH) from 1968 to 2004 [abstract]

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Newton, Sam K.; Appiah-Poku, John
The perspectives of researchers on obtaining informed consent in developing countries

Abstract: Background: The doctrine of informed consent (IC) exists to protect individuals from exploitation or harm. This study into IC was carried out to investigate how different researchers perceived the process whereby researchers obtained consent. It also examined researchers' perspectives on what constituted IC, and how different settings influenced the process. Methods: The study recorded in-depth interviews with 12 lecturers and five doctoral students, who had carried out research in developing countries, at a leading school of public health in the United Kingdom. A purposive, snowballing approach was used to identify interviewees. Results: Although the concept and application of the doctrine of IC should have been the same, irrespective of where the research was carried out, the process of obtaining it had to be different. The setting had to be taken into consideration and the autonomy of the subject had to be respected at all times. In areas of high illiteracy, and where understanding of the subject was likely to be a problem, there was an added responsibility placed on the researcher to devise innovative ways of carrying out the study, taking into consideration the peculiarities of the environment. Conclusion: The ethical issues for IC were the same, irrespective of where the research was conducted. However, because the backgrounds, setting, and knowledge of populations differed, there was the need to be similarly sensitive in obtaining consent. The problems of obtaining genuine IC were not limited to developing countries.

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* Article Document 512
Sugarman, Jeremy; Roter, Debra; Cain, Carole; Wallace, Roberta; Schmechel, Don; Welsh-Bohmer, Kathleen A.
Proxies and consent discussions for dementia research

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Consent gained from patients after breast surgery for the use of surplus tissue in research: an exploration

Journal of Medical Ethics 2007 April; 33(4): 229-233

Abstract: OBJECTIVES: (1) To investigate the quality of consent gained for the use in research of tissue that is surplus after surgery. (2) To compare the use of two consent forms: a simple locally introduced form and a more complex centrally instigated form. (3) To discuss the attitudes of patients towards the use of their surplus tissue in research. DESIGN: Data were collected through interviews and analysed with a combination of quantitative and qualitative analytical techniques. Participants and SETTING: Patients of the breast care unit at a teaching hospital were interviewed at home or in a quiet room at the hospital. RESULTS: 57 people were interviewed out of 81 approached, between October 2003 and March 2004. Most participants had a poor level of knowledge about the consent they had given, but reported being happy about having given it. The patients who had signed the locally introduced form had considerably more knowledge than those who had signed the centrally instigated form (z = -2.56; p<0.05). Participants considered being well informed to be less important than believing that their opinions were valued and respected. CONCLUSIONS: The findings suggest that traditional models of informed consent are not universally applicable and, in this case, seem to overstate what people wish to know. The simple consent form achieved a better quality of informed consent and provided a better model of practice than the complex form, and it seemed that a focused approach to consent seeking is more effective and acceptable than more complex approaches.

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

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Stephenson, Arthur C; Baker, Stuart; Zeps, Nikolajs

**Attitudes of relatives of patients in intensive care and emergency departments to surrogate consent to research on incapacitated participants.**
Critical Care and Resuscitation 2007 March; 9(1): 40-50

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Bos, Albert P.; van Zwieten, Myra C.B.

**Randomized, controlled trials in the emergency setting: a matter of physician-patient relationships, responsibility, and trust.**
Critical Care Medicine 2007 March; 35(3): 979-980

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Adams, Mary; Fischler, Ira; Simmerling, Mary;

**Deception**

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Bradburn, Norman; Simon, Gayle; Bankowski, Susan Burner; Beattie, Elizabeth; Buckwalter, Kathleen; Clark, Laura; Diehl, Dawn

**Informed consent**

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Breese, Peter; Rietmeijer, Cornelis; Burman, William

**Content among locally approved HIPAA authorization forms for research**

**Abstract:** This study was designed to access differences in the content of HIPAA authorization forms now required for clinical research. Authorization forms were collected from 111 institutions, including academic medical centers and commercial Institutional Review Boards. The requirement for an element covering the use of information acquired was fulfilled in 95% of the forms, and 100% had a statement fulfilling the core requirement of a description of the data to be collected. However, only 19% distinguished between entities that could see personal identifiers versus aggregate data. Significant differences existed in how long the disclosure agreement would remain in effect, and complex legalistic language was common. Thus, while research authorization forms technically met the requirements, the complex language and confusion over personal identifiers may raise concerns in prospective
* Document 523

Cooper, Matthew

**Sharing data and results in ethnographic research: why this should not be an ethical imperative**


**Abstract:** Researchers recently have argued that offering to share research results with study participants should be an "ethical imperative." This article considers that suggestion in light of the practice of ethnographic, particularly anthropological, research. Sharing results is discussed in relation to several issues, e.g., whether it occurs during or after completion of a project, whether the research is long-term, the complexities involved in depositing field materials in archives, the changing politics of ethnographic research, research not concerned with communities, situations in which participants and the anthropologist may be in danger, and changing styles of ethnographic research. I argue that, ideally, sharing should be a regular component of ethnographic research but should not be an ethical requirement. Given the complexity, variety and changing political contexts of ethnographic research, implementing such a requirement would often be practically impossible and sometimes would be inadvisable. I recommend instead that research ethics boards educate themselves about the nature of ethnographic research. Further, they should approach decision making on the issue of data or results sharing on a case-by-case basis. For researchers, I recommend that discussion of data and result sharing should become part of the education of all ethnographers and that discussion of the issue should be fostered.

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**Assembly gives 14-year-olds a say on key medical care [Richmond Notebook]**


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

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Resnick, Barbara; Gruber-Baldini, Ann L.; Pretzer-Aboff, Ingrid; Galik, Elizabeth; Buie, Verita Custis; Russ, Karin; Zimmerman, Sheryl

**Reliability and validity of the evaluation to sign consent measure.**

Gerontologist 2007 February; 47(1): 69-77

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Korobkin, Russell

**Autonomy and informed consent in nontherapeutic biomedical research**

UCLA Law Review 2007 February; 54(3): 605-630

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Choi, Joanna M.; Salter, Sharon A.; Kimball, Alexa B.
Innovative care, medical research, and the ethics of informed consent
Journal of the American Academy of Dermatology 2007 February; 56(2): 330-332

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Ness, Roberta B
American College of Epidemiology Policy Committee
**Biospecimen "ownership": point**
Cancer Epidemiology, Biomarkers and Prevention 2007 February; 16(2): 188-189

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Dressler, Lynn G.
**Biospecimen "ownership": counterpoint**
Cancer Epidemiology, Biomarkers and Prevention 2007 February; 16(2): 190-191

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Illes, J.; Chin, V.
**Trust and reciprocity: foundational principles for human subjects imaging research**
Canadian Journal of Neurological Sciences 2007 February; 34(1): 3-4

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Marshall, Jennifer; Martin, Toby; Downie, Jocelyn; Malisza, Krisztina
**A comprehensive analysis of MRI research risks: in support of full disclosure**
Canadian Journal of Neurological Sciences 2007 February; 34(1): 11-17

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Christopher, Paul P.; Foti, Mary Ellen; Roy-Bujnowski, Kristen; Appelbaum, Paul S.
**Consent form readability and educational levels of potential participants in mental health research**
Psychiatric Services 2007 February; 58(2): 227-232

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Liesegang, Thomas J.
**The meaning and need for informed consent in research.**

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Green, D.; Rickles, F.R.  
Enhancing participation in clinical research: keys to obtaining informed consent  

Abma, Tineke  
Patients and research partners  
EACME Newsletter 2007 January; (16): 11-12

Miller, F.G.; Kaptchuk, T.J.  
Acupuncture trials and informed consent  
Journal of Medical Ethics 2007 January; 33(1): 43-44  
Abstract: Participants are often not informed by investigators who conduct randomised, placebo-controlled acupuncture trials that they may receive a sham acupuncture intervention. Instead, they are told that one or more forms of acupuncture are being compared in the study. This deceptive disclosure practice lacks a compelling methodological rationale and violates the ethical requirement to obtain informed consent. Participants in placebo-controlled acupuncture trials should be provided an accurate disclosure regarding the use of sham acupuncture, consistent with the practice of placebo-controlled drug trials.

Hem, Marit Helene; Heggen, Kristin; Ruyter, Knut W.  
Questionable requirement for consent in observational research in psychiatry  
Nursing Ethics 2007 January; 14(1): 41-53  
Abstract: Informed consent represents a cornerstone of the endeavours to make health care research ethically acceptable. Based on experience of qualitative research on power dynamics in nursing care in acute psychiatry, we show that the requirement for informed consent may be practised in formalistic ways that legitimize the researcher's activities without taking the patient's changing perception of the situation sufficiently into account. The presentation of three patient case studies illustrates a diversity of issues that the researcher must consider in each situation. We argue for the necessity of researchers to base their judgement on a complex set of competencies. Consciousness of research ethics must be combined with knowledge of the challenges involved in research methodology in qualitative research and familiarity with the therapeutic arena in which the research is being conducted. The article shows that the alternative solution is not simple but must emphasize the researcher's ability to doubt and be based on an awareness of the researcher's fallibility.
Document 538
Slaughter, Susan; Cole, Dixie; Jennings, Eileen; Reimer, Marlene A.
Consent and assent to participate in research from people with dementia
Nursing Ethics 2007 January; 14(1): 27-40
Abstract: Conducting research with vulnerable populations involves careful attention to the interests of individuals. Although it is generally understood that informed consent is a necessary prerequisite to research participation, it is less clear how to proceed when potential research participants lack the capacity to provide this informed consent. The rationale for assessing the assent or dissent of vulnerable individuals and obtaining informed consent by authorized representatives is discussed. Practical guidelines for recruitment of and data collection from people in the middle or late stage of dementia are proposed. These guidelines were used by research assistants in a minimal risk study.

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Maloney, Dennis M.
Special consent elements required for IRB review
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Rivera, Roberto; Borasky, David; Rice, Robert; Carayon, Florence; Wong, Emelita
Informed consent: an international researchers' perspective
Abstract: We reported 164 researchers’ recommendations for information that should be included in the informed consent process. These recommendations were obtained during training workshops conducted in Africa, Europe, and the United States. The 8 elements of informed consent of the US Code of Federal Regulations were used to identify 95 items of information ("points"), most related to benefits and research description. Limited consensus was found among the 3 workshops: of the 95 points, only 27 (28%) were identified as useful by all groups. These points serve as a springboard for identifying information applicable in different geographic areas and indicate the need for involving a variety of individuals and stakeholders, with different research and cultural perspectives, in the development of informed consent, particularly for research undertaken in international settings.

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Sugarman, Jeremy
Examining the provisions for research without consent in the emergency setting
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Lorenzo, Cláudio
O consentimento livre e esclarecido e a realidade do analfabetismo funcional no Brasil: uma abordagem para a norma e para além da norma
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Sen Biswas, Mimi; Newby, L. Kristin; Bastian, Lori A.; Peterson, Eric D.; Sugarman, Jeremy
Who refuses enrollment in cardiac clinical trials?
Clinical Trials 2007; 4(3): 258-263
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Valdez, Rupa Sheth; Zayas-Cabán, Teresa
Understanding informed consent in bioinformatics research: cross-cultural issues.
American Medical Informatics Association Annual Symposium Proceedings 2007: 1142
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Truog, Robert D.
Doing research on the ethics of doing research.
Critical Care 2007; 11(1): 111; discussion 111
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Williams, Brian; Irvine, Linda; McGinnis, Alison R.; McMurdo, Marion E.T.; Crombie, Iain K.
When "no" might not quite mean "no"; the importance of informed and meaningful non-consent: results from a survey of individuals refusing participation in a health-related research project.
BMC Health Services Research 2007; 7(): 59
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Informed consent for clinical evaluations of investigational implantable medical devices.
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Robertson, Claudia S.; McCullough, Laurence B.; Brody, Baruch
Finding family for prospective consent in emergency research
Clinical Trials 2007; 4(6): 631-637
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Gibbs, Jeffrey N.; Guagnano, Gregory A.
Investigator financial disclosure and its effects on research subjects
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Francis, Leslie P.; Battin, Margaret P.; Botkin, Jeffrey R.; Jacobson, Jay A.; Smith, Charles B.
Infectious disease and the ethics of research: the moral significance of communicability
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Freidenfelds, Lara
Recruiting allies for reform: Henry Knowles Beecher's "Ethics and Clinical Research"
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Lamprill, Jane; Fowler, Patricia A.
Consent and assent in paediatric clinical trials
Call number: RJ85_G85 2007

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Informed consent for research
Call number: R724_P69 2007

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Globalization of health: informed consent
Call number: R854_A5 G38 2007

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Cahana, Alex; Romagnioli, Simone
Not all placebos are the same: a debate on the ethics of placebo use in clinical trials versus clinical practice

Journal of Anesthesia 2007; 21(1): 102-105

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Sheremeta, Lorraine

Public meets private: challenges for informed consent and umbilical cord blood banking in Canada


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Winau, Rolf

Experimentation on humans and informed consent: how we arrived where we are


Call number: R853 .H8 D37 2007

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Karlawish, Jason

Research on cognitively impaired adults


Call number: QH332 .O94 2007

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Drexler, Matthew B.

Health Law – privacy in medical research: a botched experiment


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* Chapter Document 560

Buchanan, David; Miller, Franklin G.

Justice in research on human subjects


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McCarty, Catherine A.; Nair, Anuradha; Austin, Diane M.; Giampietro, Philip F.

Informed consent and subject motivation to participate in a large, population-based genomics study: the Marshfield Clinic Personalized Medicine Research Project

Community Genetics 2007; 10(1): 2-9

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Crichton, Michael

**Body snatchers, 2006**

Wall Street Journal 2006 December 15; A20

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Verástegui, Emma L.

**Consenting of the vulnerable: the informed consent procedure in advanced care patients in Mexico**


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Link, Jessica; Haggard, Rob; Kelly, Kimberly; Forrer, Dan

**Placebo/nocebo symptom reporting in a sham herbal supplement trial.**

Evaluation and the Health Professions 2006 December; 29(4): 394-406

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Biswas, B.; Ahmad, R.

**Critical evaluation of research articles in relation to informed consent.**

Bangladesh Medical Research Council Bulletin 2006 December; 32(3): 92-97

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Lemaire, François

**The inability to consent in critical care research: emergency or impairment of cognitive function?**

Intensive Care Medicine 2006 December; 32(12): 1930-1932

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**Informed consent in clinical trials in critical care: experience from the PAC-Man study.**

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**Document 568**
Burger, Ingrid; Kass, Nancy

*Ethical conduct of radiology research with human participants.*
Journal of the American College of Radiology 2006 December; 3(12): 932-939

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*Consent for emergency care research: the Mental Capacity Act 2005*
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Appelbaum, Paul S.; Lidz, Charles W.

*Re-evaluating the therapeutic misconception: response to Miller and Joffe*
Kennedy Institute of Ethics Journal 2006 December; 16(4): 367-373

*Abstract:* Responding to the paper by Miller and Joffe, we review the development of the concept of therapeutic misconception (TM). Our concerns about TM's impact on informed consent do not derive from the belief that research subjects have poorer outcomes than persons receiving ordinary clinical care. Rather, we believe that subjects with TM cannot give an adequate informed consent to research participation, which harms their dignitary interests and their abilities to make meaningful decisions. Ironically, Miller and Joffe's approach ends up largely embracing the very position that they inaccurately attribute to us: the belief that, with some exceptions, it is only the prospect of poorer outcomes that should motivate efforts to dispel TM. In the absence of empirical studies on the steps required to dispel TM and the impact of such procedures on subject recruitment, it is premature to surrender to the belief that TM must be widely tolerated in clinical research.

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Miller, Franklin G.; Joffe, Steven

*Evaluating the therapeutic misconception*
Kennedy Institute of Ethics Journal 2006 December; 16(4): 353-366

*Abstract:* The "therapeutic misconception," described by Paul Appelbaum and colleagues more than 20 years ago, refers to the tendency of participants in clinical trials to confuse the design and conduct of research with personalized medical care. Although the "therapeutic misconception" has become a term of art in research ethics, little systematic attention has been devoted to the ethical significance of this phenomenon. This article examines critically the way in which Appelbaum and colleagues formulate what is at stake in the therapeutic misconception, paying particular attention to assumptions and implications that clinical trial participation disadvantages research participants as compared with receiving standard medical care. After clarifying the ethical significance of the therapeutic misconception with respect to the decision making of patients, we offer policy recommendations for obtaining informed consent to participation in clinical trials.

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Norman, R.; Sellman, D.; Warner, C.
Mental capacity, good practice and the cyclical consent process in research involving vulnerable people
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Clinical Ethics 2006 December; 1(4): 195-199
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Most cancer patients unconcerned about doctors' ties to drug firms; research reviewers also may often have links to industry
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The placebo effect deserves our time [review of The Placebo Effect and Health: Combining Science & Compassionate Care, by W. Grant Thompson]
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A life and death dilemma...
New Scientist 2006 October 21-27; 192(2574): 8-9
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Stryker, Jo Ellen; Wray, Ricardo J.; Emmons, Karen M.; Winer, Eric; Demetri, George
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Iorio, A.; Agnelli, G.
**Are placebo-controlled trials ethical in areas where current guidelines recommend therapy? No**
Journal of Thrombosis and Haemostasis 2006 October; 4(10): 2133-2136
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**Are placebo-controlled trials ethical in areas where current guidelines recommend therapy? Yes**
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Ecks, Stefan
**Response to Monica Konrad 'Placebo politics: on comparability, interdisciplinarity and international collaborative research'**
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Konrad, Monica
**Placebo politics: on comparability, interdisciplinarity and international collaborative research**
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Pandya, Sunil K.

**Bypassing scientific requirements [response]**

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Maloney, Dennis M.

