Online Ethics Center
FOR ENGINEERING AND SCIENCE

Human Subjects & Informed Consent Bibliography

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Description

An annotated collection of links, books, and journal articles addressing issues in research using human subjects.

Body

National and International Principles and Regulations Governing Human Research Participants

Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research

Published in 1979, the Belmont Report lays out the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects in the U.S.

Declaration of Helsinki

Developed by the World Medical Association, this statement has largely replaced the Nuremberg Code as the current international standard for experimentation using human subjects.

Federal Policy for the Protection of Human Subjects (Common Rule)

Legislation adopted by the United States governing all research involving human subjects done by or funded by federal departments or agencies.

International Ethical Guidelines for Biomedical Research Involving Human Subjects

Developed by the Council for International Organizations of Medical Sciences, these guidelines lay out internationally-accepted standards for research involving human subjects.

International Society for Ethnobiology Code of Ethics

Drawn from the 1988 Declaration of Belem, the International Society of Ethnobiology has provided a brief and concise guideline that works toward establishing genuine partnerships with indigenous peoples, traditional societies, and local communities with respect to ethnobiological research.

National Research Act (1974)

Created by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research as one result of the Tuskegee Syphilis Experiment. This Act identifies basic principles of research conduct and suggested ways to ensure those principles were followed.

Nuremberg Code

This statement arose from the Nuremberg Military Tribunal after WWII. It states that human experimentation is only justifiable if its results benefit society, and if it is carried out in accord with basic ethical and legal principles.

Public Health Services Act (1985)

This Act, amended in 1985 by the Health Research Extension Act (PUBLIC LAW 99-158-Nov. 20, 1985 [99 STAT. 873]), mandates the use of Institutional Review Boards and sets forth regulations for the protection of human subjects.

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2nd edition (TCPS 2)

This is the joint policy for the Canadian Institutes of Health Research, the national Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada. It outlines the main guidelines and regulations covering the government-funded research involving human participants.

A collection of resources on U.S. Department of Energy-funded experiments involving radioactive materials.

Conducted after World War II, they came to light a few years ago, causing a scandal because of their violation of standards for the protection of human subjects.

Web Sites & Online Training

Collaborative Institutional Training Initiative Program (CITI) Human Subjects Research

An online training module used by many universties and other insititutions to help introduce researchers to the basics of working with human research participants. Access to this content is avilable either through your home institution or for a fee.

FHI 360 Research Ethics Training Curriculum

An online training curriculum focused on applying fundamental principles of research ethics to the development, review and conduct of research involving human participants. Includes sections on community-engaged research and research with minors.

Ethical decision-making and Internet research: Recommendations from the Association of Internet Researchers Ethics Working Committee (will download a PDF)

This document includes guidelines and recommendations designed to support researchers in the social sciences who are conducting research over the internet, or studying human interactions through electronic media, such as chat, electronic message boards, Twitter, or other social networking tools. Includes issues of privacy, the expectations of the individuals participating in the study, as well as other ethical issues unique to conducting research via the internet.

Protecting Human Subject Research Partcipants

This online training program has been put together by the U.S. National Institutes of Health to introduce research teams to the basic guidelines and regulations governing research involving human subjects. Must register to view.

The Ethics of Research on Vulnerable Populations

This online resource includes a number of good case studies on research involving vulnerable populations, such as children, the mentally ill, and prisoners.

U.S. Office of Human Research Protections

The U.S. OHRP is charged with interpreting and overseeing the implementation of all regulations regarding the protection of human subjects. Includes links to ethical guidelines and regulations, fact sheets, and policy statements of the NIH.

Use of Human Tissue

Put together by the National Institutes of Health Bioethics Library, this is a listing of guidelines, opinions, and regulations on the use of human tissue samples in research.

Books

Berg, Jessica W, Paul S. Appelbaum, Charles W. Lidz, and Lisa S. Parker. 2001. *Informed Consent: Legal Theory and Clinical Practice* New York: Oxford University Press, 2001.

This volume, co-written by a lawyer, a physician, and a social scientist, takes an in-depth look at the concept of informed consent. It looks at the legal requirements for professionals in obtaining informed consent, the history of informed consent, and ethical issues that arise around informed consent in the doctor-patient relationship.

Cohen, I. G. and H. Fernandez Lynch. (2014). *Human Subjects Research Regulation: Perspectives on the Future.* Cambridge, MA: MIT Press.