**New advice on special duties for institutional review boards (IRBs)**


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**The ethics of withdrawal from study participation**

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**Proposed guidelines for emergency research aim to quell confusion [news]**

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**Factors related to volunteer comprehension of informed consent for a clinical trial.**

Southeast Asian Journal of Tropical Medicine and Public Health 2006 September; 37(5): 996-1004

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**Consent in resuscitation trials: benefit or harm for patients and society?**

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American Journal of Bioethics 2006 September-October; 6(5): 55-56

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Altruistic discourse and therapeutic misconception in research informed consent
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Improving medicine through research and the constitutive nature of altruism
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Maloney, Dennis M.
Court examines fairness of settlement between defendants and research subjects
Human Research Report 2006 September; 21(9): 8
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http://bioethics.net (link may be outdated)
Procedural misconceptions and informed consent: insights from empirical research on the clinical trials industry
Fisher, Jill A.
Kennedy Institute of Ethics Journal 2006 September; 16(3): 251-268

Abstract: This paper provides a simultaneously reflexive and analytical framework to think about obstacles to truly informed consent in social science and biomedical research. To do so, it argues that informed consent often goes awry due to procedural misconceptions built into the research context. The concept of procedural misconception is introduced to describe how individuals respond to what is familiar in research settings and overlook what is different. In the context of biomedical research, procedural misconceptions can be seen to function as root causes of therapeutic misconceptions.

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Draft guidance for institutional review boards, clinical investigators, and sponsors; exception from informed consent requirements for emergency research: notice
United States. Food and Drug Administration [FDA]
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Medicare's requirement for research participation as a condition of coverage: is it ethical?
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Informed consent: a delicate balance
Glick, Michael
Journal of the American Dental Association 2006 August; 137(8): 1060, 1062, 1064

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Randomized consent designs in randomized controlled trials: systematic literature search
Schellings, Ron; Kessels, Alfons G.; ter Riet, Gerben; Knoottnerus, J. André; Sturmans, Ferd
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Sugarman, Jeremy; Paasche-Orlow, Michael
Confirming comprehension of informed consent as a protection of human subjects
Journal of General Internal Medicine 2006 August; 21(8): 898-899
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Sudore, Rebecca L.; Landefeld, C. Seth; Williams, Brie A.; Barnes, Deborah E.; Lindquist, Karla; Schillinger, Dean
Use of a modified informed consent process among vulnerable patients: a descriptive study
Journal of General Internal Medicine 2006 August; 21(8): 867-873
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Perna, M.A.
"Fair's fair argument" and voluntarism in clinical research: but, is it fair?
Journal of Medical Ethics 2006 August; 32(8): 478-482
Abstract: This article sets out to counteract HM Evans's "fair's fair argument" in support of abolishing veto to research participation. Evans's argument attempts to assimilate ordinary clinical practice to clinical research. I shall refer to this attempt as "assimilation claim". I shall attempt to show that this assimilation, as it is carried out in Evans's argument, is misleading and, ultimately, logically undermines the conclusion. I shall then proceed to show that when the fair's fair argument is proposed independently of the assimilation claim, Evans's conclusion is not unavoidable and possible alternatives are equally open within the terms of the argument itself.
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Abboud, P-A.; Heard, K.; Al-Marshad, A.A.; Lowenstein, S.R.
What determines whether patients are willing to participate in resuscitation studies requiring exception from informed consent?
Journal of Medical Ethics 2006 August; 32(8): 468-472
Abstract: OBJECTIVES: To examine the willingness of patients to participate in a resuscitation study that requires exception from informed consent and to determine if willingness to participate is associated with demographic and other characteristics. METHODS: Adult patients in an emergency department and in a geriatric outpatient clinic were surveyed. Patients were asked to imagine that they presented to an emergency department with cardiac arrest and asked about their willingness to (1) receive a new drug outside of a study, (2) receive a new drug as part of a study and (3) participate in a randomised controlled trial (RCT) for a new drug. Patients were also asked about participation in studies of invasive procedures. RESULTS: 213 patients from a geriatric clinic and 207 from an emergency department were surveyed. Two thirds of patients from the geriatric clinic and 83% from the emergency department were willing to receive an experimental drug outside of a study. Patients were less willing to participate in a study of the new drug and even less likely to participate in an RCT for the new drug (chi(2) test for trend, p<0.001 for both settings). Patients were less likely to participate in a study of thoracotomy than in a study that required placement of a femoral catheter (p = 0.008 for the geriatric clinic, p = 0.01 for the emergency department). Willingness to participate was not associated with trust in the doctors. CONCLUSIONS: Study design and invasiveness of the
intervention were associated with the willingness of patients to participate in resuscitation studies that require exception from informed consent.

Document 610

Allmark, P.; Mason, S.

Improving the quality of consent to randomised controlled trials by using continuous consent and clinician training in the consent process

Journal of Medical Ethics 2006 August; 32(8): 439-443

Abstract: OBJECTIVE: To assess whether continuous consent, a process in which information is given to research participants at different stages in a trial, and clinician training in that process were effective when used by clinicians while gaining consent to the Total Body Hypothermia (TOBY) trial. The TOBY trial is a randomised controlled trial (RCT) investigating the use of whole-body cooling for neonates with evidence of perinatal asphyxia. Obtaining valid informed consent for the TOBY trial is difficult, but is a good test of the effectiveness of continuous consent.

METHODS: Semistructured interviews were conducted with 30 sets of parents who consented to the TOBY trial and with 10 clinicians who sought it by the continuous consent process. Analysis was focused on the validity of parental consent based on the consent components of competence, information, understanding and voluntariness.

RESULTS: No marked problems with consent validity at the point of signature were observed in 19 of 27 (70%) couples. Problems were found mainly to lie with the competence and understanding of the parents: mothers, particularly, had problems with competence in the early stages of consent. Problems in understanding were primarily to do with side effects. Problems in both competence and understanding were observed to reduce markedly, particularly for mothers, in the post-signature phase, when further discussion took place. Randomisation was generally understood but unpopular. Information was not always given by clinicians in stages during the short period available before parents gave consent. Most clinicians, however, were able to give follow-up information.

DISCUSSION: Consent validity was found to compare favourably with similar trials examined in the Euricon study.

CONCLUSION: Adopting the elements of the continuous consent process and clinician training in RCTs should be considered by researchers, particularly when they have concerns about the quality of consent they are likely to obtain by using a conventional process.

Document 611

Iltis, Ana

Lay concepts in informed consent to biomedical research: the capacity to understand and appreciate risk

Bioethics 2006 August; 20(4): 180-190

Abstract: Persons generally must give their informed consent to participate in research. To provide informed consent persons must be given information regarding the study in simple, lay language. Consent must be voluntary, and persons giving consent must be legally competent to consent and possess the capacity to understand and appreciate the information. This paper examines the relationship between the obligation to disclose information regarding risks and the requirement that persons have the capacity to understand and appreciate the information. There has been insufficient attention to the extent to which persons must be able to understand and appreciate study information in order to have their consent deemed valid when the information is provided in simple, lay language. This paper argues that (1) the capacity to understand and appreciate information that should be deemed necessary to give valid consent should be defined by the capacity of the typical, cognitively normal adult and (2) the capacity of the typical, cognitively normal adult to understand and appreciate the concept of risk is limited. Therefore, (3) all things being equal, potential subjects must possess a limited capacity to understand and appreciate risk to be deemed competent to consent to research participation. (4) In some cases investigators ought to require that persons possess a greater than typical capacity to understand and appreciate risk.
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Singleton, Peter; Wadsworth, Michael
Confidentiality and consent in medical research: consent for the use of personal medical data in research
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Wendler, David
One-time general consent for research on biological samples: is it compatible with the health insurance portability and accountability act?
Archives of Internal Medicine 2006 July 24; 166(14): 1449-1452
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Kalra, Dipak; Gertz, Renate; Singleton, Peter; Inskip, Hazel M.
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Are placebos in advanced cancer trials ethically justified?
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Schrag, Brian
Research with groups: group rights, group consent, and collaborative research
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Maloney, Dennis M.
In court: court approves settlement between defendants and former research subjects
Human Research Report 2006 July; 21(7): 8

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Blackwood, Bronagh
Informed consent for research in critical care: implications for nursing
Nursing in Critical Care 2006 July-August; 11(4): 151-153

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Ungar, David; Joffe, Steven; Kodish, Eric
Children are not small adults: documentation of assent for research involving children
Journal of Pediatrics 2006 July; 149(1, Supplement): S31-33

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A developmental approach to child assent for nontherapeutic research

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Murff, Harvey J.; Pichert, James W.; Byrne, Daniel W.; Hedstrom, Christa; Black, Margo; Churchill, Larry; Speroff, Ted
General clinical research center staff nurse perceptions and behaviors regarding informed consent: results of a national survey
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When informed consent is not required for research

Dimond, Bridgit
Dermatology: obtaining patient consent in clinical trials
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Informed consent for research and authorization under the health insurance portability and accountability act
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Maloney, Dennis M.

The defendants must attempt to find all former research subjects

Human Research Report 2006 May; 21(5): 8

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Providing research participants with findings from completed cancer-related clinical trials: not quite as simple as it sounds [opinion]

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Communication and informed consent in phase 1 trials: a review of the literature

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No trial needed when financial settlement benefits the former research subjects
Human Research Report 2006 April; 21(4): 8
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Dalton, Rex
Trauma trials leave ethicists uneasy [news]
Nature 2006 March 23; 440(7083): 390-391
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Intensive Care Medicine 2006 March; 32(3): 439-444
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JGIM: Journal of General Internal Medicine 2006 March; 21(3): 279-280
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Wendler, David
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Placebo, meaning, and health
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Bell, H.; Busch, N. Bridget; DiNitto, D.
Can you ask that over the telephone? Conducting sensitive or controversial research using random-digit dialing
**Abstract:** Social science, medical, and legal researchers often study sensitive or controversial topics and behaviors. This research raises methodological and ethical issues. Using examples from the literature and a recent statewide telephone prevalence survey on sexual assault, we focus on the relative merits of various survey methods, especially those employing new technologies; developing instrumentation that includes explicit behavioral questions; obtaining an appropriate sample in a cost efficient way; gaining informed consent and inquiring about sensitive topics while protecting participants from harm or retraumatization; presenting findings in a way that does not further stigmatize participants; and responding to the media.

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**Document 656**

Marshall, Patricia A.

**Informed consent in international health research**


**Abstract:** Informed consent is universally recognized as a central component of ethical conduct in scientific research. Investigators working with diverse populations throughout the world face myriad challenges. The application of standards for informed consent can be daunting for researchers when they face the pragmatic constraints of the field and the reality of cultural beliefs about consent that may be in direct conflict with regulatory requirements. This paper explores cultural and social factors underlying informed consent for health research with diverse populations in international settings. Sociocultural influences on comprehension of information, perceptions of risk, and beliefs regarding decisional authority are reviewed. The implications of power inequities between study sponsors, researchers and participants are also considered. Issues associated with the development and preparation of consent forms, including translation and documentation are highlighted. Recommendations for good practices are outlined and future directions for research are explored.

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**Document 657**

Willis, Gordon

**Cognitive interviewing as a tool for improving the informed consent process**


**Abstract:** Consent materials often contain complex information, legalese, and other features that render them difficult to comprehend in such a way that consent is truly informed. I propose that researchers adapt cognitive interviewing, normally used for the pretesting of survey questionnaires, to evaluate the understandability of consent materials and the way which subjects use this information to make decisions regarding participation. Cognitive interviewing involves the intensive probing of small samples of volunteer subjects to elucidate thought processes that otherwise remain hidden. Cognitive interviewing can be applied: (a) to further the basic science of informed consent; (b) to pretest materials for a specific study; and (c) as embedded procedure for assessing subject thought processes in the course of obtaining consent.

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Ross, Colin A.

**The sham ECT literature: implications for consent to ECT**

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Lancet Oncology 2006 March; 7(3): 266-269

Naarden, Allan L.; Cissik, John
Inform consent [opinion]
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Kipnis, Ken; King, Nancy M.P.; Nelson, Robert M.
Trials and errors: barriers to oversight of research conducted under the emergency research consent waiver

Hyder, Adnan A.; Wali, Salman A.
Informed consent and collaborative research: perspectives from the developing world
Developing World Bioethics 2006 March; 6(1): 33-40

Abstract: Introduction: Informed consent has been recognized as an important component of research protocols and procedures of disclosure and consent in collaborative research have been criticized, as they may not be in keeping with cultural norms of developing countries. This study, which is part of a larger project funded by the United States National Bioethics Advisory Commission, explores the opinions of developing country researchers regarding informed consent in collaborative research. Methods: A survey of developing country researchers, involved in human subject research, was conducted by distributing a questionnaire with 169 questions, which included questions relating to informed consent. In addition, six focus group discussions, eight in-depth interviews and 78 responses to open-ended questions in the questionnaire provided qualitative data. Results: 203 surveys were considered complete and were included in the analysis. Written consent was not used by nearly 40% of the researchers in their most recent studies. A large proportion of respondents recommended that human subject regulations should allow more flexibility in ways of documenting informed consent. 84% of researchers agreed that a mechanism to measure understanding should be incorporated in research studies as part of the process of informed consent. Discussion: This paper is an empirical step in highlighting the ethical issues concerning disclosure. Health researchers in developing countries are well aware of the importance of consent in health research, and equally value the significance of educating human subjects regarding study protocols and associated risks and benefits. However, respondents emphasize the need for modifying ethical regulations in collaborative research.

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Journal of Clinical Oncology 2006 February 20; 24(6): 891-897

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**Disclosure of HIV status on informed consent forms presents an ethical dilemma for protection of human subjects**

Journal of Acquired Immune Deficiency Syndromes 2006 February 1; 41(2): 246-248

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Morris, Norma; Bálmer, Brian

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Social Science and Medicine 2006 February; 62(4): 998-1008

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Protecting participants in family medicine research: a consensus statement on improving research integrity and participants' safety in educational research, community-based participatory research, and practice network research
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Maloney, Dennis M.
Defendants claim that research subjects do not qualify for a class action lawsuit
Human Research Report 2006 February; 21(2): 8
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New approach to informed consent and privacy issues
Human Research Report 2006 February; 21(2): 4
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Dunn, Laura B.; Palmer, Barton W.; Keehan, Monique
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Brief report on the experience of using proxy consent for incapacitated adults
Journal of Medical Ethics 2006 January; 32(1): 61-62
Abstract: The Medicines for Human Use (Clinical Trials) Regulations 2004, which came into force in the UK in May 2004, cover the conduct of clinical trials on medicinal products. They allow a legal representative (a person not connected with the conduct of the trial) to consent to the participation of incompetent adults in medical research. Currently, very little is known about how such representatives will make their decisions. We have experience with proxy consent for older adults in a large, national trial. From 2445 potentially eligible but incapacitated patients, proxy, relative assent resulted in trial participation of only 87 (3.6%) patients. The reasons for this were that a large number of incapacitated patients had no relative available for assent (2286), but also a high proportion of relatives approached refused to provide assent (72/159, 45.3%). In comparison, 17.7% of patients declined participation in the trial. Proxy consent allowed only a small increase in trial recruitment of incapacitated patients. The fact that a greater proportion of relatives than patients refused to provide assent implies that they were more cautious than the patients themselves, or perhaps used different criteria, when making their decision. In future research involving incapacitated older patients there is likely to be heavy reliance on proxy consent provision by legal representatives. Our findings imply that consent decisions of legal representatives will not necessarily reflect those of patients themselves.
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Appelbaum, Paul S.
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Jeste, Dilip V.; Depp, Colin A.; Palmer, Barton W.
Magnitude of impairment in decisional capacity in people with schizophrenia compared to normal subjects: an overview

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Carpenter, William T.
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Tharyan, Prathap
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Protection of human subjects and scientific progress: can the two be reconciled? [reply]
Jansen, Lynn

Protection of human subjects and scientific progress: can the two be reconciled? [reply]
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The informed consent process.


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Jafarey, Aamir

Informed consent: views from Karachi


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Gu, Shi (Mark)

The ethics of placebo-controlled studies on perinatal HIV transmission and its treatment in the developing world


Abstract: Perinatal HIV transmission in the United States has been greatly reduced since the 1993 discovery of zidovudine, known as protocol 076. However, a feasible treatment in developing countries has not yet been found due to the high cost and medical standards needed to implement protocol 076. This presents an ethical question: whether placebo or active control should be used in testing new treatments. Proponents of a placebo control argue that a placebo control is the only method that provides definitive evidence of efficacy and side-effects, especially important given the scarce financial resources present in developing countries. Critics, however, argue that the use of a placebo controlled study when an effective treatment exists would be jeopardizing the health of individuals in developing countries. The key to resolving this debate is realizing that protocol 076 would not necessarily be effective when transplanted to developing countries due to the lack of adequate medical infrastructure, malnutrition, prevalence of disease, and low standard of living—it is not certain protocol 076 would be better than placebo at all. Following this line of reasoning, quite a few placebo-controlled studies on perinatal HIV treatment have already been performed. Upon examination of this accumulated evidence, one finds that protocol 076, and shortened courses of it, are indeed effective in non-breastfeeding participants in developing countries; however, no treatment has been proven effective for breastfeeding populations. Therefore, it would be ethical to conduct placebo-controlled studies on breastfeeding populations, but not on non-breastfeeding populations.
Inclusion of patients with severe mental illness in clinical trials: issues and recommendations surrounding informed consent
Welie, Sander P.K.; Berghmans, Ron L.P.
CNS Drugs 2006; 20(1): 67-83

Randomization, informed consent and physicians' communication skills in pediatric oncology: a delicate balance
Massimo, Luisa M.; Wiley, Thomas J.
Bulletin du Cancer 2005 December 1; 92(12): E67-E69

Informed consent
Zink, Sheldon; Wertlieb, Stacey; Kimberly, Laura

Public perception of emergency research: a questionnaire
Booth, Malcolm G.; Lind, A.; Read, E.; Kinsella, J.
European Journal of Anaesthesiology 2005 December; 22(12): 933-937

Quantitative aspects of informed consent: considering the dose response curve when estimating quantity of information
Lynoe, N; Hoeyer, K.
Journal of Medical Ethics 2005 December; 31(12): 736-738
Abstract: Information is usually supposed to be a prerequisite for people making decisions on whether or not to participate in a clinical trial. Previously conducted studies and research ethics scandals indicate that participants have sometimes lacked important pieces of information. Over the past few decades the quantity of information believed to be adequate has increased significantly, and in some instances a new maxim seems to be in place: the more information, the better the ethics in terms of respecting a participant's autonomy. The authors hypothesise that the dose-response curve from pharmacology or toxicology serves as a model to illustrate that a large amount of written information does not equal optimality. Using the curve as a pedagogical analogy when teaching ethics to students in clinical sciences, and also in engaging in dialogue with research institutions, may promote reflection on how to adjust information in relation to the preferences of individual participants, thereby transgressing the maxim that more information means better ethics.
Document 702
Moodley, K.; Pather, M.; Myer, L.
**Informed consent and participant perceptions of influenza vaccine trials in South Africa**
Journal of Medical Ethics 2005 December; 31(12): 727-732

**Abstract:** BACKGROUND AND OBJECTIVES: There are few insights from sub-Saharan Africa on research participants' experiences of the informed consent process, particularly in the context of randomised controlled trials, where issues of randomisation and the use of placebos may be confusing concepts for participants. This study investigated the knowledge and perceptions of the informed consent process among individuals participating in influenza vaccine trials in two disadvantaged communities in South Africa.