This book analyzes the current framework used internationally for protecting human research subjects and looks at its benefits and flaws. This collection of essays discusses how the system could be improved.

Darby, Mary and Gerry McGlynn. Informed Consent for Human Subjects: A Primer. Boston: Management Decision and Research Center, Health

Services Research and Development Service, Office of Research and Development, Department of Veterans Affairs, 2002.
This publication provides an overview of informed consent, pertinent regulations, and the process of obtaining consent from potential research participants for research done under the jurisdiction of the U.S. Department of Veterans Affairs.

Desposato, Scott (ed.) 2016. *Ethics and Experiments: Problems and Solutions for Social Scientists and Policy Professionals* New York: Routledge.
For most of political science's history, discussions about professional ethics had nothing to do with human subjects. Professional ethics involved integrity in the classroom, fair tenure and promotion rule, and the careful avoidance of plagiarism. As most research was observational, there was little need for attention to how scholarly activities might directly affect the subjects of our work. Times have changed. The dramatic growth in the use of experiments in social science, especially overseas, is generating unexpected ethical controversies. The purpose of this volume is to identify, debate, and propose practical solutions to the most critical of these new ethical issues.

Emanuel, Ezekiel J. Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Baltimore: Johns Hopkins University Press, 2003.
This well-written volume includes a large number of essays looking at all different ethical aspects of clinical research involving human participants.

Ermie, Willie, Raven Sinclair, Bonnie Jeffrey. 2004. *The Ethics of Research Involving Indigenous Peoples. Report of the Indigenous Peoples' Health Research Centre to the Interagency Advisory Panel on Research Ethics.* Indigenous Peoples' Health Research Centre.
An excellent report looking at methodologies and frameworks for working with indigenous communities, including guidelines, setting up research ethics boards, and issues that can come up in these partnerships. Includes an extensive annotated bibliography.

Federman, D.D. et al. 2002. *Responsible Research: A Systems Approach to Protecting Research Participants.* Washington, D.C. , National Academies Press.
This book outlines a three-pronged approach to ensure the protection of research

participants through the establishment of effective Human Research Participant Programs. Issues addressed in the book include the need for in-depth, complimentary reviews of science, ethics, and conflict of interest reviews; desired qualifications for investigators and reviewers; the process of informed consent; federal and institutional oversight; and the role of accreditation. Recommendations for areas of key interest include suggestions for legislative approaches, compensation for research-related injury, and the refocusing of the mission of institutional review boards.

Gostin, Lawrence O. and Cori Vanchieri. Ethical Considerations for Research Involving Prisoners. Washington D.C.: National Academies Press, 2007

This report looks at the ethical considerations related to research involving prisoners, and the special protections needed for prisoner participants in research because of the restrictions placed on their liberty and autonomy.

Kahn, J.P., A.C. Mastroianni, and J. Sugarman, eds. 1998. Beyond Consent: Seeking Justice in Research. New York: Oxford University Press.

Surveying the history of the use of human participants in research, this book examines aspects of justice in research. The author looks at the need to expand access to potentially beneficial research to all members of society, concerns about the exploitation of research participants, and the need for research ethics and institutional review boards to be more sensitive to the needs of marginalized persons. While this book focuses on medical research, many of the issues dealt with apply es to almost all research involving human participants.

Manson, Neil C. and Onora O'Neill. 2007. *Rethinking Informed Consent in Bioethics*. New York: Cambridge University Press.

The authors of this volume look at the issue of trying to set defensible and feasible standards for informed consent in research. They look at the reasons why informed consent cannot be fully specific or fully explicit, and why more specific consent is not always ethical better. Instead, the authors argue for a more flexible idea of informed consent that is negotiated through accurate, honest communication between the doctor/researcher and the patient.

The National Academies of Science, Engineering and Medicine. 2013. *Proposed Revisions to the Common Rule: Perspectives of Social and Behavioral Scientists: Workshop Summary*. Washington D.C.: National

Academies Press. http://www.onlineethics.org/?id=34405&preview=true
This Workshop Summary focuses on six broad topic areas: 1. Evidence on the functioning of the Common Rule and of institutional review boards (IRBs), to provide context for the proposed revisions. 2. The types and levels of risks and harms encountered in social and behavioral sciences, and issues related to the severity and probability of harm. 3. The consent process and special populations. 4. Issues related to the protection of research participants in studies that involve use of existing data and data sharing. 5. Multidisciplinary and multisite studies. 6. The purview and roles of IRBs.

The National Academies of Science, Engineering and Medicine. 2010. *Conducting Biosocial Surveys: Collecting, Storing, Accessing, and Protecting Biospecimens and Biodata.* Washington D.C.: National Academies Press. http://www.onlineethics.org/?id=34112&preview=true
This report offers findings and recommendations concerning the best approaches in the Biosocial field. The topics covered include: informed consent, privacy issues and the best practice, but also additional legal, ethical, and social issues, as well as practical issues related to the storage, retrieval, and sharing of data.

The National Academies of Science, Engineering and Medicine. 2007. *Ethical Considerations for Research Involving Prisoners*. Washington D.C.: National Academies Press.
http://www.onlineethics.org/?id=34246&preview=true
Because prisoners face restrictions on liberty and autonomy, have limited privacy, and often receive inadequate health care, they require specific protections when involved in research, This book emphasizes five broad actions to provide prisoners involved in research with critically important protections: expand the definition of 'prisoner'; ensure universally and consistently applied standards of protection; shift from a category-based to a risk-benefit approach to research review; update the ethical framework to include collaborative responsibility; and enhance systematic oversight of research involving prisoners.

The National Academies of Science, Engineering and Medicine. 2004. *The Ethical Conduct of Clinical Research Involving Children.* Washington DC: National Academies Press
http://www.onlineethics.org/?id=34240&preview=true

This report provides background and makes recommendations regarding (1) the regulation of clinical research involving children; (2) the evaluation of the risks and benefits to children; (3) the use of informed consent; (4) the use of payments related to research participation; (5) the enforcement of regulations on this are of research; and (6) the roles and responsibilities of those involved.

The National Academies of Science, Engineering and Medicine. *Research Ethics in Complex Humanitarian Emergencies: Summary of a Workshop*. Washington DC: National Academies Press
http://www.onlineethics.org/Resources/34378.aspx
Situations involving conflict and forced migration have become increasingly commonplace in today's world. The need to understand the causes, consequences, and characteristics of these situations is creating a burgeoning field of research. But given the nature of complex emergency settings, traditional research guidelines may be inappropriate. The research and policy community has recognized this problem and has begun to address issues surrounding the ethics of doing research in emergency settings and among conflict-affected and displaced populations. The Roundtable on the Demography of Forced Migration, under the aegis of the Committee on Population of the National Research Council, held a workshop to examine some of these issues. This report to the roundtable summarizes the workshop presentations and discussion.

National Bioethics Advisory Commission (NBAC). Research Involving Human Biological Materials: Ethical Issues and Policy Guidance. 2 vols. Rockville, MD: U.S. Government Printing Office, 1999. *This report discusses ethical issues raised in the use of human biological materials (cells collected through biopsies, organs and tissues removed during surgeries) for research purposes. It talks about issues related to notifying individuals about the use of their specimens, as well as privacy, and intellectual property issues related with the use of these specimens for biomedical research purposes.* The full text of the report can be found in this **list of NBAC Publications.**

National Bioethics Advisory Commission (NBAC). 2001. Ethical and Policy Issues in Research Involving Human Participants. Volume I: Report and Recommendations of the National Bioethics Advisory Commission, Full Report. [Ch. 4: “Assessing Risks and Potential Benefits and Evaluating Vulnerability”]. Volume II: Commissioned Papers. Bethesda, MA: NBAC.
This is the final report and related papers from the U.S. National Bioethics Advisory

Commission laying out best practices for the use of human participants in research. Discusses issues of informed consent, working with vulnerable populations, the role of Institutional Review Boards and issues surrounding the ongoing monitoring of research involving human participants. The full text of the report can be found in this **list of NBAC Publications.**

Penslar, R. L. and the U.S. National Institutes of Health, Office for the Protection of Human Subjects in Research. 1993. *Protecting Human Subjects: Institutional Review Board Guidebook*. Washington, D.C.: Gocernment Printing Office.
This is the official guidebook for institutional review boards (IRB)in charge of reviewing federally-funded projects involving human research subjects. The guidebook covers regulations and policies, the duties of an IRB, scientific research design and ethical considerations raised by these designs and techniques, and special classes of research subjects that merit an enhanced level of protection.

Presidential Commission for the Study of Bioethical Issues. 2011. "Ethically Impossible" STD Research in Guatemala from 1946-1948. Washington, D.C.
This reports on a study done by the U.S. Public Health Service done from 1946-1948 that involved intentionally exposing and infecting vulnerable populations to sexually transmitted diseases without the subjects' consent.