**Method:** Four to 12 months after completion of the trials, participants were contacted to return to participate in the informed consent study. The semistructured questionnaire administered to assess recall of trial procedures and the informed consent process covered key issues including: purpose of the study; awareness that the study was not part of routine treatment; voluntary nature of participation and freedom to withdraw; randomisation; placebos; and remuneration.

**RESULTS:** A total of 334 participants (93% of the original vaccine trial sample; mean age 68 years, median level of education grade 8, 69% women) completed the questionnaire. Only 21% were able to recall that they were allocated randomly to the different treatment arms. Only 19% of those involved in the placebo controlled study had interpreted the concept of placebo as an inactive medication.

**CONCLUSION:** Although a good general recall of trial concepts was demonstrated, only a small proportion of the participants correctly interpreted and recalled the concepts of randomisation and placebos. Informed consent in this and similarly disadvantaged communities may often be inadequate and new ways to improve understanding of the research process should be explored.

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Document 703
Maloney, Dennis M.
**Plaintiffs claim that research subject was too drowsy to give informed consent**
Human Research Report 2005 December; 20(12): 8

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

Document 704
Miller, Franklin G.; Moreno, Jonathan D.
**Informed consent and the ethics of clinical research: reply to commentaries**

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

Document 705
Evans, H.M.
**Response to F.G. Miller and J.D. Moreno, "The state of research ethics: a tribute to John C. Fletcher"**

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Document 706

* Article
policy-makers
Georgetown users check Georgetown Journal Finder for access to full text

* Document 713
Vester, A.E.; Christensen, E.F.; Andersen, S.K.; Tonnesen, E.
Ethical and practical problems in blood sampling for research purposes during pre-hospital emergencies
Acta Anaesthesiologica Scandinavica 2005 November; 49(10): 1540-1543
Georgetown users check Georgetown Journal Finder for access to full text

* Document 714
Sivarajah, Neeraja
Neuroregenerative gene therapy: the implications for informed consent laws
Health Law in Canada 2005 November; 26(2): 19-28
Georgetown users check Georgetown Journal Finder for access to full text

* Document 715
Eriksson, S.; Helgesson, Gert
Keep people informed or leave them alone? A suggested tool for identifying research participants who rightly want only limited information
Journal of Medical Ethics 2005 November; 31(11): 674-678
Abstract: People taking part in research vary in the extent to which they understand information concerning their participation. Since they may choose to limit the time and effort spent on such information, lack of understanding is not necessarily an ethical problem. Researchers who notice a lack of understanding are in the quandary of not knowing whether this is due to flaws in the information process or to participants' deliberate choices. We argue that the two explanations call for different responses. A tool for identifying those research participants who want limited information is presented. This consists of a restricted number of questions about trust in and appraisal of research, priority of time and privacy, and perception of a duty to participate. It is argued that an important group of participants who purposely lack understanding of the study can be identified with this tool. Some limitations to this approach are also discussed.
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http://www.jmedethics.com (link may be outdated)

* Document 716
Helgesson, Gert; Ludvigsson, J.; Gustafsson Stolt, U.
How to handle informed consent in longitudinal studies when participants have a limited understanding of the study
Journal of Medical Ethics 2005 November; 31(11): 670-673
Abstract: Empirical findings from a Swedish longitudinal screening study show that many of the research subjects had a limited understanding of the study. Nevertheless they were satisfied with the understanding they had and found it sufficient for informed continued participation. Were they wrong? In this paper, it is argued that the kind of understanding that is morally required depends partly on the kind of understanding on which the research subjects want to base their decisions, and partly on what kind of knowledge they lack. Researchers must ensure that the information process is not flawed and that participants receive the information they want. To achieve this, new information efforts may be needed. Researchers must also ensure that research subjects have knowledge about aspects of importance to them. Lack of understanding may, however, be the result of conscious choices by research
subjects to disregard some of the information because it is not important to them. Such choices should normally be respected.

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Document 717

Stead, Martine; Eadie, D.; Gordon, D.; Angus, K.

"Hello, hello -- it's English I speak!": a qualitative exploration of patients' understanding of the science of clinical trials

Journal of Medical Ethics 2005 November; 31(11): 664-669

**Abstract:** Informed consent may be seriously compromised if patients fail to understand the experimental nature of the trial in which they are participating. Using focus groups, the authors explored how prospective trial participants interpret and understand the science of clinical trials by using patient information sheets relative to their medical condition. An opportunity was provided to hear in the patients' own words how they interpret the information and why there is variable understanding. Respondents struggled to comprehend the meaning and purpose of concepts such as randomisation and double blinding, and found them threatening to their ideas of medical care. Suggestions are made about how to improve the national guidelines on written information for trial participants and pretesting of the information sheets is advocated.

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

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Document 718

Kass, Nancy E.; Maman, Suzanne; Atkinson, Joan

Motivations, understanding, and voluntariness in international randomized trials


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Document 719

Maloney, Dennis M.

Complaint alleges that informed consent procedures were used after experiment began


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Document 720

Polgar, Stephen; Ng, Joanna

Ethics, methodology and the use of placebo controls in surgical trials


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Document 721

Al-Shahi, Rustam; Vousden, Celine; Warlow, Charles
Bias from requiring explicit consent from all participants in observational research: prospective, population based study
BMJ: British Medical Journal 2005 October 22; 331(7522): 942- 945

Abstract: OBJECTIVE: To evaluate the differences between adults who consent to participate in observational research, and those who do not. DESIGN: Prospective, population based cohort study. SETTING: Primary and secondary care throughout Scotland. PARTICIPANTS: 187 adults (aged > or = 16 years) resident in Scotland at the time of their first diagnosis of a brain arteriovenous malformation in 1999-2002. INTERVENTION: Postal consent form sent via participants’ general practitioner. MAIN OUTCOME MEASURES: Differences between consenters and non-consenters in demographic and clinical features at first presentation, and outcome during follow-up. RESULTS: 111 adults (59%) consented to participate in the study. These consenters were not significantly different from non-consenters in age, sex, or socioeconomic status at first presentation. However, consenters were significantly more likely than non-consenters to present alive and independent, and with a seizure. During follow-up, consenters were significantly more likely to receive interventional treatment. Although consenters' survival was significantly better, they were more likely to have a seizure during follow-up. Presentation with intracranial haemorrhage conferred a higher risk of subsequent haemorrhage when the whole cohort was analysed, but not when it was restricted to consenters. CONCLUSIONS: We have found differences between adults who consent to participate in observational records-based research and those who do not, or cannot, consent. Blanket requirements for explicit consent for the use of individuals' identifiable data can bias disease registers, epidemiological studies, and health services research.

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*  Document 722
Junghans, Cornelia; Feder, Gene; Hemingway, Harry; Timmis, Adam; Jones, Melvyn
Recruiting patients to medical research: double blind randomised trial of "opt-in" versus "opt-out" strategies
BMJ: British Medical Journal 2005 October 22; 331(7522): 940- 942

Abstract: OBJECTIVE: To evaluate the effect of opt-in compared with opt-out recruitment strategies on response rate and selection bias. DESIGN: Double blind randomised controlled trial. SETTING: Two general practices in England. PARTICIPANTS: 510 patients with angina. INTERVENTION: Patients were randomly allocated to an opt-in (asked to actively signal willingness to participate in research) or opt-out (contacted repeatedly unless they signalled unwillingness to participate) approach for recruitment to an observational prognostic study of patients with angina. MAIN OUTCOME MEASURES: Recruitment rate and clinical characteristics of patients. RESULTS: The recruitment rate, defined by clinic attendance, was 38% (96/252) in the opt-in arm and 50% (128/258) in the opt-out arm (P = 0.014). Once an appointment had been made, non-attendance at the clinic was similar (20% opt-in arm v 17% opt-out arm; P = 0.86). Patients in the opt-in arm had fewer risk factors (44% v 60%; P = 0.053), less treatment for angina (69% v 82%; P = 0.010), and less functional impairment (9% v 20%; P = 0.023) than patients in the opt-out arm. CONCLUSIONS: The opt-in approach to participant recruitment, increasingly required by ethics committees, resulted in lower response rates and a biased sample. We propose that the opt-out approach should be the default recruitment strategy for studies with low risk to participants.

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*  Document 723
Baylis, François; Ram, Natalie
Eligibility of cryopreserved human embryos for stem cell research in Canada

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http://www.bmj.com (link may be outdated)
Document 724

Barnes, L; Matthews, F. E.; Barber, B.; Davies, L.; Lloyd, D.; Brayne, C.; Parry, B.

**Brain donation for research: consent and re-consent post Alder Hey**
Bulletin of Medical Ethics 2005 October-November; (211): 17-21

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Documento 725

**Amending the clinical trials regulations** [news]
Bulletin of Medical Ethics 2005 October-November; (211): 7-8

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Documento 726

Coats, T.J.; Shakur, H.

**Consent in emergency research: new regulations**
Emergency Medicine Journal 2005 October; 22(10): 683-685

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Documento 727

Jacobson, Gloria A.

**Vulnerable research participants: anyone may qualify**

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Documento 728

Riessman, Catherine Kohler; Mattingly, Cheryl

**Introduction: toward a context-based ethics for social research in health**
Health (London) 2005 October; 9(4): 427-429

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Documento 729

Blixen, Carol E.; Agich, G.J.

**Stroke patients' preferences and values about emergency research**
Journal of Medical Ethics 2005 October; 31(10): 608-611

**Abstract:** BACKGROUND: In the USA, the Food and Drug Administration waiver of informed consent permits certain emergency research only if community consultation occurs. However, uncertainty exists regarding how to define the community(ies) or their representatives. OBJECTIVE: To collect data on the actual preferences and values of a group-those at risk for stroke-most directly affected by the waiver of informed consent for emergency research.
DESIGN: Face to face focused interviews were conducted with 12 patients who were hospitalised with a stroke diagnosis in the previous year. The interviews were audiotaped and a transcript based method was used for their analysis. RESULTS: All 12 participants felt "that it was important that new treatments for stroke be developed", but they were initially confused about the distinction between "research for stroke" and "emergency research for stroke". However, after explanation, most (n = 10; 83%) expressed willingness to participate in the latter. In the absence of a surrogate to give informed consent in a stroke emergency situation, the majority (n = 11; 92%) said they would want the physician to "go ahead and enrol them in the trial". CONCLUSIONS: This study is the first to identify the values and concerns of individuals most directly affected by stroke emergency research. Further interviews and focus groups are needed to develop and test a validated questionnaire on the preferences and values surrounding emergency research for stroke.

http://www.jmedethics.com (link may be outdated)
Kachuck, Norman J.

**Challenges and opportunities: what we are learning from the clinical natalizumab experience**

Expert Review of Neurotherapeutics 2005 September; 5(5): 605-615

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London, Alex John

**Undue inducements and reasonable risks: will the dismal science lead to dismal research ethics? [comment]**

American Journal of Bioethics 2005 September-October; 5(5): 29-32

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Reid, Lynette

**Nice work if you can get it [comment]**


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VanderWalde, Ari

**Undue inducement: the only objection to payment? [comment]**


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McGregor, Joan

**'Undue inducement' as coercive offers [comment]**

American Journal of Bioethics 2005 September-October; 5(5): 24-25

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[http://bioethics.net](http://bioethics.net) (link may be outdated)
Document 740
Schonfeld, Toby L.; Brown, Joseph S.; Gordon, Bruce G.
Subject protection and the risk-benefit relationship [comment]
American Journal of Bioethics 2005 September-October; 5(5): 22-23
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http://bioethics.net (link may be outdated)

Document 741
Klitzman, Robert
The importance of social, cultural, and economic contexts, and empirical research in examining "undue inducement" [comment]
American Journal of Bioethics 2005 September-October; 5(5): 19-21
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Document 742
Vanderpool, Harold Y.
A quartet of criticisms [comment]
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http://bioethics.net (link may be outdated)

Document 743
Brody, Howard
The welcome reassessment of research ethics: is "undue inducement" suspect? [comment]
American Journal of Bioethics 2005 September-October; 5(5): 15-16
Georgetown users check Georgetown Journal Finder for access to full text
http://bioethics.net (link may be outdated)

Document 744
Fost, Norman
Gather ye shibboleths while ye may [comment]
Georgetown users check Georgetown Journal Finder for access to full text
http://bioethics.net (link may be outdated)
Document 745

Emanuel, Ezekiel J.

Undue inducement: nonsense on stilts?

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Document 746

Glass, Kathleen Cranley; Waring, Duff

The physician/investigator's obligation to patients participating in research: the case of placebo controlled trials
Journal of Law, Medicine and Ethics 2005 Fall; 33(3): 575-585

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Document 747

Geluda, Katia; Bisaglia, Joana Buarque; Moreira, Vivian; Maldonado, Beatriz Motta; Cunha, Antônio J.L.A.; Trajman, Anete

Third-party informed consent in research with adolescents: the good, the bad and the ugly
Social Science and Medicine 2005 September; 61(5): 985-988

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Document 748

Dawson, Liza; Kass, Nancy E.

Views of US researchers about informed consent in international collaborative research
Social Science and Medicine 2005 September; 61(6): 1211-1222

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Document 749

Halila, Ritva; Lotjonen, Salla

Children and medical research
Medicine and Law: World Association for Medical Law 2005 September; 24(3): 505-513

Abstract: A considerable proportion of medical treatments for children are based on estimates and assumptions rather than clinical evidence. Clinical research on children provokes intensive discussion internationally. While children are protected from the risks of clinical trials, they are hindered from receiving the benefits of pharmaceutical innovations obtained by adults. The recruitment of children into research trials is more complicated than that of adults for several reasons: 1) the physical size and relative water content of the body differs not just compared to adults but also amongst subgroups of children making the group of potential participants relatively small; 2) diseases common among adults may be rare among children and vice versa; 3) children's ability to understand the significance of a study varies and depends on the age and developmental stage of the child; and 4) depending on the level of understanding, differing views have been given on the degree of respect that should be paid to a child's right to consent, assent, or refuse to participate in a trial. We suggest that: 1) the number of children recruited in research trials should be kept as small as possible, but large enough to enable scientifically valid results; 2) special training should be made mandatory for researchers who study diseases of children; 3) children or adolescents should participate in decision-making that concerns them whenever possible; and 4) in minor procedures, the consent of just
one parent is sufficient.

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Orentlicher, David

**Making research a requirement of treatment: why we should sometimes let doctors pressure patients to participate in research**

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[http://www.jstor.org/action/showPublication?journalCode=hastcentrepo](http://www.jstor.org/action/showPublication?journalCode=hastcentrepo) (link may be outdated)

* Document 751
Sabik, Lindsay; Pace, Christine A.; Forster-Gertner, Heidi P.; Wendler, David; Bebchuk, Judith D.; Tavel, Jorge A.; McNay, Laura A.; Killen, Jack; Emanuel, Ezekiel J.; Grady, Christine

**Informed consent: practices and views of investigators in a multinational clinical trial**

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* Document 752
Maloney, Dennis M.

**Complaint alleges "coercion" and "undue influence" in IRB- approved consent form**
Human Research Report 2005 September; 20(9): 8

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* Document 753
Maloney, Dennis M.

**Informed consent is required for vaccine**
Human Research Report 2005 September; 20(9): 5

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Gibson, Katie

**South Africa: book publisher ordered to pay damages for disclosing women's HIV status**

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Dein, Simon; Bhui, Kamaldeep

**Issues concerning informed consent for medical research among non-westernized ethnic minority patients in the UK**


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* Document 756

Cone, David C.; O'Connor, Robert E.

**Are US informed consent requirements driving resuscitation research overseas?**

Resuscitation 2005 August; 66(2): 141-148

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* Document 757

Adam, Dieter; Kasper, S.; Moller, H.J.; Singer, E.A.

**Placebo-controlled trials in major depression are necessary and ethically justifiable: how to improve the communication between researchers and ethical committees**

European Archives of Psychiatry and Clinical Neuroscience 2005 August; 255(4): 258-260

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* Document 758

Russell, F.M.; Carapetis, J.R.; Liddle, H.; Edwards, T.; Ruff, T.A.; Devitt, J.

**A pilot study of the quality of informed consent materials for Aboriginal participants in clinical trials**

Journal of Medical Ethics 2005 August; 31(8): 490-494

*Abstract*: **OBJECTIVE**: To pilot informed consent materials developed for Aboriginal parents in a vaccine trial, and evaluate their design and the informed consent process. **METHODS**: Cross sectional quantitative and qualitative survey of 20 Aboriginal and 20 non-Aboriginal women in Alice Springs. Information about the proposed research was presented to Aboriginal participants by an Aboriginal researcher, using purpose designed verbal, visual, and written materials. Non-Aboriginal participants received standard materials developed by the sponsor. Questionnaires were used to evaluate recall and understanding immediately and five days later. Qualitative analysis of Aboriginal participants’ interviews was performed. **RESULTS**: There were no differences between the groups in understanding of diseases prevented by the vaccine, the potential risks of participating, or the voluntary nature of participation. Most Aboriginal participants had difficulty with the concept of a "licensed" versus "unlicensed" vaccine. The non-Aboriginal group had a good understanding of this. Aboriginal participants identified the use of the flipchart, along with a presentation by a doctor and Aboriginal health worker, as preferred delivery modes. Group presentations were preferred rather than one-on-one discussions. The use of the questionnaire posed considerable methodological difficulties. **CONCLUSIONS**: A one-off oral presentation to Aboriginal participants is unlikely to produce "informed consent". Key but unfamiliar concepts require identification and particularly considered presentation.