Presidential Commission for the Study of Bioethical Issues. 2011. Moral Science: Protecting Participants in Human Subjects Research. Washington, D.C.
Provides a thorough review of current regulations and international standards that protect human research subjects.

Rhodes, R., N. Gilgorov, and A.P. Schwab. 2013. *The Human Microbiome: ethical, legal and social concerns.* Oxford, UK: Oxford University Press.
Looking at the bacteria, viruses, and fungi that cover our skin, line our intestines, and flourish in our body cavities, this book looks at how human microbiome research challenges reigning views on public health and research ethics, and how this research changes views on human identity, property rights, and privacy.

Shamoo, Adil E. and Felix A. Khin-Maung-Gyi. 2002. *Ethics of the Use of Human Subjects in Research*. New York, Garland Science.
Provides a practical introduction to ethical issues of human participants in research.

Schneider, Carl. 2015. *The Censor's Hand: the misregulation of human-subject research.* Cambridge, MA: MIT Press.
Discusses if Institutional Review Boards – which oversee federally funder research involving human participants – possibly do more harm than good in delaying and deterring research that may save lives.

Vanderpool H.Y. 1996 *The Ethics of Research Involving Human Subjects: Facing the 21st Century*. Frederick, Maryland, University Publishing Group.
A collection of essays discussing the complex issues of research involving human participants, including research ethics and regulations, conflicts of interest, cross-cultural research, and critical issues in specialized areas of research, such pediatric and genome research.

Journal Articles

Appelbaum, P. S, C.W. Lidz, and R. Klitzman. 2009. "Voluntariness of consent to research: a conceptual model." *Hastings Center Report* 39(1):30-39.
Discusses the concept of informed consent in research, especially in terms of voluntariness and questions of impairment in giving consent. The authors look at the legal model of informed consent to try and define these elusive terms.

Barchi, F., M.K. Singleton, and J.F. Merz. 2014. "Fostering IRB Collaboration for Review of International Research." *American Journal of Bioethics* 14 (5):3-8. doi: 10.1080/15265161.2014.892168.
This article presents a review of the literature, summarizes current initiatives, and provides a heuristic for assessing the effectiveness of a range of institutional review board (IRB) collaborative strategies that can reduce the regulatory burden of ethics review while ensuring protection of human subjects, with a particular focus on international research. Broad adoption of IRB collaborative strategies will reduce regulatory burdens posed by overlapping oversight mechanisms and has the potential to enhance human subjects protections.

Blomfield, Megan. 2012. "Ethics in Economics: Lessons from Human Subjects Research." *Erasmus Journal for Philosophy and Economics* 5 (1):24-44.
Many economists are inclined to deny that moral philosophy has anything to do with

economics. In this paper the author challenges such inclinations by drawing an analogy between economic interventions and human subjects research. It is undeniable that investigators engaged in the latter should adhere to specific ethical principles. She argues that analogous features of economic interventions should lead us to recognise that similar ethical concerns actually arise in both activities, and thus that economic interventions should also be conducted in accordance with ethical principles. By exploring the analogy further I formulate some ethical guidelines for economic practice, which in turn imply that ethical responsibilities will extend to all members of the economics profession.

Bok, Sissela. 1995. “Shading the truth in seeking informed consent for research purposes.” *Kennedy Institute of Ethics Journal*, 5(1): 386-388. doi: 10.1353/ken.0.0116.

The author argues that what some researchers take to be a simple trade-off between minor violations of the truth in recruiting research participants, represents a profound miscalculations with far-reaching and cumulative ethical issues raised. Truth-telling in research projects is important not only to the integrity of that individual’s project but also for the fragile research environment in its own right.

Cabrera Trujillo, Laura Yenisa, and Sabrina Engel-Glatter. 2015. "Human-Animal Chimera: A Neuro Driven Discussion? Comparison of Three Leading European Research Countries." *Science and Engineering Ethics* 21 (3):595-617. doi: 10.1007/s11948-014-9556-6

Research with human-animal chimera raises a number of ethical concerns, especially when neural stem cells are transplanted into the brains of non-human primates (NHPs). Besides animal welfare concerns and ethical issues associated with the use of embryonic stem cells, the research is also regarded as controversial from the standpoint of NHPs developing cognitive or behavioural capabilities that are regarded as "unique" to humans. However, scientists are urging to test new therapeutic approaches for neurological diseases in primate models as they better mimic human physiology than all current animal models. As a response, various countries have issued reports on the topic. Our paper summarizes the ethical issues raised by research with human-animal brain chimeras and compares the relevant regulatory instruments and different recommendations issued in national reports from three important European research nations: Germany, Switzerland and the United Kingdom.

Castellano, Marlene Brant. 2004. "Ethics of Aboriginal research." *International Journal of Indigenous Health* 1 (1):98 -114.
This paper proposes a set of principles to assist in developing ethical codes for the conduct of research within the Aboriginal community or with external partners.

Chan, D.K. K. 2015. "The Concept of Human Dignity in the Ethics of Genetic Research." *Bioethics* 29 (4):274-282. doi: 10.1111/bioe.12102
Despite criticism that dignity is a vague and slippery concept, a number of international guidelines on bioethics have cautioned against research that is contrary to human dignity, with reference specifically to genetic technology. What is the connection between genetic research and human dignity? In this article, the author investigates the concept of human dignity in its various historical forms, and examine its status as a moral concept.

Clausen, J. 2013. "Bonding Brains to Machines: Ethical Implications of Electroceuticals for the Human Brain." *Neuroethics* 6 (3):429-434. doi: 10.1007/s12152-013-9186-8
Novel neurotechnologies like deep brain stimulation and brain-computer interfaces promise clinical benefits for severely suffering patients. Nevertheless, such electroceuticals raise several ethical issues on different levels: while on the level of clinical neuroethics issues with direct relevance for diagnosis and treatment have to be discussed, on the level of research neuroethics questions regarding research and development of these technological devices like investigating new targets and different diseases as well as thorough inclusion criteria are dealt with. On the level of theoretical neuroethics more general questions are examined including anthropological considerations on “normal” human functioning as well as implications on personality, personal identity and authenticity. This paper presents a brief review on ethical issues of deep brain stimulation and brain computer interfacing and simultaneously introduces to this themed issue with thirteen contributions dealing from different perspectives with ethical implications of electroceuticals for the human brain.

Cox, S.M., and M. McDonald. 2013. "Ethics is for human subjects too: Participant perspectives on responsibility in health research." *Social Science & Medicine* 98:224-231. doi: 10.1016/j.socscimed.2013.09.015.
Despite the significant literature as well as energy devoted to ethical review of research involving human subjects, little attention has been given to understanding the experiences of those who volunteer as human subjects. Why and

how do they decide to participate in research? Is research participation viewed as a form of social responsibility or as a way of obtaining individual benefits? What if anything do research subjects feel they are owed for participation? And what do they feel that they owe the researcher? Drawing on in-depth individual interviews conducted in 2006 and 2007 with 41 subjects who participated in a variety of types of health research in Canada, this paper focuses on subject perspectives on responsibility in research.

Devaney, S. 2014. "Rewards and Incentives for the Provision of Human Tissue for Research." ***Journal of Medical Ethics: The Journal of the Institute of Medical Ethics*** **40 (1):48-50. doi: 10.1136/medethics-2012-101080**

The Nuffield Council on Bioethics' 2011 report, Human Bodies: Donation for Medicine and Research, proposes a system for examining the ethical implications of different types of incentives for the provision of human tissue for use in medicine and research. The cornerstone of this system is the principle of altruism which, the Council recommends, should, where possible, remain the starting point for any such tissue provision. Using the Council's example of ova provision for research as an area in which altruism-based rewards might be departed from, this article argues that such a system has the potential to become inconsistent and unnecessarily complex. It suggests that the outcomes-focussed and motivations-focussed justifications the Council provides do not sit easily within the fast-paced and unpredictable area of biotechnology research. Further, it may undermine the focus on autonomy that is enshrined in the relevant legislation.

Dickert, N. W. 2009. “Re-examining respect for human research participants*.” Kennedy Institute of Ethics Journal.* 19(4): 311-338.

The author re-examines the concept of respect for persons when conducting clinical research and discusses that this cannot just be reduced to autonomy, there are many was to show respect for a person. He argues that along with autonomous agency, respect demands attention to important subjective experiences, a person’s existence as a part of a community, and considerations of comportment.