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**Informed consent to research and ethnic minority patients** [news]

Bulletin of Medical Ethics 2005 August-September; (210): 5-6

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Bernstein, Mark
**Fully informed consent is impossible in surgical clinical trials**
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Document 761
Maloney, Dennis M.
**Former human subjects sue over their allegations of inadequate informed consent**
Human Research Report 2005 August; 20(8): 8
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Document 762
Diallo, Dapa A.; Doumbo, Ogobara K.; Plowe, Christopher V.; Wellem, Thomas E.; Emanuel, Ezekial J.; Hurst, Samia A.
**Community permission for medical research in developing countries**
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Document 763
Barrett, Roseann
**Quality of informed consent: measuring understanding among participants in oncology clinical trials**
Oncology Nursing Forum 2005 July 1; 32(4): 751-755
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Document 764
Levine, Aran
**Clinical trials research: challenges of patient education and informed consent**
Oncology Nursing Forum 2005 July; 32(4): 737-739
Georgetown users check [Georgetown Journal Finder](http://www.bullmedeth.info/) for access to full text

Document 765
Albrecht, Terrance L.; Franks, Melissa M.; Ruckdeschel, John C.
**Communication and informed consent**
Current Opinion in Oncology 2005 July; 17(4): 336-339
Georgetown users check [Georgetown Journal Finder](http://www.bullmedeth.info/) for access to full text
When is research on patient records without consent ethical? [opinion]


The ethicist: subject to research

New York Times Magazine 2005 June 26; p. 22

Suthers v. Amgen [Date of Decision: 2005 June 6]


Abstract: The United States District Court for the Southern District of New York declined to issue a preliminary injunction compelling Amgen to furnish plaintiffs Suthers and Martin with an experimental treatment for their illness. Suthers and Martin participated in a clinical trial conducted by Amgen for Parkinson's Disease. For drug delivery, catheters were surgically inserted into their brains. The plaintiffs believed the treatment beneficial, but Amgen perceived it to be a risk to them, so the trial was discontinued. The court rejected the argument that the drug company owed a duty to the patients that required it to continue experimental treatment as long as the plaintiffs requested it. Instead, the court asserted that researchers do not develop a duty to act for the best interest of specific participants as they seek the broader goal of general public benefit.

Research scandal forces Israel to tighten up supervision

Lancet 2005 June 4-10; 365(9475): 1915
Moser, David J.; Reese, Rebecca L.; Schultz, Susan K.; Benjamin, Michelle L.; Arndt, Stephan; Fleming, Frank W.; Andreasen, Nancy C.

**Informed consent in medication-free schizophrenia research**
American Journal of Psychiatry 2005 June; 162(6): 1209-1211

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

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* Article  Document 772

Thomas, C.

**The use and control of heel prick blood samples**

**Abstract:** The human body is assuming new meanings and value. When tissue, such as hair, blood and saliva is subjected to DNA analysis, detailed intimate information can be revealed about a person that may predict information about behavioural traits and future disorders. Such genetic information may lead to the development of beneficial therapeutic treatments, but it may also lead to employment or insurance discrimination. Human tissue is commonly used by law enforcement agencies to detect perpetrators of crimes and to identify corpses. There are many sources of such tissue samples. One is from samples routinely collected from newborn babies for a test known as the "Guthrie test" or heel prick test. At about two days of age the child's heel is pricked and the resultant drops of blood are applied to filter paper attached to a test card. This is dried and analysed and, in New Zealand, the cards are stored indefinitely. The potential range of research purposes using such blood samples is increasing, and expanding markets have increased their value. This paper considers the status of the samples in light of recent developments in New Zealand and suggests appropriate approaches for retention and further use of the samples, or third party access to them.

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* Article  Document 773

Kompanje, E.J.O.; Maas, A.I.R.; Hilhorst, M.T.; Slieker, F.J.A.; Teasdale, G.M.

**Ethical considerations on consent procedures for emergency research in severe and moderate traumatic brain injury**

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* Article  Document 774

Satin, David J.

**More realism about informed consent**

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* Article  Document 775

Schellings, Ron; Kessels, Alfons G.; ter Riet, Gerben; Kleijnen, Jos; Leffers, Pieter; Knottnerus, J. Andre; Sturmans, Ferd

**Members of research ethics committees accepted a modification of the randomized consent design**

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**Document 776**

McMillan, Gigi

*What do researchers say? What do subjects hear? Not what they would like to hear. What do subjects need?*

More information
Protecting Human Subjects 2005 Summer; (12): 10-11

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Cyranoski, David

*Consenting adults? Not necessarily... [news]*

Nature 2005 May 12; 435(7039): 138-139

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White, Jerolee

*Discussion of patient recruitment and the informed consent process in clinical drug trials*

Nephrology Nursing Journal 2005 May-June; 32(3): 354

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**Document 779**

Edward, Sarah J.L.; Stevens, Andrew J.; Braunholtz, David A.; Lilford, Richard J.; Swift, Teresa

*The ethics of placebo-controlled trials: a comparison of inert and active placebo controls*


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**Document 780**

Mirarchi, Nina M.

*Clinical research on the subject with dementia: ethical concerns and research regulation*


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Farber, N.J.; Castellano, J.; Leary-Prowse, J.

*A survey of clinical research investigators and clinical research coordinators about the process of informed consent [abstract]*

JGIM: Journal of General Internal Medicine 2005 April; 20(Supplement 1): 167

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Littenberg, B.; Maclean, C.D.
Waiver of alteration of consent for clinical research [abstract]
JGIM: Journal of General Internal Medicine 2005 April; 20(Supplement 1): 90

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Ferris, Ann M.; Marquis, Grace S.
Bioethics in scientific research: conflicts between subject's equitable access to participate in research and current regulations
Journal of Nutrition 2005 April; 135(4): 916-917

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Kahn, Jeffrey
Informed consent in the context of communities
Journal of Nutrition 2005 April; 135(4): 918-920

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Silverman, Henry J.; Luce, John M.; Lanken, Paul N.; Morris, Alan H.; Harabin, Andrea L.; Oldmixon, Cathryn F.; Thompson, B. Taylor; Bernard, Gordon R.
Recommendations for informed consent forms for critical care clinical trials
Critical Care Medicine 2005 April; 33(4): 867-882

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Tait, Alan R.; Voepel-Lewis, Terri; Malviya, Shobha; Philipson, Sandra J.
Improving the readability and processability of a pediatric informed consent document: effects on parents' understanding
Archives of Pediatric and Adolescent Medicine 2005 April; 159(4): 347-352

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Spigt, M.G.; Knipschild, P.G.; van Schayck, C.P.; Knottnerus, J.A.
The validity and ethics of giving placebo in a randomized nonpharmacologic trial was evaluated

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Pilon, Susan
Protecting psychiatric patients in research [comment]
Indian Journal of Medical Ethics 2005 April-June; 2(2): 59

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* Document 789
Kimmelman, J.; Palmour, N.
Therapeutic optimism in the consent forms of phase 1 gene transfer trials: an empirical analysis
Journal of Medical Ethics 2005 April; 31(4): 209-214

Abstract: BACKGROUND: "Therapeutic misconception" arises when human subjects interpret a clinical trial as aimed primarily at therapy rather than producing knowledge. Therapeutic misconceptions may be more prevalent in trials enrolling gravely ill subjects or involving novel and well publicized investigational agents. OBJECTIVE: To examine the extent to which investigators express therapeutic optimism in phase 1 human gene transfer consent documents, whether highly active gene transfer researchers are more prone to expressing therapeutic optimism, and whether consent forms have grown more optimistic in their descriptions of personal benefit over the last decade. DESIGN: Content analysis was performed on 277 consent documents to measure the number of sentences describing possibility of benefit, terminology used for experimental agents, the proportion of statements describing personal versus societal benefits, and whether investigators attempted to thwart therapeutic misconceptions. RESULTS: Consent forms generally used therapeutic terminology to describe study agents, devoted more sentences to describing possible personal benefits than to describing benefits to society, and infrequently explained that a particular benefit was unlikely. Consent documents used by highly active gene transfer researchers tended to portray significantly greater optimism about personal benefit than less active investigators, though they were also significantly more cautious with agent terminology. Finally, therapeutic optimism expressed in consent forms has declined over the past decade. CONCLUSIONS: Consent documents used in phase 1 gene transfer trials, although increasingly attentive to possible therapeutic misconceptions, are inappropriately optimistic about direct benefits of trial participation. Such optimism is expressed more emphatically in trials involving highly active gene transfer researchers as principal investigators.

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* Document 790
Maloney, Dennis M.
New recommendations for informed consent

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* Document 791
Edwards, Sarah J.L.
Research participation and the right to withdraw
**Abstract**: Most ethics committees which review research protocols insist that potential research participants reserve unconditional or absolute 'right' of withdrawal at any time and without giving any reason. In this paper, I examine what consent means for research participation and a sense of commitment in relation to this right to withdraw. I suggest that, once consent has been given (and here I am excluding incompetent minors and adults), participants should not necessarily have unconditional or absolute rights to withdraw. This does not imply that there should be a complete absence of rights, or, indeed, an abandonment of the right to withdraw. The point of this paper is to show that the supposed unconditional or absolute nature of these rights may be self-defeating and so fail to respect the autonomy of participants. In addition, and on a more positive note, I suggest that, attaching certain conditions on the right to withdraw, may better respect the autonomy of these participants by underlining the idea that autonomy is more than mere whim or indifference to the fate of others. On the contrary, research staff are currently unable to 'push' participants, who may merely have logistical difficulties unrelated to the research itself, but who really want to stay the course, for fear of coercing them. Furthermore, researchers now try to 'screen out' people they think may be unreliable to protect the science of the study and so groups at risk of dropping out may be unfairly denied access to research treatments. I conclude that on-going negotiation between the relevant parties could be on balance the only truly acceptable way forward but concede certain important limitations to take into account.

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**Research with stored biological samples: what do research participants want?**

Chen, Donna T.; Rosenstein, Donald L.; Muthappan, Palaniappan; Hilsenbeck, Susan G.; Miller, Franklin G.; Emanuel, Ezekiel J.; Wendler, David

*Archives of Internal Medicine* 2005 March 28; 165(6): 652-655

**Abstract**: BACKGROUND: There is widespread disagreement about the type of consent needed for research with stored biological samples. Many believe consent for each future use is required to respect individuals. Others worry this approach may block important research. METHODS: We analyzed 1670 consent forms signed by research participants at the Warren G. Magnuson Clinical Center, National Institutes of Health, between January 1, 2000, and May 31, 2002, that offer options for future research with participants' biological samples. The research participants were healthy volunteers, family members of affected individuals, and individuals with a broad range of medical conditions enrolled in clinical research studies with and without the prospect of direct medical benefit. RESULTS: Overall, 87.1% of research participants given the option chose to authorize future research on any medical condition. More than 85% permitted unlimited future research with their stored biological samples regardless of sex, age, geographic location, or whether the individual was affected by the disease being studied or a healthy volunteer. Only 6.7% of those given the option to refuse all future research did so. Although African Americans were less likely to permit future research, 75.0% of African Americans still authorized unlimited future research with their samples. CONCLUSIONS: Most research participants authorize the unlimited future research use of their biological samples when given the opportunity to do so. These findings suggest that providing research participants with a simple binary choice to authorize or refuse all future research might allow individuals to control use of their samples, simplify consent forms, and allow important research to proceed.

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**Lay Public's Understanding of Equipoise and Randomisation in Randomised Controlled Trials**

Becker, Gary J.

*Health Technology Assessment* 2005 March; 9(8): iii-177

**Call number**: Special Issue shelf

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**Human subjects investigation: timeless lessons of Nuremberg and Tuskegee.**
* Article  Document 795
Stang, Andreas; Hense, Hans-Werner; Jockel, Karl-Heinz; Turner, Erick H.; Tramer, Martin R.
**Is it always unethical to use a placebo in a clinical trial?**

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McCabe, Melvina; Morgan, Frank; Curley, Helen; Begay, Rick; Gohdes, Dorothy M.
**The informed consent process in a cross-cultural setting: is the process achieving the intended result?**
Ethnicity and Disease 2005 Spring; 15(2): 300-304

* Article  Document 797
Klassen, Anne F.; Lee, Shoo K.; Barer, Morris; Raina, Paminder
**Linking survey data with administrative health information: characteristics associated with consent from a neonatal intensive care unit follow-up study**

* Article  Document 798
Stolt, Ulrica Gustafsson; Helgesson, Gert; Liss, Per-Erik; Svensson, Tommy; Ludvigsson, Johnny
**Information and informed consent in a longitudinal screening involving children: a questionnaire survey**

* Article  Document 799
Wicher, Camille P.; Michalek, Arthur M.
**When is informed consent not enough?**
Journal of Cancer Education 2005 Spring; 20(1): 9-10

* Article  Document 800
McQuay, H.J.; Moore, R.A.
**Placebo**
**Document 801**

Dawson, A.; Spencer, S.A.  
**Informing children and parents about research**  
Archives of Disease in Childhood 2005 March; 90(3): 233-235

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**Document 802**

Adamis, D.; Martin, F.C.; Treloar, A.; Macdonald, A.J.D.  
**Capacity, consent, and selection bias in a study of delirium**  
Journal of Medical Ethics 2005 March; 31(3): 137-143

*Abstract:* OBJECTIVES: To investigate whether different methods of obtaining informed consent affected recruitment to a study of delirium in older, medically ill hospital inpatients. DESIGN: Open randomised study. SETTING: Acute medical service for older people in an inner city teaching hospital. PARTICIPANTS: Patients 70 years or older admitted to the unit within three days of hospital admission randomised into two groups. INTERVENTION: Attempted recruitment of subjects to a study of the natural history of delirium. This was done by either (a) a formal test of capacity, followed by either a request for consent or an attempt at obtaining assent from a proxy, or (b) a combined informal capacity/consent process. MAIN OUTCOME MEASURES: Prevalence and severity of delirium, and, as case mix measures, length of hospital stay and destination on discharge. RESULTS: Recruitment of subjects through establishing formal capacity and then informed consent was less successful (43.9% v 74% of those approached) and, compared with those recruited through the usual combined capacity/consent approach, yielded a sample with less cognitive impairment, lower severity of delirium, lower probability of case note diagnosis of delirium and lower rate of entering a care home. CONCLUSIONS: Methods of obtaining informed consent may significantly influence the case mix of subjects recruited to a study of delirium. Stringent testing of capacity may exclude patients with delirium from studies, thus rendering findings less generalizable. A different method is necessary to achieve an ethical balance between respecting autonomy through obtaining adequate informed consent and avoiding sample bias.

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

**Document 803**

Andanda, Pamela  
**Module two: informed consent**  
Developing World Bioethics 2005 March; 5(1): 14-29

*Abstract:* The objective of this module is to familiarise you with the concept of informed consent, its ethical basis, its elements, and typical problems that are encountered even by the most well intentioned researchers when trying to achieve genuine informed consent.

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Maloney, Dennis M.  
**Congressmen say military should have the right to informed consent**  

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University uses "implied informed consent"
Human Research Report 2005 March; 20(3): 6-7
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Maloney, Dennis M.
No informed consent for the U.S. military
Georgetown users check Georgetown Journal Finder for access to full text

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Tolich, Martin; Baldwin, Kate Mary
Informing consent in New Zealand research: researchers' conflict of interest and patient vulnerability
Georgetown users check Georgetown Journal Finder for access to full text

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Reiser, Stanley Joel
Research compensation and the monetarization of medicine
JAMA: The Journal of the American Medical Association 2005 February 2; 293(5): 613-614
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Dunn, Laura B.; Gordon, Nora E.
Improving informed consent and enhancing recruitment for research by understanding economic behavior
JAMA: The Journal of the American Medical Association 2005 February 2; 293(5): 609-612
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Katsnelson, Alla
Researchers probe the real effect of placebos [news]
Nature Medicine 2005 February; 11(2): 105
**Document 811**
Lertsitichai, Panuwat

*Waiver of consent in clinical observational research*
Journal of the Medical Association of Thailand 2005 February; 88(2): 275-281

**Document 812**
Greaves, Claire D.; Tindale, Wendy B.

*Implications of the UK NHS consent policy for nuclear medicine practice*
Nuclear Medicine Communications 2005 February; 26(2): 167-174

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Miller, A.

*Ethical issues in MS clinical trials*
Multiple Sclerosis 2005 February; 11(1): 97-98

**Document 814**
Loder, Elizabeth; Goldstein, R.; Biondi, D.

*Placebo effects in oral triptan trials: the scientific and ethical rationale for continued use of placebo controls*
Cephalalgia 2005 February; 25(2): 124-131

**Document 815**
Iltis, Ana Smith

*Timing invitations to participate in clinical research: preliminary versus informed consent*

**Abstract:** This article addresses the impact of the potential conflict between the roles of physicians who are both clinicians and researchers on the recruitment of persons into research trials. It has been proposed (1) that a physician breaches inter-role confidentiality when he or she uses information gathered in his or her clinical role to inform patients about trials for which they may be eligible and (2) that clinician-researchers should adopt a model of preliminary consent to be approached about research prior to commencing a clinical relationship. This article argues that even if we grant the legitimacy of inter-role confidentiality (which is open to question), there are circumstances in which other obligations physicians bear override the obligation of inter-role confidentiality. Moreover, it is argued that the practice of preliminary consent is morally suspect and that such consent cannot be deemed valid. The article concludes with a series of recommendations of ways in which the legitimate concern regarding the conflicting roles of clinician-researchers can be addressed in the recruitment stage of research.

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Maloney, Dennis M.

**University says research subjects' family members are not research subjects too**


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Maloney, Dennis M.