Dresser, R. 2012. "Building an Ethical Foundation for First-in-Human Nanotrials." ***Journal of Law, Medicine and Ethics: A Journal of the American Society of Law, Medicine and Ethics*** **40 (4):802-808. doi: 10.1111/j.1748-720X.2012.00708.x**

Novel nanomedical interventions require human testing to evaluate their safety and effectiveness. To establish a proper evidentiary basis forhuman trials, nanomedical

innovations must first be subjected to animal and other laboratory testing. But it is uncertain whether the traditional laboratory approaches to safety evaluation will supply adequate information on nanotechnology risks to humans. This uncertainty, together with other features of nanomedical innovation, heightens the ethical challenges in conducting FIH nanotrials.

Erikkson, S., A.T. Hoglund, and G. Helgesson. 2008. "Do ethical guidelines give guidance? A critical examination of eight ethics regulations." ***Cambridge Quarterly of Healthcare Ethics.*** **17(1) 15-29.**
As an example of how biomedical legislations and guidelines are not very useful tools for the development of ethical competence, the author looks at eight ethical guidelines on obtaining informed consent and shows how complications can arise when these kinds of guidelines are used by themselves to guide ethical behavior and develop ethical competence.

Eckenwiler, L.. 2001. "Moral Reasoning and the Review of Research Involving Human Subjects." ***Kennedy Institute of Ethics Journal.*** **11(1): 37-69.**

The author argues that the model of moral reasoning used in Institutional Review Board review fails to uphold ethical ideals for research participants as it does not adequately acknowledge the particular context of research or of subjects, including their gender, their socioeconomic status, and the communities in which they lead their lives. The author looks at instances where the current review model falls short, and suggests a number of solutions, including the need for effective consultation with the various communities affected by research and greater reliance on subject representatives.

Edwards, S. J. L. 2005. "Research Participation and the Right to Withdraw." ***Bioethics*** **19(2): 112-30.**
This author discusses the right of human participants in research have to withdraw from a study at any time, and why this right to withdraw should not be unconditional. It instead, the author suggests, should be an ongoing set of negotiations between the patient and researcher.

Evers, D.L., C.B. Fowler, and J.T. Mason. 2015. "Deliberate Microbial Infection Research Reveals Limitations to Current Safety Protections of Healthy Human Subjects." ***Science and Engineering Ethics*** **21 (4):1049-**

1064. doi: 10.1007/s11948-014-9579-z
The authors identify approximately 40,000 healthy human volunteers who were intentionally exposed to infectious pathogens in clinical research studies dating from late World War II to the early 2000s. Microbial challenge experiments continue today under contemporary human subject research requirements. In fact, the authors estimate 4,000 additional volunteers who were experimentally infected between 2010 and the present day. They examine the risks and benefits of these experiments and present areas for improvement in protections of participants with respect to safety. These are the absence of maximum limits to risk and the potential for institutional review boards to include questionable benefits to subjects and society when weighing the risks and benefits of research protocols.

Fleischman, A., C. Levine, and L. Eckenwiler. 2011. "Dealing with the Long-Term Social Implications of Research." *American Journal of Bioethics* 11 (5):5-9. doi: 10.1080/15265161.2011.568576
Biomedical and behavioral research may affect strongly held social values and thereby create significant controversy over whether such research should be permitted in the first place. Institutional review boards (IRBs) responsible for protecting the rights and welfare of participants in research are sometimes faced with review of protocols that have significant implications for social policy and the potential for negative social consequences. Although IRB members often raise concerns about potential long-term social implications in protocol review, federal regulations strongly discourage IRBs from considering them in their decisions. Yet IRBs often do consider the social implications of research protocols and sometimes create significant delays in initiating or even prevent such research. The social implications of research are important topics for public scrutiny and professional discussion. This article examines the reasons that the federal regulations preclude IRBs from assessing the social risks of research, and examines alternative approaches that have been used with varying success by national advisory groups to provide such guidance. The article concludes with recommendations for characteristics of a national advisory group that could successfully fulfill this need, including sustainability, independence, diverse and relevant expertise, and public transparency.

Gefenas, E., V. Dranseika, and J. Serepkaite. 2012. "Turning Residual Human Biological Materials into Research Collections: Playing with Consent." *Journal of Medical Ethics: The Journal of the Institute of Medical*

***Ethics* 38 (6):351-355. doi: 10.1136/medethics-2011-100113.**
This article focuses on three scenarios in which residual biological materials are turned into research collections during the procedure of procuring these materials for diagnostic, therapeutic or other non-research purposes. These scenarios offer additional sources of biological samples for research purposes and at the same time seem to offer even more flexibility in terms of stringency of consent as compared with the more traditional models of broad consent in prospective research collections and the waiver of consent in retrospective research. Our discussion leads us to think that precautionary consent is preferable to presumed consent and no consent when handling issues of consent in the use of residual human biological materials for research. However, such precautionary consent should not be construed as blanket, unrestricted consent for any future use.

Gerlach, J.W. 2002. "What should IRBs consider when applying the privacy rule to research?" *Kennedy Institute of Ethics.* 12(3): 299-303.

Discusses relevant regulation involving the protection of information about human participants in research, and participants' rights regarding the use of that information.

Gostin, L.O. 2007. "Biomedical Research Involving Prisoners." *JAMA: Journal of the American Medical Association* 297(7): 737-740.

Discusses the history , ethics and regulatory issues involved when using prisoners in biomedical research. Suggests safeguards that should be put in place to promote responsible research and to reduce risks to participating prisoners.

Grady, C. 2001. "Money for Research Participation: Does it Jeopardize Informed Consent?" *The American Journal of Bioethics.* 1(2): 40-44.
This article explores the idea that offering money for research participation can constitute coercion or undue influence capable of distorting the judgment of potential research subjects and compromising the voluntariness of their informed consent.

Guillemin, Marilys, Lynn Gillam, Emma Barnard, Paul Stewart, Hannah Walker, and Doreen Rosenthal. 2016. ""We're checking them out": Indigenous and non-Indigenous research participants' accounts of deciding to be involved in research." *International Journal for Equity in Health* 15:8. doi: 10.1186/s12939-016-0301-4.

It is important for researchers to understand the motivations and decision-making processes of participants who take part in their research. This enables robust informed consent and promotes research that meets the needs and expectations of the community. It is particularly vital when working with Indigenous communities, where there is a history of exploitative research practices. In this paper, the authors examine the accounts of Australian Indigenous and non-Indigenous research participants in terms of how and why they agree to take part in research.

Gunsalus, C.K., E. M. Bruner, N.C. Burbules, L. Dash, M. Finkin, J. P. Goldberg, W. T. Greenough, G.A. Miller, M.G. Pratt, M.Iriye, and D. Aronson. 2007. "The Illinois White Paper: Improving the System for Protecting Human Subjects: Counteracting IRB “Mission Creep”." *Qualitative Inquiry* 13 (5):617-649. doi: 10.1177/1077800407300785.
This White Paper reports on two years' work by a group convened by the Center for Advanced Study at the University of Illinois, following an invitational, national, interdisciplinary conference Human Subject Policy Conference: An Examination of the Interaction Between Human Subject Protection Regulations and Research Outside the Biomedical Sphere. We describe the pernicious effects of mission creep on the work of Institutional Review Boards, which is diverting the attention of some IRBs from critical ethical oversight in favor of often-meaningless paperwork. We make recommendations to help the IRB system focus its efforts on those research projects most in need of careful ethical review to protect human subjects of and participants in research. The recommendations include the idea that some methodologies do not need advance review and approval by IRBs and that there are procedural changes that can strengthen the core missions of IRBs. We hope that this paper will further the discussion about what reasonable procedures can be instituted to provide improved ethical protection for people who participate in research projects.

Have, H. 2015. "Respect for Human Vulnerability: The Emergence of a New Principle in Bioethics." *Journal of Bioethical Inquiry* 12 (3):395-408. doi: 10.1007/s11673-015-9641-9
Vulnerability has become a popular though controversial topic in bioethics, notably since 2000. As a result, a common body of knowledge has emerged (1) distinguishing between different types of vulnerability, (2) criticizing the categorization of populations as vulnerable, and (3) questioning the practical implications. It is argued that two perspectives on vulnerability, i.e., the

philosophical and political, pose challenges to contemporary bioethics discourse: they re-examine the significance of human agency, the primacy of the individual person, and the negativity ofvulnerability. As a phenomenon of globalization, vulnerability can only be properly addressed in a global bioethics that takes the social dimension of human existence seriously.

Holland, T.D. 2015. "Since I Must P lease Those Below" : Human Skeletal Remains, Research, and the Law." American Journal of Law & Medicine 41 (4):617-655.