**Adding study results to informed consent forms**


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Wadman, Meredith

**Medicare compels heart patients to enlist in follow-up research** [news]

Nature 2005 January 27; 433(7024): 341

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Simpson, Bob

**Response to Athula Sumathipala and Sisira Siribaddana, "Revisiting 'Freely Given Informed Consent' in Relation to the Developing World: the Role of an Ombudsman" (AJOB 4:3)**


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Sears, Jeanne M.

**Context is key for voluntary and informed consent**


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Jairath, Nalini; Ulrich, Connie M.; Ley, Cathaleen

**Ethical considerations in the recruitment of research subjects from hospitalized, cardiovascular patient populations**
Excluding particular information from consent forms
Dickert, Neal; Kass, Nancy; Paasche-Orlow, Michael; Taylor, Holly
Abstract: Although the informed consent process is crucial to protecting human research subjects, there are cases when particular information within the consent form may present risks to those subjects. In this paper, we examine a case in which including the sponsor's name on the consent form may allow the form to serve as a surrogate for subjects' HIV status. There is no literature addressing the ethical acceptability of excluding particular information from consent forms, and there exists little regulatory guidance on this issue. We argue that excluding information from the consent form is, in fact, obligatory when that information is disclosed orally during the consent process but its presence on the form poses risks to the subjects the consent process is designed to protect. Further, we argue that the regulations ought to be amended to reflect this obligation.

Full disclosure: telling patients when not being a research subject is a good choice
Menikoff, Jerry
Perspectives in Biology and Medicine 2005 Winter; 48(1, Supplement): S139-S149

"Step into my Zapatos, doc": understanding and reducing communication disparities in the multicultural informed consent setting
Simon, Christian M.; Kodish, Eric D.
Perspectives in Biology and Medicine 2005 Winter; 48(1, Supplement): S123-S138

The quality of informed consent in a clinical research study in Thailand
Pace, Christine; Emanuel, Ezekiel J.; Chuenyam, Theshinee; Duncombe, Chris; Bebchuk, Judith D.; Wendler, David; Tavel, Jorge A.; McNay, Laura A.; Phanuphak, Praphan; Forster, Heidi P.; Grady, Christine

Consent forms and the therapeutic misconception: the example of gene transfer research
King, Nancy M.P.; Henderson, Gail E.; Churchill, Larry R.; Davis, Arlene M.; Hull, Sara Chandros; Nelson, Daniel K.; Parham- Vetter, P. Christy; Rothschild, Barba Bluestone; Easter, Michele M.; Wilfond, Benjamin S.
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Maloney, Dennis M.
Informed consent in genotoxicity studies
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United Kingdom. Academy of Medical Sciences; United Kingdom. Medical Research Council; United Kingdom. Royal college of Physicians; Wellcome Trust
Briefing on the research provisions of the Mental Capacity Bill. Pending a second reading in the House of Lords
Call number: citation only
http://www.acmedsci.ac.uk/p100puid71.html (link may be outdated)

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Panno, Joseph
Jesse Gelsinger: down to earth
Call number: RB155.8 .P36 2005

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Eldridge, Sandra M.; Ashby, Deborah; Feder, Gene S.
Informed patient consent to participation in cluster randomized trials: an empirical exploration of trials in primary care
Clinical Trials 2005; 2(2): 91-98
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Plomer, Aurora
Non-therapeutic research: domestic remedies and convention rights.
Call number: R853 .H8 P56 2005

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Haigh, Carol; Neild, Angela; Duncan, Fiona
Balance of power -- do patients use researchers to survive hospital?
Nurse Researcher 2005; 12(4): 71-81
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Sugarman, Jeremy; Lavori, Philip W.; Boeger, Maryann; Cain, Carole; Edsond, Robert; Morrison, Vicki; Yeh, Shing Shing
**Evaluating the quality of informed consent**
Clinical Trials 2005; 2(1): 34-41
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Lamb, H. Richard
**Commentary: on research and forensic patients' capacity**
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McDermott, Barbara E.; Gerbasi, Joan B.; Quanbeck, Cameron; Scott, Charles L.
**Capacity for forensic patients to consent to research: the use of the MacCAT-CR**
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Javitt, Gail H.
**Old legacies and new paradigms: confusing "research" and "treatment" and its consequences in responding to emergent health threats**
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* Document 837
Caulfield, Timothy
**Legal and ethical issues associated with patient recruitment in clinical trials: the case of competitive enrolment**
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* Document 838
Knoppers, Bartha Maria
**Consent revisited: points to consider**
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Vieta, Eduard; Camé, Xavier

The use of placebo in clinical trials on bipolar disorder: a new approach for an old debate
Psychotherapy and Psychosomatics 2005; 74(1): 10-16

Varnhagen, Connie K.; Gushta, Matthew; Daniels, Jason; Peters, Tara C.; Parmar, Neil; Law, Danielle; Hirsch, Rachel; Takach, Bonnie Sadler; Johnson, Tom

How informed is online informed consent?

Abstract: We examined participants' reading and recall of informed consent documents presented via paper or computer. Within each presentation medium, we presented the document as a continuous or paginated document to simulate common computer and paper presentation formats. Participants took slightly longer to read paginated and computer informed consent documents and recalled slightly more information from the paginated documents. We concluded that obtaining informed consent online is not substantially different than obtaining it via paper presentation. We also provide suggestions for improving informed consent—in both face-to-face and online experiments.

Druml, Christiane

Informed consent of incapable (ICU) patients in Europe: existing laws and the EU Directive
Current Opinion in Critical Care 2004 December; 10(6): 570-573

Sharp, S. Michael

Consent documents for oncology trials: does anybody read these things?
American Journal of Clinical Oncology 2004 December; 27(6): 570-575

Maaroos, Heidi-Ingrid; Tahepold, Heli; Kalda, Ruth

Patient consent rates for video-recording
Family Practice 2004 December; 21(6): 706

Frissell, Kevin C.; McCarthy, Denis M.; D'Amico, Elizabeth J.; Metrik, Jane; Ellingstad, Timothy P.; Brown, Sandra A.
abstract: autonomy has been hailed as the foremost principle of bioethics, and yet patients' decisions and research subjects' voluntary participation are being subjected to frequent restrictions. it has been argued that patient care is best served by a limited form of paternalism because the doctor is better qualified to take critical decisions than the patient, who is distracted by illness. the revival of paternalism is unwarranted on two grounds: firstly, because prejudging that the sick are not fully autonomous is a biased and unsubstantial view; secondly, because the technical knowledge of healthcare professionals does not include the ethical qualifications and prerogative to decide for others. clinical research settings are even more prone to erode subjects' autonomy than clinical settings because of the tendency and temptation to resort to such practices as shading the truth when consent to participation is sought, or waiving consent altogether when research is done in emergency settings. instead of supporting such dubious practices with unconvincing arguments, it would seem to be the task of bioethics to insist on reinforcing autonomy.
**Ethics in human subjects research: do incentives matter?**

**Abstract:** There is considerable confusion regarding the ethical appropriateness of using incentives in research with human subjects. Previous work on determining whether incentives are unethical considers them as a form of undue influence or coercive offer. We understand the ethical issue of undue influence as an issue, not of coercion, but of corruption of judgment. By doing so we find that, for the most part, the use of incentives to recruit and retain research subjects is innocuous. But there are some instances where it is not. Specifically, incentives become problematic when conjoined with the following factors, singly or in combination with one another: where the subject is in a dependency relationship with the researcher, where the risks are particularly high, where the research is degrading, where the participant will only consent if the incentive is relatively large because the participant's aversion to the study is strong, and where the aversion is a principled one. The factors we have identified and the kinds of judgments they require differ substantially from those considered crucial in most previous discussions of the ethics of employing incentives in research with human subjects.

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* Article Document 850

Wendler, David

**Can we ensure that all research subjects give valid consent?**
Archives of Internal Medicine 2004 November 8; 164(20): 2201-2204

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* Article Document 851

Oberdorfer, Kevin L.J.

**The lessons of Greenberg: informed consent and the protection of tissue sources' research interests**
Georgetown Law Journal 2004 November; 93(1): 365-394

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* Article Document 852

Regidor, Enrique

**The use of personal data from medical records and biological materials: ethical perspectives and the basis for legal restrictions in health research**
Social Science and Medicine 2004 November; 59(9): 1975-1984

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* Article Document 853

Bramstedt, Katrina A.

**A guide to informed consent for clinician-investigators**
Cleveland Clinic Journal of Medicine 2004 November; 71(11): 907-910

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* Article Document 854

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Es etico realizar ensayos clinicos controlados con placebo en el desarrollo de un nuevo farmaco para el trastorno depresivo mayor? (y II). Relacion beneficio/riesgo y consentimiento informado. Conclusions / Is it ethical conducting placebo-controlled clinical trials as part of the development of new drugs for the treatment of major depressive disorder? (and II). Benefit/risk ratio and informed consent. Conclusions

Interventions to improve research participants' understanding in informed consent for research

Abstract: CONTEXT: Available data suggest that prospective research participants may frequently not understand information disclosed to them in the informed consent process. Little is known about how understanding can be improved. OBJECTIVE: To review research on interventions to improve research participants' understanding of information disclosed in the informed consent process. DATA SOURCES AND STUDY SELECTION: A search of MEDLINE was performed using the terms informed consent and clinical research and informed consent and (comprehension or understanding) from 1966 to March 2004, which included randomized controlled trials, longitudinal trials, and controlled trials with nonrandom allocation that compared the understanding of research participants who had undergone only a standard informed consent process to that of participants who had received an intervention to improve their understanding. A comprehensive bibliography of empirical research on informed consent published in January 1999 was also reviewed, as were personal files and all issues of the journals IRB and Controlled Clinical Trials. DATA EXTRACTION: Study design, quality criteria, population characteristics, interventions, and outcomes for each trial were extracted. The statistical significance of the interventions' effects on understanding were noted, as were mean scores for understanding for each group of each trial. For those trials that measured the secondary outcomes of satisfaction and willingness to enroll, results were also summarized. DATA SYNTHESIS: Thirty studies described 42 trials that met inclusion criteria. Of 12 trials of multimedia interventions, 3 showed significant improvement in understanding. Of 15 trials of enhanced consent forms, 6 showed significant improvement in understanding (all P<.05), but 5 of 6 trials were of limited quality, casting doubt on their practical relevance. Of 5 trials of extended discussion, 3 showed significant improvement in understanding (all P<.001) and 2 showed trends toward improvement (P=.054 and P=.08). Of 5 trials of test/feedback, all showed significant improvement in understanding (all P<.05) but were flawed in that they may have mistaken rote memorization for improvement in understanding. Another 5 trials were put into a miscellaneous category and had varying impact on understanding. Some demographic factors, particularly lower education, were associated with less understanding. Satisfaction and willingness to enroll were never significantly diminished by an intervention. CONCLUSIONS: Efforts to improve understanding through the use of multimedia and enhanced consent forms have had only limited success. Having a study team member or a neutral educator spend more time talking one-on-one to study participants appears to be the most effective available way of improving research participants' understanding; however, further research is needed.
Parkes, S.E.

**Legal aspects of records based medical research**
Archives of Disease in Childhood 2004 October; 89(10): 899-901

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Document 858

Schmidt, Terri A.; Salo, David; Hughes, Jason A.; Abbott, Jean T.; Geiderman, Joel M.; Johnson, Catherine X.; McClure, Katie B.; McKay, Mary Pat; Razzak, Junaid A.; Scheers, Raquel M.; Solomon, Robert C.

Society for Academic Emergency Medicine [SAEM]. Ethics Committee

**Confronting the ethical challenges to informed consent in emergency medicine research**
Academic Emergency Medicine 2004 October; 11(10): 1082-1089

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Document 859

Marco, Catherine A.

Society for Academic Emergency Medicine [SAEM]. Ethics Committee

**The Society for Academic Emergency Medicine position on informed consent for emergency medicine research**
Academic Emergency Medicine 2004 October; 11(10): 1090-1091

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Document 860

Bhutta, Zulfiqar A.

**Beyond informed consent**


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Document 861

Gammelgaard, A.; Mortensen, O.S.; Rossel, P.

DANAMI-2 Investigators

**Patients' perceptions of informed consent in acute myocardial infarction research: a questionnaire based survey of the consent process in the DANAMI-2 trial**
Heart 2004 October; 90(10): 1124-1128

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Document 862

Maloney, Dennis M.

**Exception to informed consent requirements**
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Abstract: OBJECTIVES: To determine the effects of risk and payment on subjects' willingness to participate, and to examine how payment influences subjects' potential behaviours and risk evaluations. METHODS: A 3 (level of risk) x 3 (level of monetary payment), between subjects, completely randomised factorial design was used. Students enrolled at one of five US pharmacy schools read a recruitment notice and informed consent form for a hypothetical study, and completed a questionnaire. Risk level was manipulated using recruitment notices and informed consent documents from hypothetical biomedical research projects. Payment levels were determined using the payment models evaluated by Dickert and Grady as a guide. Five dependent variables were assessed in the questionnaire: willingness to participate, willingness to participate with no payment, propensity to neglect to tell about restricted activities, propensity to neglect to tell about negative effects, and risk rating. RESULTS: Monetary payment had positive effects on respondents' willingness to participate in research, regardless of the level of risk. However, higher monetary payments did not appear to blind respondents to the risks of a study. Payment had some influence on respondents' potential behaviours regarding concealing information about restricted activities. However, payment did not appear to have a significant effect on respondents' propensity to neglect to tell researchers about negative effects. CONCLUSIONS: Monetary payments appear to do what they are intended to do: make subjects more willing to participate in research. Concerns about payments blinding subjects to risks could not be substantiated in the present study. However, the findings do raise other concerns—notably the potential for payments to diminish the integrity of a study's findings. Future research is critical to make sound decisions about the payment of research subjects.

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Randomisation in trials: do potential trial participants understand it and find it acceptable?
Journal of Medical Ethics 2004 February; 30(1): 80-84

Abstract: OBJECTIVE: To examine lay persons' ability to identify methods of random allocation and their acceptability of using methods of random allocation in a clinical trial context. DESIGN: Leaflets containing hypothetical medical, non-medical, and clinical trial scenarios involving random allocation, using material from guidelines for trial information leaflets. SETTING AND PARTICIPANTS: Adults attending further education colleges (n = 130), covering a wide range of ages, occupations, and levels of education. MAIN MEASURES: Judgements of whether each of five methods of allocation to two groups was random in a medical or non-medical scenario. Judgements of whether these allocation methods were acceptable in a randomised clinical trial scenario, with or without a scientific justification for randomisation. RESULTS: The majority of our group of participants judged correctly that allowing people their preference was not random, and that the following were random: using a computer with no information about the individual (recommended wording for MREC trial leaflets), tossing a coin, drawing a name out of a hat. Judgements were split over allocating people in turn (not a random allocation method but shares features with randomisation). Judgements were no different in medical and non-medical scenarios. Few of the correctly identified random methods were judged to be acceptable in a clinical trial scenario. Inclusion of a scientific justification for randomising significantly increased the acceptability of only one random method: allocation by computer. CONCLUSIONS: Current UK guidelines' recommended description of random allocation by computer seems warranted. However, while potential trial participants may understand what random allocation means, they may find it unacceptable unless offered an acceptable justification for its use.

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Potential research participants' views regarding researcher and institutional financial conflicts of interest
Journal of Medical Ethics 2004 February; 30(1): 73-79
Abstract: BACKGROUND: Financial conflict of interest in clinical research is an area of active debate. While data exist on the perspectives and roles of academic institutions, investigators, industry sponsors, and scientific journals, little is known about the perspectives of potential research participants. METHODS: The authors surveyed potential research participants over the internet, using the Harris Interactive Chronic Illness Database. A potential research participant was defined by: (1) self report of diagnosis by a health care professional and (2) willingness to participate in clinical trials. Email invitations were sent to 20,205 persons with coronary artery disease, breast cancer, or depression; a total of 6363 persons were screened; of these, 86% or 5478 met inclusion criteria and completed the survey. The outcome measures were respondents' ratings on: importance of knowing conflict of interest information, whether its disclosure ought to be required, and its effect on willingness to participate-across seven widely discussed scenarios of financial conflicts of interest (ranging from commercial funding to equity ownership). RESULTS: Majority responded that knowing conflict of interest information was "extremely" or "very" important; a larger majority felt financial conflicts of interest should be disclosed as part of informed consent (64% to 87%). In all seven scenarios, a majority was still willing to participate but in some scenarios a sizable minority would be wary of participation. Respondents were more wary of individual than institutional conflicts of interest. Illness group and sociodemographic factors had modest effects and did not affect the main trends. CONCLUSIONS: The prevailing practice of non-disclosure of financial conflicts of interest in clinical research appears contrary to the values of potential research participants.

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Abstract: The most recent (Fifth) revision of the Declaration of Helsinki, adopted in October 2000 by the World Medical Association (WMA), reinforces the longstanding prohibition against offering placebo instead of effective therapy. The WMA left no doubt that if a beneficial treatment for a condition has already been recognised, it is unethical to offer placebo in place of such treatment to anyone in a study of the same condition. We have previously drawn attention to the discrepancy between the spirit of the Declaration and the common practice of using placebo controls in randomised trials even if effective treatment exists. Despite the mandates of the Declaration of Helsinki and concern from ethicists and scientists, the US Food and Drug Administration (FDA) continues to demand and defend placebo-controlled evidence of efficacy and safety for the development of many new pharmaceuticals, even if effective therapy exists. We suggest that the FDA's arguments defending their practice are insufficient to justify medical research that violates the Declaration of Helsinki.
Document 1074
Tcheng, James E.; Madan, Mina; O'Shea, J, Conor; Cohen, Eric A.; Buller, Christopher E.; Lincoff, A. Michael; Popma, Jeffrey J.; Teirstein, Paul S.; Kitt, Michael M.; Lorenz, Todd J.; Greenberg, Sally; Fost, Norman; Califf, Robert M.; The ESPRIT Investigators
Ethics and Equipoise: Rationale for a Placebo-Controlled Study Design of Platelet Glycoprotein IIB/IIIa Inhibition in Coronary Intervention
Journal of Interventional Cardiology 2003 April; 16(2): 97-105
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Document 1075
Rosenmayr, A.; Hartwell, L.; Egeland, T.
World Marrow Donor Association. Ethics Working Group
Informed consent -- suggested procedures for informed consent for unrelated haematopoietic stem cell donors at various stages of recruitment, donor evaluation, and donor workup
Bone Marrow Transplantation 2003 April; 31(7): 539-545
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Joubert, Gina; Steinberg, Hannes; van der Ryst, Elna
Consent for participation in the Bloemfontein vitamin A trial: how informed and voluntary?
American Journal of Public Health 2003 April; 93(4): 582-584
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http://www.ajph.org (link may be outdated)

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Barrett, Robert J.; Parker, Damon B.
Rites of consent: negotiating research participation in diverse cultures
Monash Bioethics Review 2003 April; 22(2): 9-26
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Williams, Barbara F.; French, John K.; White, Harvey D.
HERO-2 Consent Substudy Investigators
Informed consent during the clinical emergency of acute myocardial infarction (HERO-2 consent substudy): a prospective observational study
Lancet 2003 March 15; 361(9361): 918-922
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http://www.thelancet.com/journal (link may be outdated)
Maschke, Karen J.
Proxy research consent and the decisionally impaired: science, the common good, and bodily integrity

Great Britain. Department of Health; Medicines and Healthcare Products Regulatory Agency (Great Britain)
Draft guidance on consent by a legal representative on behalf of a person not able to consent under the Medicines for Human Use (Clinical Trials) Regulations 2003

Magder, Sheldon; Lefebvre, Annette
Obtaining consent for research studies on incompetent subjects: the Quebec experience
Intensive Care Medicine 2003 March; 29(3): 496-498

Alliance for Human Research Protection (AHRP)
A recent study by Johns Hopkins concludes medical consent forms are confusing
CERES (Consumers for Ethics in Research) NEWS 2003 Spring; (33): 5-6

Rubinstein, Efi
Going beyond parents and institutional review boards in protecting children involved in nontherapeutic research [opinion]
Golden Gate University Law Review 2003 Spring; 33(2): 251-294

Chin, Lisa Judy
Informed consent in clinical research: a review for professional practice

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Document 1085

Diallo, Aldiouma; Ly, Coudy; Simondon, Francois; Simondon, Kirsten B.

Consentement éclairé pour la recherche biomedicale dans les pays en développement: procedures et attitudes parentales dans un essai randomisé de supplémentation alimentaire de nourrissons senegalais

[Informed consent for biomedical research in developing countries: procedures and parental attitudes in a random trial of food supplementation for infants in Senegal] [French and English abstracts]


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Document 1086

Stone, T. Howard

The invisible vulnerable: the economically and educationally disadvantaged subjects of clinical research


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Document 1087

Bobinski, Mary Anne

Information, consent, and high dose chemotherapy with autologous bone marrow transplant [sic; transplant]

LAB (Law and Bioethics) Report 2003 March; 2(3): 2-4

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http://www.louisville.edu/medschool/ibhpl/Lab_report/ (link may be outdated)

Document 1088

Paasche-Orlow, Michael K.; Taylor, Holly A.; Brancati, Frederick L.

Readability standards for informed-consent forms as compared with actual readability

New England Journal of Medicine 2003 February 20; 348(8): 721-726

Abstract: BACKGROUND: Institutional review boards (IRBs) are charged with safeguarding potential research subjects with limited literacy but may have an inadvertent role in promulgating unreadable consent forms. We hypothesized that text provided by IRBs in informed-consent forms falls short of the IRBs' own readability standards and that readability is influenced by the level of research activity, local literacy rates, and federal oversight. METHODS: To test these hypotheses, we conducted a cross-sectional study linking data from several public-use sources. A total of 114 Web sites of U.S. medical schools were surveyed for IRB readability standards and informed-consent-form templates. Actual readability was measured with the Flesch-Kincaid scale, which assigns a score on the basis of the minimal grade level required to read and understand English text (range, 0 to 12). Data on the level of research activity, local literacy rates, and federal oversight were obtained from organizational Web sites. RESULTS: The average readability score for text provided by IRBs was 10.6 (95 percent confidence interval, 10.3 to 10.8) on the Flesch-Kincaid scale. Specific readability standards, found on 61 Web sites (54 percent), ranged from a 5th-grade reading level to a 10th-grade reading level. The mean Flesch-Kincaid scores for the readability of sample text provided by IRBs exceeded the stated standard by 2.8 grade levels (95 percent confidence interval, 2.4 to 3.2; P<0.001). Readability was not associated with either the level of research funding (P=0.89) or local rates of literacy (P=0.92). However, the 52 schools that had been made subject to oversight by the Office for Human Research Protections (46 percent) had lower Flesch-Kincaid scores than the other schools (10.2 vs. 10.9, P=0.005). CONCLUSIONS: IRBs commonly provide text for informed-consent forms that falls short of their own readability standards. Federal oversight is associated with better readability.

Georgetown users check Georgetown Journal Finder for access to full text
Patients' consent preferences for research uses of information in electronic medical records: interview and survey data

BMJ: British Medical Journal 2003 February 15; 326(7385): 373-376

Abstract: OBJECTIVES: To assess patients' preferred method of consent for the use of information from electronic medical records for research. DESIGN: Interviews and a structured survey of patients in practices with electronic medical records. SETTING: Family practices in southern Ontario, Canada. PARTICIPANTS: 123 patients: 17 were interviewed and 106 completed a survey. MAIN OUTCOME MEASURES: Patients' opinions and concerns on use of information from their medical records for research and their preferences for method of consent. RESULTS: Most interviewees were willing to allow the use of their information for research purposes, although the majority preferred that consent was sought first. The seeking of consent was considered an important element of respect for the individual. Most interviewees made little distinction between identifiable and anonymised data. Research sponsored by private insurance firms generated the greatest concern, and research sponsored by foundation the least. Sponsorship by drug companies evoked negative responses during interview and positive responses in the survey. CONCLUSIONS: Patients are willing to allow information from their medical records to be used for research, but most prefer to be asked for consent either verbally or in writing.

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Ethics group gives qualified nod to placebos [news]
Science 2003 February 14; 299(5609): 995, 997

Georgetown users check Georgetown Journal Finder for access to full text

GP suspended for enrolling patients in drug trials without consent [Robert Macindoe Adams] [news]
BMJ: British Medical Journal 2003 February 8; 326(7384): 304

Georgetown users check Georgetown Journal Finder for access to full text

Conducting research related to treatment of Alzheimer's disease
Journal of Gerontological Nursing 2003 February; 29(2): 6-12

Georgetown users check Georgetown Journal Finder for access to full text
* Document 1093
Baldwin, David; Broich, Karl; Fritze, Jurgen; Kasper, Siegfried; Westenberg, Herman; Moller, Hans-Jurgen
Placebo-controlled studies in depression: necessary, ethical and feasible
European Archives of Psychiatry and Clinical Neuroscience 2003 February; 253(1): 22-28

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* Document 1094
Jansson, Roger L.
Researcher liability for negligence in human subject research: informed consent and researcher malpractice actions

Georgetown users check Georgetown Journal Finder for access to full text

* Document 1095
Sade, Robert M.
Publication of unethical research studies: the importance of informed consent
Annals of Thoracic Surgery 2003 February; 75(2): 325-328

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* Document 1096
Maloney, Dennis M.
INDs [Investigational new drug application] and review of informed consent

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* Document 1097
Ferguson, P.R.
Information giving in clinical trials: the views of medical researchers
Bioethics 2003 February; 17(1): 101-111

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* Document 1098
Brainard, Jeffrey
Study finds research consent forms difficult to comprehend

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* Document 1099
Menikoff, Jerry

**The hidden alternative: getting investigational treatments off-study**


**Abstract:** Research studies commonly randomise patients between standard care and some new form of treatment. In a substantial number of studies, the new treatment could have been obtained by the patient directly from their doctor, without participating in a study. Yet it is a common practice, endorsed and encouraged by the US government, not to advise potential research participants about their ability to get the new treatment outside of the study. This policy is even occurring in one of the largest studies ever funded by the US government, the 22000 patient, 5-year comparison of tamoxifen and raloxifene in the prevention of breast cancer. This practice has the effect of encouraging more individuals to participate in research studies, but the result is that their consent to participate is not fully voluntary. Many ongoing studies may therefore be of questionable ethical soundness.

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

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**Document 1100**

Chvetzoff, Gisele; Tannock, Ian F.

**Placebo effects in oncology**

*Journal of the National Cancer Institute* 2003 January 1; 95(1): 19-29

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**Document 1101**

Wang, Linda

**In clinical trials and in the clinic, what is the placebo’s effect?**

*Journal of the National Cancer Institute* 2003 January 1; 95(1): 6-7

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**Document 1102**

Leavitt, Frank J.

**Compromised autonomy, and Asian autonomy: commentaries on Glock and Goldim, and Dena Hsin-Chen Hsin**


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**Document 1103**

Glock, Rosana Soibelmann; Goldim, José Roberto

**Informed consent in gerontology**


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Schmidt, Terri A.

**The legacy of the Tuskegee syphilis experiments for emergency exception from informed consent**
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Shah, Amit Navin; Sugarman, Jeremy
Protecting research subjects under the waiver of informed consent for emergency research: experiences with efforts to inform the community

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McQuillan, Geraldine M.; Porter, Kathryn S.; Agelli, Maria; Kington, Raynard
Consent for genetic research in a general population: the NHANES experience

Document 1107
Horng, Sam; Grady, Christine
Misunderstanding in clinical research: distinguishing therapeutic misconception, therapeutic misestimation, and therapeutic optimism

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Kemmelmeier, Markus; Davis, Deborah; Follette, William C.
Seven "sins" of misdirection?: ethical controversies surrounding the use of deception in research.

Document 1109
Skegg, P.D.G.
Consent and information disclosure.

Document 1110
Fisher, Celia B.
Goodness-of-fit ethic for informed consent to research involving adults with mental retardation and developmental disabilities
Document 1111
Meran, Johannes Gobertus
Consent and equipoise, the crucial ethical issues in randomised clinical trials
Onkologie 2003; 26(6): 524-528

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Lefkowitz, Joel
Research ethics: I. Informed consent and confidentiality.
Call number: HF5548.8 .L3644 2003

Document 1113
Panel on Institutional Review Boards, Surveys, and Social Science Research
Enhancing informed consent.
Call number: HD62 .P763 2003

Document 1114
van Wyk, Christa
The participation of minors in preventive HIV research trials in South Africa: legal and human rights considerations
Abstract: The constitutional prohibition of experimentation/research without the individual subject's (own) consent is investigated. A distinction is drawn between therapeutic and non-therapeutic research. A minor of 14 is competent to consent independently to medical treatment (which would include therapeutic research), but not to non-therapeutic research. A minor must be at least 18 years to be able to do so. Proxy consent can be secured for the participation of minors under 18 in non-therapeutic research only if they assent, if their participation in the research is indispensable and the research carries no more than negligible risk. Since the risks inherent in HIV preventive vaccine trials may carry more than negligible risk, these trials may not be carried out on children under 18. The limitation of rights and the consideration of foreign and international law in the interpretation of the South African Bill of Rights are investigated.

Document 1115
Reymond, Marc A.; Allal, Abdelkarim S.; Steinert, Ralf; Eder, Frank; Halangk, Walter; Lippert, Hans
Informed consent for molecular-based diagnostic and prognostic studies in the cancer patient
Digestive Diseases 2003; 21(4): 351-356
Abandon all hope? The therapeutic misconception and informed consent
Moreno, Jonathan D. Cancer Investigation 2003; 21(3): 481-482

Informed consent in human genetic research.

Community consent for genetic research.

Consent form for participation in a study of inheritable genetic modification.

Informed consent in clinical research: policies and practices in Singapore

Patient expectations of benefit from phase I clinical trials: linguistic considerations in diagnosing a therapeutic misconception

Abstract: The ethical treatment of cancer patients participating in clinical trials requires that patients are well-informed about the potential benefits and risks associated with participation. When patients enrolled in phase I clinical trials report that their chance of benefit is very high, this is often taken as evidence of a failure of the informed consent process. We argue, however, that some simple themes from the philosophy of language may make such a conclusion less certain. First, the patient may receive conflicting statements from multiple speakers about the expected outcome of the trial. Patients may be reporting the message they like best. Second, there is a potential problem of multivocality. Expressions of uncertainty of the frequency type (e.g., "On average, 5 out of
every 100 patients will benefit") can be confused with expressions of uncertainty of the belief type (e.g., "The chance that I will benefit is about 80%"). Patients may be informed using frequency-type statements and respond using belief-type statements. Third, each speech episode involving the investigator and the patient regarding outcomes may subserve multiple speech acts, some of which may be indirect. For example, a patient reporting a high expected benefit may be reporting a belief about the future, reassuring family members, and/or attempting to improve his or her outcome by a public assertion of optimism. These sources of linguistic confusion should be considered in judging whether the patient's reported expectation is grounds for a bioethical concern that there has been a failure in the informed consent process.

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* Article Document 1122

Benbow, Shannon

**Conflict + interest: financial incentives and informed consent in human subject research**


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* Article Document 1123

Sterling, Cheryl M.; Walco, Gary A.

**Protection of children's rights to self-determination in research**

Ethics and Behavior 2003; 13(3): 237-247

**Abstract:** Federal guidelines require that informed consent be obtained from participants when they are enrolled in a research study. When conducting research with children, the guidelines utilize the term permission to describe parents' agreement to enroll their children in a study. The basic components of consent and permission are well described and identical, with the exception of the person for whom the decision to participate is being made (i.e., oneself as opposed to one's child). Beyond permission, when enrolling minor participants in research, affirmative agreement to participate in research or assent must be obtained from the child participants themselves. The concept of children's assent to research, however, is poorly defined, resulting in inconsistency in its pursuit and consequently, in its utility. The interface between cognitive development, emotional, and social development must be examined as it pertains to this special situation of decision making. For this process to meaningfully protect minors, the assent process must be clarified, decisions regarding parental veto power must be more convincingly justified, and researchers must be better educated and held accountable for the valid execution of this process. Strategies for implementing the assent process more effectively are presented.

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* Article Document 1124

Menache, Andre

**The era of valid informed consent**

Medicine and Law 2003; 22(3): 421-427

**Abstract:** The concept of informed consent in clinical trials is well understood, although when viewed from the perspective of legal consent and valid consent, problems arise. Legal consent can be as simple as the signing of a document of informed consent. Valid consent, however, implies that the participant in the clinical trial is aware of the risks involved in being exposed to a new medical drug, including the risk of possible severe adverse drug reactions. Since most pre-clinical data is based largely on animal experiments, and animal data cannot be extrapolated to human beings with any degree of confidence, valid consent cannot be provided by the participant. It is therefore suggested that animal experiments be replaced with human-based methodologies, which rely on modern methods of molecular biology and human genetics.

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Trouet, Caroline

**Informed consent for the research use of human biological materials**

*Abstract:* New medical developments have increased the use of human tissue, especially for research purposes. The attention of lawyers concerned with research has traditionally focused on the protection of research subjects and on data-protection. Legal aspects of the secondary research use of human tissue are still unclear. On an international level consensus is growing that sources of tissue should consent to the secondary use of their tissue. We offer some guidelines for drafting consent forms for the research use of human biological materials, elaborating in a more concrete manner the rule of consent for the secondary use of tissue. Topics covered concern amongst others layered consent, new findings, protection of informational privacy, withdrawal of consent and commercialization.

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Berghmans, Ron L.P.; Widdershoven, Guy A.M.

**Ethical perspectives on decision-making capacity and consent for treatment and research**

*Abstract:* Decision-making capacity for treatment and research raises complex conceptual issues. Given the fact that both considerations of respect for patient autonomy and beneficence/harm prevention have moral relevance in many cases, in the practice of health care the need exists to balance both in a moral responsible way. The moral concept of (mental) capacity or decisional capacity has a role to play in this balancing process. The current dominant approach towards the conceptualization and assessment of decision-making capacity, which focuses on cognition and rationality, has some serious shortcomings. In order to compensate for these shortcomings of the dominant approach, a number of alternative approaches may be promising. A first alternative focuses on issues of emotion and narrative; a second on identity and identification, and a third on dialogue and deliberation. By paying attention to the way in which people interpret their world (not only by cognition, but also by emotion), and how they shape their lives by processes of identification and communication, a broader perspective on capacity assessment in health care can be developed. Above that, these alternative approaches are less focused on the assessment of (in)capacity and more on enabling a person to become more competent through a process of empowerment, participation, and shared decision-making.

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Brody, Janet L.; Scherer, David G.; Annett, Robert D.; Pearson-Bish, Melody

**Voluntary assent in biomedical research with adolescents: a comparison of parent and adolescent views**

*Abstract:* An informed consent and voluntary assent in biomedical research with adolescents is contingent on a variety of factors, including adolescent and parent perceptions of research risk, benefit, and decision-making autonomy. Thirty-seven adolescents with asthma and their parents evaluated a high or low aversion form of a pediatric asthma research vignette and provided an enrollment decision; their perceptions of family influence over the participation decision; and evaluations of risk, aversion, benefit, and burden of study procedures. Adolescents and their parents agreed on research participation decisions 74% of the time, yet both claimed ultimate responsibility for the participation decision. Both rated most study procedures as significantly more aversive than risky. Parents were more likely to rate aspects of the hypothetical study as beneficial and to provide higher risk ratings for procedures. Disagreements concerning research participation decisions and decision-making autonomy have implications for the exercise of voluntary assent in biomedical research.

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**Document 1128**

Horng, Sam; Emanuel, Ezekiel J.; Wilfond, Benjamin; Rackoff, Jonathan; Martz, Karen; Grady, Christine

**Descriptions of benefits and risks in consent forms for phase 1 oncology trials**


**Abstract:** BACKGROUND: Ethicists have suggested that written consent forms encourage participants in phase 1 cancer trials to expect benefit from the experimental agent and to overlook serious risks. METHODS: To evaluate the written description of direct benefit as well as risk, all consent forms for 1999 phase 1 cancer trials were compiled from 80 percent of the National Cancer Institute-designated cancer centers and from six of eight large pharmaceutical developers of anticancer drugs. In each case, we evaluated the characteristics of the trial, the descriptions of the purpose and procedures of the research, the promise of benefit, the description of risks, and the description of alternatives. RESULTS: Of 272 forms, 268 explicitly mentioned that the trial was research, and 249 stated that the trial was testing for safety. Nearly all forms (269) mentioned the right to withdraw from the trial. Almost all forms (260) referred to the experimental agent as "treatment" or "therapy." Only one consent form promised direct benefit to subjects. Most forms (181) mentioned death as a risk, and very few (14) mentioned cure as even a possible benefit. Most (229) stated that there was unknown risk involved and indicated that severe or permanent harms were possible (224). CONCLUSIONS: Consent forms for phase 1 oncology studies almost never promise direct benefit to subjects, rarely mention cure, and usually communicate the seriousness and unpredictability of risk. Although there is room for improvement, the substance of these forms is unlikely to be the primary source of misunderstanding by subjects in phase 1 oncology trials. Copyright 2002 Massachusetts Medical Society

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**Document 1129**

De Blasi, Zelda; Kaptchuk, Ted J.; Weinman, John; Kleijnen, Jos

**Informing participants of allocation to placebo at trial closure: postal survey**

BMJ: British Medical Journal 2002 December 7; 325(7376): 1329-1331

**Abstract:** OBJECTIVES: To assess whether and how investigators of placebo controlled randomised trials inform participants of their treatment allocation at trial closure and to assess barriers to feedback. DESIGN: Postal survey with a semistructured questionnaire. PARTICIPANTS: All investigators who published a placebo controlled randomised trial in 2000 in five leading medical journals, and a random sample of 120 trials listed in the national research register database. MAIN OUTCOME MEASURES: Number of investigators who informed participants of their treatment allocation at trial closure, methods for delivering the information, and barriers to unmasking treatment. RESULTS: 45% of investigators informed either all or most participants of their treatment allocation, and 55% did not inform any participant or only informed those who asked. The main reasons for not informing participants were that the investigators never considered this option (40%) or to avoid biasing results at study follow up (24%). CONCLUSION: Further research is required to examine sensitive ways to communicate treatment information to trial participants.

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**Document 1130**

Loh, Winnie Y.; Butow, Phyllis N.; Brown, Richard F.; Boyle, Frances

**Ethical communication in clinical trials -- issues faced by data managers in obtaining informed consent**

Cancer 2002 December 1; 95(11): 2414-2421

Georgetown users check [Georgetown Journal Finder](http://www.bmj.com) for access to full text
**Sham surgery trial: ethical reflections**

Brody, Baruch A.


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http://www.louisville.edu/medschool/ibhpl/Lab_report/ (link may be outdated)

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**Consent to open label extension studies: some ethical issues**

Wainwright, P.

Journal of Medical Ethics 2002 December; 28(6): 373-376

*Abstract:* A frequent feature of pharmaceutical research is the open label extension study, in which patients participating in double blind placebo controlled trials of new medications are invited, on completion of the initial trial, to take the study drug for some further period. Patients are openly given the active substance at this stage, regardless of their assignment in the initial trial. Investigators are typically reluctant to unblind the patients' assignment at the point of entry into the open label phase, on the grounds that this may introduce ascertainment bias in the main study. It is argued that patients invited to participate in open label extension studies cannot give a proper consent to such research unless they know to which arm of the main trial they were recruited. It is further argued that to recruit certain groups of patients from placebo controlled trials into open label extension studies may also be unethical for clinical reasons.

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

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**Informed consent and research involving the newly dead**

Wicclair, Mark R.

Kennedy Institute of Ethics Journal 2002 December; 12(4): 351- 372

*Abstract:* This paper examines informed consent in relation to research involving the newly dead. Reasons are presented for facilitating advance decision making in relation to postmortem research, and it is argued that the informed consent of family members should be sought when the deceased have not made a premortem decision. Regardless of whether the dead can be harmed, there are two important respects in which family consent can serve to protect the dead: (1) protecting the deceased's body from being used for research that is incompatible with the person's premortem preferences and values and (2) protecting the deceased's body from being subject to disrespectful treatment. These claims are explained and justified, and several objections are critically examined. Additional reasons for securing family consent are presented including to protect them from additional emotional distress, to respect their wishes about wanting to have a say, and to maintain public trust in the medical profession and medical research. The paper also examines the scope of disclosure in relation to postmortem research.

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**Artificial heart implant leads to suit over consent process: recipient's widow says she and her husband were misinformed and misled on risks, benefits**

Goldberg, Debbie

Washington Post 2002 November 30; p. A3
Document 1135
Fallowfield, Lesley; Jenkins, Valerie
**Acronymic trials: the good, the bad, and the coercive** [commentary]
*Lancet* 2002 November 23; 360(9346): 1622
Georgetown users check *Georgetown Journal Finder* for access to full text

Document 1136
Dalton, Rex
**Tribe blasts 'exploitation' of blood samples** [news]
*Nature* 2002 November 14; 420(6912): 111
Georgetown users check *Georgetown Journal Finder* for access to full text

Document 1137
Childress, James F.
**Protestant perspectives on informed consent (particularly in research involving human participants)**
Georgetown users check *Georgetown Journal Finder* for access to full text

Document 1138
Rosenfeld, Barry
**The psychology of competence and informed consent: understanding decision-making with regard to clinical research**
Georgetown users check *Georgetown Journal Finder* for access to full text

Document 1139
Harris, John
**Law and regulation of retained organs: the ethical issues**
*Legal Studies* 2002 November; 22(4): 527-549
Georgetown users check *Georgetown Journal Finder* for access to full text

Document 1140
Arar, Nedal H.; Plaetke, Rosemarie; Arar, Mazen Y.; Kasinath, Balakuntalam S.; Abboud, Hanna E.
**Incorporating the contextual assessment approach to regimens used in genetic family studies**
*Genetics in Medicine* 2002 November-December; 4(6): 451-463
Document 1141

Maloney, Dennis M.

**Defendant-researcher claims that federal regulations on informed consent are too vague**

Human Research Report 2002 November; 17(11): 8

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

Document 1142

Pulver, Ann E.

Johns Hopkins Medical Institutions

**Research subject information and consent form: the collection of a control sample for genetic studies of complex diseases in the Ashkenazi Jewish community**


**Abstract:** Sample enrollment document from the repository for Ashkenazi Jewish controls: A resource for genetic association studies, principal investigator Ann E. Pulver, Sc.D.; materials include: informed consent statement for enrollment in an anonymous sample of Ashkenazi Jewish individuals to be used in molecular studies; flyer to attract volunteers at the October 2002 ASHG meeting; a medical and psychiatric history screening form

Document 1143

Arar, N.H.; Sartorio, V.; Plaetke, R.; Abboud, H.

**Ethical issues among a low-income minority population participating in genetic research [abstract]**

American Journal of Human Genetics 2002 October; 71(4 Suppplment): 380

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

Document 1144

Bernhardt, B.A.; Hamby, L.A.; Geller, G.

**Genetic disease registries and informed consent [abstract]**

American Journal of Human Genetics 2002 October; 71(4 Supplement): 380

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

Document 1145

Smith, M.E.; Manasco, P.K.; Arledge, T.

**A dynamic informed consent process for population based genetic research [abstract]**

American Journal of Human Genetics 2002 October; 71(4 Supplement): 380

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

Document 1146

Habiba, Marwan; Evans, Martyn

**The inter-role confidentiality conflict in recruitment for clinical research**
Abstract: Recruiting patients into clinical research is essential for the advancement of medical knowledge. However, when the physician undertaking the care of the patient is also responsible for recruitment into clinical research, a situation arises of an inter-role breach of confidentiality which is distinguishable from other conflicts of interest. Such discord arises as the physician utilizes confidential information obtained within the therapeutic relationship beyond its primary objective, and safeguards ought to be observed in order to avert this important, and generally overlooked, problem. The moral worth of the pledge of confidentiality is based not on its innate value but on its being a promise on which subsequent interactions and disclosures are founded. Within the patient-doctor interaction, confidentiality is an important facet of the promised fidelity and, as such, a loose interpretation of the notion threatens the essence of the relationship, and any violation thereof requires compelling moral justification. To avoid conflict, patients' confidential information ought not be used for the purpose of recruitment, which needs to be undertaken through general education and non-directed appeals, and a preliminary consent to be approached for research should be obtained from the patient prior to her being identified as a suitable research subject. Securing this prior consent would avoid one source of potential, albeit unintended, coercion.

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* Article Document 1147
Pullman, Daryl
Conflicting interests, social justice and proxy consent to research
Journal of Medicine and Philosophy 2002 October; 27(5): 523-545
Abstract: Historically the primary role of the Institutional Review Board (IRB) has been "to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in research" (U.S. FDA, 1996). However, there is much to suggest that IRBs have been unable to fulfil this mandate, particularly in regard to the matter of informed consent. Part of the problem in this regard is that the competing interests of other stakeholders often undermine the IRB's capacity to serve the best interests of research subjects. This paper proposes an alternative view of the role of the IRB. It begins by treating the interests of other stakeholders as legitimate matters of concern for IRBs. Hence the process established to review and monitor human research should be treated as an exercise in social justice in which the interests of all legitimate stakeholders must be represented and considered. A variation of Rawls’ (1971) heuristic "the veil of ignorance" is employed to explore the dynamic relationship between knowledge and interests that ensues when the role of the IRB is characterized in this manner. Inadequacies in the informed consent process are taken as illustrative of the inability of IRBs as they are presently construed to attend to the interests of research subjects. The major normative implication of the analysis offered here is that the role of the IRB must be expanded to include the granting of a provisional proxy consent on behalf of prospective research subjects. This provision is necessary, it is argued, if the interests of research subjects are to be fairly assessed by IRBs as a matter of social justice. It is necessary as well to ensure that an adequate standard of informed consent is attained. Somewhat paradoxically it is argued that the interests of research subjects are better served when treated as one among a number of competing sets of interests the IRB must serve, rather than as the primary concern of the IRB.

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* Article Document 1148
Albin, R.L.
Sham surgery controls: intracerebral grafting of fetal tissue for Parkinson's disease and proposed criteria for use of sham surgery controls
Journal of Medical Ethics 2002 October; 28(5): 322-325
Abstract: Sham surgery is a controversial and rarely used component of randomised clinical trials evaluating surgical interventions. The recent use of sham surgery in trials evaluating efficacy of intracerebral fetal tissue grafts in Parkinson's disease has highlighted the ethical concerns associated with sham surgery controls. Macklin, and Dekkers and Boer argue vigorously against use of sham surgery controls. Macklin presents a broad argument against sham surgery controls while Dekkers and Boer present a narrower argument that sham surgery is unnecessary in the specific setting of fetal tissue engraftment for Parkinson's disease. I defend sham surgery controls against both these criticisms. Appropriate clinical trial design, sometimes including sham surgery, is needed to ensure that false positive trial results do not occur and endanger public safety. Results of a completed trial of fetal tissue engraftment for Parkinson's disease are used to illustrate the potential benefits of, and problems associated with,
sham surgery controls. Sham surgery controls, however, should be employed only when absolutely necessary. I suggest criteria for appropriate use of sham surgery controls.

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

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Cassell, J.; Young, A.
Why we should not seek individual informed consent for participation in health services research
Journal of Medical Ethics 2002 October; 28(5): 313-317
Abstract: Ethics committees now require that individuals give informed consent to much health services research, in the same way as for clinical research. This is misguided. Existing ethical guidelines do not help us decide how to seek consent in these cases, and have allowed managerial experimentation to remain largely unchecked. Inappropriate requirements for individual consent can institutionalise health inequalities and reduce access to services for vulnerable groups. This undermines the fundamental purpose of the National Health Service (NHS), and ignores our rights and duties as its members, explored here. Alternative forms of community consent should be actively pursued.

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* Document 1150
Consent for research on stored body samples

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Lidz, Charles W.; Appelbaum, Paul S.
The therapeutic misconception: problems and solutions
Medical Care 2002 September; 40(9, Supplement): V55-V63

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Nelson, Robert M.; Merz, Jon F.
Voluntariness of consent for research -- an empirical and conceptual review
Medical Care 2002 September; 40(9, Supplement): V69-V80

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Bosk, Charles L.
Obtaining voluntary consent for research in desperately ill patients
* Article  Document 1154
Holmes-Rovner, Margaret; Wills, Celia E.
**Improving informed consent -- insights from behavioral decision research**
Medical Care 2002 September; 40(9, Supplement): V30-V38
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Chen, Donna T.; Miller, Franklin G.; Rosenstein, Donald L.
**Enrolling decisionally impaired adults in clinical research**
Medical Care 2002 September; 40(9, Supplement): V20-V29
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Karlawish, Jason H.T.; Fox, Ellen; Pearlman, Robert
**How changes in health care practices, systems, and research challenge the practice of informed consent**
Medical Care 2002 September; 40(9, Supplement): V12-V19
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Feussner, John R.; Burris, James F.; McGlynn, Geraldine; Lavori, Philip W.
**Enhancing protections for human participants in clinical and health services research -- a continuing process**
Medical Care 2002 September; 40(9, Supplement): V4-V11
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Kuczewski, Mark G.; Marshall, Patricia
**The decision dynamics of clinical research: the context and process of informed consent**
Medical Care 2002 September; 40(9, Supplement): V45-V54
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Gray, Clifton R.
**The "greater good"... at what cost?: How nontherapeutic scientific studies can now create viable negligence claims in Maryland after Grimes v. Kennedy Krieger Institute, Inc.**
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The right of subjects to see the protocol
IRB: Ethics and Human Research 2002 September-October; 24(5): 6-8

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Karlawish, Jason H.T.; Knopman, David; Clark, Christopher M.; Morris, John C.; Marson, Daniel; Whitehouse, Peter J.; Kawas, Claudia H.
Informed consent for Alzheimer's disease clinical trials: a survey of clinical investigators

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Poythress, Norman G.
Obtaining informed consent for research: a model for use with participants who are mentally ill
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Symposium on human subjects research: redux
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Miller, Franklin G.; Shorr, Andrew F.
Unnecessary use of placebo controls: the case of asthma clinical trials [commentary]
Archives of Internal Medicine 2002 August 12/26; 162(15): 1673-1677

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Jones, James W.; McCullough, Laurence B.
When does conventional surgical therapy become research?
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Casarett, David; Karlawish, Jason; Asch, David A.
**Paying hypertension research subjects: fair compensation or undue inducement?**
JGIM: Journal of General Internal Medicine 2002 August; 17(8): 650-652
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**Informing clinical trial participants about study results [commentary]**
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Horng, Sam; Miller, Franklin G.
**Is placebo surgery unethical? [sounding board]**
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**Document 1169**
Wendler, Dave; Emanuel, Ezekiel
**The debate over research on stored biological samples: what do sources think?**
Archives of Internal Medicine 2002 July 8; 162(13): 1457-1462
Abstract: BACKGROUND: The debate over informed consent for research on stored biological samples has enormous scientific implications. Unfortunately, there are no data on individuals' attitudes regarding when their consent should be obtained for such research. METHODS: Data were gathered using a telephone survey of 504 individuals living in the United States. Two cohorts were studied: (1) individuals who had participated in clinical research and contributed biological samples and (2) randomly selected Medicare recipients. RESULTS: Of the respondents, 65.8% would require their consent for research on clinically derived, personally identified samples; 27.3% would require it for research on clinically derived samples that are "anonymized." For research-derived samples, 29.0% of the respondents would require their consent if the samples retain personal identifiers; 12.1% would require it if the samples are anonymized before the research is conducted. Also, 88.8% would want to be informed of results of uncertain clinical significance, and 91.9% would not impose greater safeguards on future research on a different disease. CONCLUSIONS: Current practice and policy recommendations regarding research using stored biological samples may be inconsistent with sources' preferences in several respects. In particular, it appears that most sources want to control whether their samples are used for research purposes, are not concerned with the particular disease that will be studied, and want to receive results of uncertain clinical significance. Follow-up research will be needed to assess the generalizability of the current data.
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Clinical trials without consent: some experiments simply cannot be done
Medical Journal of Australia 2002 July 1; 177(1): 40-42
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Maloney, Dennis M.
Informed consent and living human cells
Human Research Report 2002 July; 17(7): 3
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Roff, Sue Rabbitt
Project Sunshine and the slippery slope: the ethics of tissue sampling for strontium-90
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Agre, Patricia; Rapkin, Bruce; Dougherty, James; Wilson, Roger
Barriers encountered conducting informed consent research
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Kaptchuk, Ted J.
The placebo effect in alternative medicine: can the performance of a healing ritual have clinical significance?
Annals of Internal Medicine 2002 June 4; 136(11): 817-825
Abstract: In alternative medicine, the main question regarding placebo has been whether a given therapy has more than a placebo effect. Just as mainstream medicine ignores the clinical significance of its own placebo effect, the placebo effect of unconventional medicine is disregarded except for polemics. This essay looks at the placebo effect of alternative medicine as a distinct entity. This is done by reviewing current knowledge about the placebo effect and how it may pertain to alternative medicine. The term placebo effect is taken to mean not only the narrow effect of a dummy intervention but also the broad array of nonspecific effects in the patient-physician relationship, including attention; compassionate care; and the modulation of expectations, anxiety, and self-awareness. Five components of the placebo effect--patient, practitioner, patient-practitioner interaction, nature of the illness, and treatment and setting--are examined. Therapeutic patterns that heighten placebo effects are especially prominent in unconventional healing, and it seems possible that the unique drama of this realm may have "enhanced" placebo effects in particular conditions. Ultimately, only prospective trials directly comparing the placebo effects of unconventional and mainstream medicine can provide reliable evidence to support such claims. Nonetheless, the possibility of enhanced placebo effects raises complex conundrums. Can an alternative ritual with only nonspecific psychosocial effects have more positive health outcomes than a proven, specific conventional treatment? What makes therapy legitimate, positive clinical outcomes or culturally acceptable methods of attainment? Who decides?
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Information and advice for people taking part in research
CERES (Consumers for Ethics in Research) NEWS 2002 Summer; (32): 3-4

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In that case [case study]
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The Green Lane Heart Library: ethical and cultural implications
New Zealand Bioethics Journal 2002 June; 3(2): 4-7

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Informed consent doesn't exist in AMI [acute myocardial infarction] trials
Journal of Medical Ethics 2002 June; 28(3): 190-191

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Hilden, J.; Gammelgaard, A.
Premature stopping and informed consent in AMI [acute myocardial infarction] trials
Journal of Medical Ethics 2002 June; 28(3): 188-189

Abstract: Clinical trials give rise to ethical dilemmas, especially in the acutely ill, but we take issue with two points raised in a recent comment on a specific acute myocardial infarction (AMI) trial. The commentators judged that the trial most likely could, and therefore should, have been terminated much earlier. By analysing the problem statistically we arrive at results that go against their intuitive judgment-they also see it as mandatory to update the patient Information sheet as trial results accrue and trends begin to emerge. In our view, interpreting subtle trends and borderline p-values must rest with data monitoring boards, not patients. Moreover, patients with AMI or in other
medical emergencies need very simple instructions. Empirical studies of the consent process confirm that the idea of a genuinely informed consent is problematic in such cases.

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Clinical Trial Web Sites: A Promising Tool to Foster Informed Consent

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Bramstedt, Katrina A.
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IRB: Ethics and Human Research 2002 May-June; 24(3): 10-13
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Enough is enough? Disclosure in cross-cultural research
IRB: Ethics and Human Research 2002 May-June; 24(3): 7-9
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Consent for continuing research participation: what is it and when should it be obtained?
IRB: Ethics and Human Research 2002 May-June; 24(3): 1-6
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Document 1186

Castillo, Fatima Alvarez

Limiting factors impacting on voluntary first person informed consent in the Philippines

Developing World Bioethics 2002 May; 2(1): 21-27

Abstract: How well can institutional guidelines help ensure the dignity, rights, safety and well being of research participants in an underdeveloped country? In this paper I describe the limits of informed consent as an instrument for the protection of participants in the context of the Philippines. I bring to this paper my experiences as an advocate of rights, a member of an ethics review board, a researcher on the ethics of research and as an observer of the dynamics of clinical practice in an academic public teaching hospital of the University of the Philippines where I am professor.

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Document 1187

Benitez, Oscar; Devaux, Dominique; Dausset, Jean

Audiovisual documentation of oral consent: a new method of informed consent for illiterate populations

Lancet 2002 April 20; 359(9315): 1406-1407

Abstract: Informed consent is a legal and ethical requirement of most research in human beings, but obtaining proof of consent in illiterate populations can prove problematic. We used audiovisual documentation of oral consent (video and audiotape recording and photography), a new method of informed consent designed for illiterate populations, in the Guaraní Indians Project, a genetic study in the Paraguayan Guaraní Indians. We obtained consent from 42 of about 100 potential participants. We believe that our procedure allowed more than half the potential participants to exercise their freedom of refusal. We propose to include this new method as a standard procedure for clinical research in illiterate populations as an alternative to written and signed consent.

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Placebo-controlled trials and the Declaration of Helsinki

Lancet 2002 April 13; 359(9314): 1337-1340

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The biggest concern of all for research volunteers: Am I going to be stuck with a placebo?

Wall Street Journal 2002 April 11; p. D2

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Berghout, Caspar; van Ginkel, Joost; Groeneweg, Nikolaj; Israels, Han; Kas, Arnoud; Lesniewski, Ulrike; van Stempvoort, Jeannette
Should subjects be forewarned of the possible psychological consequences of filling out a PTSD questionnaire?

Psychological Reports 2002 April; 90(2): 461-465

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Miller, Franklin G.; Shorr, Andrew F.
Ethical assessment of industry-sponsored clinical trials -- a case analysis
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Cummings, Mary L.
Informed consent and investigational new drug abuses in the U.S. military
Accountability in Research 2002 April-June; 9(2): 93-103

Abstract: Objective: The focal point of this investigation was to research the ethical issues surrounding the military's requests for informed consent waivers when using investigational drugs, and the recent debate surrounding the anthrax vaccine as an investigational new drug (IND). Design: The military's management of the informed consent process was examined using documents obtained through the Freedom of Information Act, Institutional Review Board (IRB) minutes, legal pleadings, and protocols for specific investigational drugs. Results: In December 1990, prior to Operation Desert Storm, the Federal Drug Administration (FDA) granted the Department of Defense (DoD) an unprecedented waiver to the federally mandated informed-consent requirement for the use of investigational drugs. However, the waiver approval was conditional, and the FDA insisted on several safeguards. Partially in response to the subsequent Gulf War Syndrome debate, the FDA recently evaluated the military's use of investigational drugs during the Gulf War. The FDA cited the military for significant deviations from the originally approved protocols. Most notably, the military was found to be abusing the IRB process by convening a second IRB when the first IRB concluded that waiving informed consent was unethical. In addition, there was a gross lack of documentation and no monitoring of adverse reactions. The DoD's plan to use the current anthrax vaccine on all 2.4 million troops against inhalation anthrax has kindled an additional investigational drug controversy. The safety and efficacy of the use of the anthrax vaccine as a prophylactic against inhalation anthrax have been questioned by both military and medical organizations. There have never been any published studies of human efficacy or long-term effects for the anthrax vaccine. In addition, the military is not using the vaccine for its intended purpose, and it is also not adhering to prescribed dosing schedules. There is clear evidence to support the claim that, in fact, the military's use of the anthrax vaccine should be considered unethical. Conclusions: I argue that in medical situations, the military is obligated to treat its troops as autonomous persons entitled to basic rights and protections. The DoD is currently using an approved drug, the anthrax vaccine, for an unapproved purpose and in an unapproved manner. In doing so, the DoD is not only violating the FDA's regulations against such practices, it is also violating an executive order which only allows the president to authorize the use of INDs on service members without their consent.

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Opinions on who should consent to research on an incompetent individual [abstract]
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Knowledge of the legislation that regulates consent to treatment and research in Quebec [abstract]
Journal of the American Geriatrics Society 2002 April; 50(Supplement): S151

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The effect of symptoms on cancer patients' capacity to give consent for research [abstract]
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Deconstructing the placebo effect and finding the meaning response

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The California Scale of Appreciation: a new instrument to measure the appreciation component of capacity to consent to research
American Journal of Geriatric Psychiatry 2002 March-April; 10(2): 166-174
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Chang, Esther
**Fitting a square peg into a round hole?: imposing informed consent and post-trial obligations on United States sponsored clinical trials in developing countries**

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Nature Reviews Genetics 2002 March; 3(3): 221-224

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Charney, Dennis S.; Nemeroff, Charles B; Lewis, Lydia; Laden, Sally K.; Gorman, Jack M.; Laska, Eugene M.; Borenstein, Michael; Bowden, Charles L.; Caplan, Arthur; Emslie, Graham J.; Evans, Dwight L.; Geller, Barbara; Grabowski, Lenore E.; Herson, Jay; Kalin, Ned H.; Keck, Paul E., Jr.; Kirsch, Irving; Krishnan, Ranga R.; Kupfer, David J.; Makuch, Robert W.; Miller, Franklin G.; Pardes, Herbert; Post, Robert; Reynolds, Mildred M.; Roberts, Laura; Rosenbaum, Jerrold F.; Rosenstein, Donald L.; Rubinow, David R.; Rush, A. John; Ryan, Neal D.; Sachs, Gary S.; Schatzberg, Alan F.; Solomon, Susan
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Pharos 2002 Spring; 65(2): 4-9

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Human Research Report 2002 March; 17(3): 5
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Sprumont, Dominique

**Ethical evaluation of heroin-prescription research: an insider's view** [commentary]
American Journal of Bioethics 2002 Spring; 2(2): 63-64

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McLeod, Carolyn

**Authenticity and the hijacked brain** [commentary]

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Freckelton, Ian

**Choice, rationality, and substance dependence** [commentary]

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Roberts, Laura Weiss

**Addiction and consent** [commentary]

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Katz, Dana; Neuberger, J.R.

**A `fix' of reality** [commentary]

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Ling, Walter

**Cynthia's dilemma** [commentary]

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**Commentary: Cynthia's dilemma**
O'Brien, Charles P.
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**Ethics and heroin prescription: no more fuzzy goals! [commentary]**
Orr, Amber S.; Wynia, Matthew K.
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**Resisting the temptations of addiction rhetoric [commentary]**
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**Unsafe presumptions in clinical research [commentary]**
Rhodes, Rosamond
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**Who holds the leash? [commentary]**
Elliott, Carl
American Journal of Bioethics 2002 Spring; 2(2): 48
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**Cynthia's dilemma: consenting to heroin prescription**
Charland, Louis C.
**Abstract:** Heroin prescription involves the medical provision of heroin in the treatment of heroin addiction. Rudimentary clinical trials on that treatment modality have been carried out and others are currently underway or in development. However, it is questionable whether subjects considered for such trials are mentally competent to consent to them. The problem has not been sufficiently appreciated in ethical and clinical discussions of the topic. The challenges involved throw new light on the role of value and accountability in contemporary discussions of mental competence.

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**Therapeutic beneficence and patient recruitment in randomized controlled clinical trials**

Kowalski, Charles J.

**Placebo controls: scientific and ethical issues**
American Journal of Bioethics 2002 Spring; 2(2): 33-34

Kovach, Karen

**Distinguishing dilemmas in the ethics of placebo-controlled trials**
American Journal of Bioethics 2002 Spring; 2(2): 32-33

Glass, Kathleen Cranley; Waring, Duff

**Effective trial design need not conflict with good patient care**

Cohen, Peter J.

**Failure to conduct a placebo-controlled trial may be unethical**

Appelbaum, Paul S.

**Clarifying the ethics of clinical research: a path toward avoiding the therapeutic misconception**
What makes placebo-controlled trials unethical?

**Abstract:** The leading ethical position on placebo-controlled clinical trials is that whenever proven effective treatment exists for a given condition, it is unethical to test a new treatment for that condition against placebo. Invoking the principle of clinical equipoise, opponents of placebo-controlled trials in the face of proven effective treatment argue that they (1) violate the therapeutic obligation of physicians to offer optimal medical care and (2) lack both scientific and clinical merit. We contend that both of these arguments are mistaken. Clinical equipoise provides erroneous ethical guidance in the case of placebo-controlled trials, because it ignores the ethically relevant distinction between clinical trials and treatment in the context of clinical medicine and the methodological limitations of active-controlled trials. Placebo controls are ethically justifiable when they are supported by sound methodological considerations and their use does not expose research participants to excessive risks of harm.

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**Document 1231**
Cohen, Peter J.

**Untreated addiction imposes and ethical bar to recruiting addicts for non-therapeutic studies of addictive drugs**
Journal of Law, Medicine and Ethics 2002 Spring; 30(1): 73-81

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**Document 1232**
Weijer, Charles

**I need a placebo like I need a hole in the head**

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**Document 1233**
Clark, Peter A.

**Placebo surgery for Parkinson's disease: do the benefits outweigh the risks?**

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**Document 1234**
Carter-Edwards, Lori; Fisher, John T.; Vaughn, Benjamin J.; Svetkey, Laura P.

**Church rosters: is this a viable mechanism for effectively recruiting African Americans for a community-based survey?**
Ethnicity and Health 2002 February; 7(1): 41-55

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Skene, Loane

**Ownership of human tissue and the law [opinion]**
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Maloney, Dennis M.
**Lawsuit claims that informed consent procedures did not follow regulations**
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Maloney, Dennis M.
**Research subjects to be told about conflicts of interest**

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* Document 1238
Wendler, David
**What research with stored samples teaches us about research with human subjects**
Bioethics 2002 February; 16(1): 33-54

Abstract: There is widespread discussion concerning the safeguards appropriate for human research subjects. Less discussed is the fact that the safeguards one deems appropriate depend, in large part, on the model of research participation that one assumes. Therefore, to determine what safeguards are appropriate, it is necessary first to clarify the competing models of research participation. The ostensibly obscure debate over informed consent for research on stored biological samples is of particular interest in this regard because such research can involve varying subsets of the three central elements of research involvement. As a result, analysis of this debate provides an opportunity to identify the competing models of research participation. Based on this analysis, this paper describes a new model of research participation that is emerging, and considers its implications for clinical research.

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Ferguson, P. R.
**Patients' perceptions of information provided in clinical trials**
Journal of Medical Ethics 2002 February; 28(1): 45-48

Abstract: BACKGROUND: According to the Declaration of Helsinki, patients who take part in a clinical trial must be adequately informed about the trial's aims, methods, expected benefits, and potential risks. The declaration does not, however, elaborate on what "adequately informed" might amount to, in practice. Medical researchers and Local Research Ethics Committees attempt to ensure that the information which potential participants are given is pitched at an appropriate level, but few studies have considered whether the patients who take part in such trials feel they have been given adequate information, or whether they feel able to understand that information. OBJECTIVES: To explore trial participants' views (i) on the amount of information provided, and (ii) of their own understanding of that information. DESIGN: Structured interviews of patients participating in clinical trials for the treatment of chronic medical condition. FINDINGS: Patients generally felt they were given an appropriate amount of information, and that they were able to understand all or most of it. They felt they were given adequate time to ask questions before agreeing to take part. In comparison with treatment given out with the research setting, patients generally felt they received more information when participating in a clinical trial. CONCLUSIONS: Researchers sometimes complain that patients are given too much information during clinical trials, and have limited understanding of that information.
The present study shows that this perception is not necessarily shared by patients. More research is needed in this area, particularly to gauge whether patient understanding is indeed accurate.

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**When Science Offers Salvation: Patient Advocacy and Research Ethics, by Rebecca Dresser** [book review]

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**Do we need placebos to evaluate new drugs in children with schizophrenia?**

Psychopharmacology 2002 January; 159(2): 117-124

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White, Mary Terrell; Gamm, Jennifer

**Informed consent for research on stored blood and tissue samples: a survey of institutional review board practices**

Accountability in Research 2002 January-March; 9(1): 1-16

**Abstract:** Numerous position papers have outlined informed consent recommendations for the collection, storage, and future use of biological samples; however, there currently is no consensus regarding what kinds of information should be included in consent forms. This study aimed to determine whether institutional review boards (IRBs) vary in their informed consent requirements for research on stored biological samples, and whether any variation observed could be correlated to factors such as volume of work, IRB members' familiarity with ethical issues in genetic research, and IRBs' use of either of two policy guidelines as resources. A brief survey was mailed to all IRB chairpersons on a mailing list obtained from the Office for Human Research Protections. Survey questions included whether consent forms for the collection of biological samples for future use address each of six provisions recommended in current guidelines and position statements, and whether IRBs used the Office for Protection from Research Risks' 1993 Protecting Human Research Subjects: Institutional Review Board Guidebook, chapter 5 (hereinafter IRB Guidebook) or the National Bioethics Advisory Commission's 1999 Research Involving Human Biological Materials: Ethical Issues and Policy Guidance, Volume I (hereinafter Report) in their deliberations. Despite a low response rate (22%, 427 respondents), results indicate that IRB practices vary substantially. The degree to which the provisions were included in consent forms was found to correlate positively with IRBs that review a greater volume of protocols annually, those that use the National Bioethics Advisory Commission Report in their deliberations, and those that draw on both the Report and the IRB Guidebook.

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"Therapeutic misconception" and "recruiting doublespeak" in the informed consent process
IRB: Ethics and Human Research 2002 January-February; 24(1): 11-12

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Making Informed Consent Meaningful
MEDICAL CARE 2002 September; 40(9, Supplement): V1-V80

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The ubiquity and utility of the therapeutic misconception.
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Call number: **RA564.8 .I8 2002**

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Loue, Sana

**Ethical issues in informed consent in the conduct of research with aging persons.**


Call number: **RA564.8 .I8 2002**

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**Child assent and parental permission for clinical research -- some considerations**

Bioethics Forum 2002; 18(3-4): 36-42

**Abstract:** The success of our future efforts to understand and improve the ethics of pediatric informed consent may depend, in large measure, on our willingness and ability to conceive of child assent and parental permission as joint, mutually affective processes. Given current trends, our empirical efforts may need to unfold at the interface of assent and parental permission, rather than exclusively or even primarily in one domain or the other. This shift will permit researchers to identify those areas in which the two mechanisms function in concert -- in the best interests of patients, parents, and clinicians -- and those in which they do not. Targeting these problematic areas for intervention and improvement may result in a more effective consent process for clinical research involving minors.

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Dresser, Rebecca

**Patient advocacy and research bioethics**


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**How research will adapt to HIPAA [Health Insurance Privacy and Accountability Act]: a view from within the healthcare delivery system**


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Lough, Joseph W.H.
Informed consent: a necessity for human research
Abstract: As flaws in the informed consent process have come to light, rising research costs and heightened competition have exposed informed consent to increasing scrutiny as a possible source for industry savings. However, we believe that the informed consent process needs to be refined and strengthened, not weakened or abandoned. This article describes why protecting human research participants through informed consent is necessary for institutions that conduct human research.
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Fast track to disaster? Considerations raised by current recruitment techniques for clinical research subjects

Abstract: Efforts to obtain Food and Drug Administration (FDA) approval of new drugs on a "fast track" are not without hazards for physicians and other providers involved in conducting clinical research. Increasingly, research sponsors have implemented competitive subject recruitment techniques that encourage investigators and their staffs to move studies along rapidly, but may also raise concerns about subject safety. The purpose of this article is to examine competitive recruitment practices and to examine the ethical and legal issues related to obtaining information consent for clinical research trials within this current framework.

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Trial design and informed consent for a clinic-based study with a treatment as usual control arm

Abstract: Employing the National Institute of Mental Health-funded Prevention of Suicide in Primary Care Elderly Collaborative Trial as a case study, we discuss 2 sets of ethical issues: obtaining informed consent for a clinic-based intervention study and using treatment as usual (TAU) as the control condition. We then address these ethical issues in the context of the debate about the quality improvement efforts of health care organizations. Our analysis reveals the tension between ethics and scientific integrity involved with using TAU as a control condition and the difficulty in designing high-quality research in a community-based setting.

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