The ethics of non-invasive scientific research on human skeletal remains are poorly articulated and lack a single, definitive analogue in western law. Laws governing invasive research on human fleshed remains, as well as bio-ethical principles established for research on living subjects, provide effective models for the establishment of ethical guidelines for non-invasive research on human skeletal remains. Specifically, non-invasive analysis of human remains is permissible provided that the analysis and collection of resulting data (1) are accomplished with respect for the dignity of the individual, (2) do not violate the last-known desire of the deceased, (3) do not adversely impact the right of the next of kin to perform a ceremonious and decent disposal of the remains, and (4) do not unduly or maliciously violate the privacy interests of the next of kin.

Hudson, Peter. & Sharon Taylor-Henley. 2001. "Beyond Rhetoric: Implementing a Culturally Appropriate Research Project in First Nations Communities." *American Indian Culture and Research Journal* 25(2), 93-105. doi: 10.17953/aicr.25.2.wm706483h416245j

The authors report on the development of a collaborative research project in southeastern Manitoba. Rising teenage suicide rates, addictions, and youth appearing in the courts raised concerns among the nine participating Ojibwa tribes and the Southeast Resource Development Council (SERDC). The research process was guided by four principles: elder input, use of traditional language in implementation, clear demonstration of benefit to community, and First Nations control. Importantly, the authors argue the need to design ways to involve communities at an earlier stage (front-end) and to create more time for evaluating and making recommendations in the final report (back-end).

Huntington, I. and W. Robinson. 2007. "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* 29(3): 6-10.
This article contains a qualitative report and reflections of a research coordinator working on recruiting research participants for two minimal risk studies involving children and adults with cystic fibrosis. She discusses the challenges of obtaining informed consent, and some strategies to overcome these challenges without pressuring someone into participating in the study.

Iltis, A. 2006. “Lay Concepts in Informed Consent to Biomedical Research: The Capacity to Understand and Appreciate Risk.” *Bioethics* 20(4): 180-90.
This paper examines the relationship between the obligation to disclose information regarding risks in informed consent, and the requirement that persons have the capacity to understand and appreciate the information. As a normal person often has a limited capacity to comprehend the risk involved in research, some research projects should require human participants to have a higher than normal ability to appreciate risk in order to give consent to participate.

Javitt, G. H. 2013. "Take Another Little Piece of My Heart: Regulating the Research Use of Human Biospecimens." *Journal of Law, Medicine and Ethics: A Journal of the American Society of Law, Medicine and Ethics* 41 (2):424-439. doi: 10.1111/jlme.12053
This article reviews the history of the debate over use of biospecimens in research, the legal and ethical arguments that have been presented both in support of and in opposition to such use, court cases and judicial opinions involving disputes between specimen contributors, researchers, and institutions, and public attitudes regarding the use of biospecimens in research. The paper argues that proposed changes to the Common Rule are inadequate to resolve the legal and ethical concerns that have been raised with respect to the use of biospecimens. It argues that there is a need to distinguish between the dual roles - subject and donor - played by contributors of biospecimens.

Joffe, S. 2006.” Altruistic Discourse and Therapeutic Misconception in Research Informed Consent”. *American Journal of Bioethics* 6(5): 53-54.
Discusses misconceptions patients involved in research can have about the benefits of the research they are participating in.

Johansson, M., and L. Broström. 2012. "Does 'Peer' Benefit Justify Research on Incompetent Individuals? The Same-Population Condition in Codes of

Research Ethics." ***Medicine, Health Care and Philosophy: A European Journal*** **15 (3):287-294. doi: 10.1007/s11019-011-9324-1**

Research on incompetent humans raises ethical challenges, especially when there is no direct benefit to these research subjects. Contemporarycodes of research ethics typically require that such research must specifically serve to benefit the population to which the research subjects belong. The article critically examines this "same-population condition", raising issues of both interpretation and moral justification. Of particular concern is the risk that the way in which the condition is articulated and rationalized in effect disguises or downplays the instrumentalization of incompetent individuals.

Kimmelman, J.. 2012. "Beyond Human Subjects: Risk, Ethics, and Clinical Development of Nanomedicines." ***Journal of Law, Medicine and Ethics: A Journal of the American Society of Law, Medicine and Ethics*** **40 (4):841-847. doi: 10.1111/j.1748-720X.2012.00712.x.**

Clinical testing of nanomedicines presents two challenges to prevailing, human subject-centered frameworks governing research ethics. First, some nanomedical applications may present risk to persons other than research subjects. Second, pressures encountered in testingnanomedicines may present threats to the kinds of collaborations and collective activities needed for supporting clinical translation and redeeming research risk. In this article, the author describes how similar challenges were encountered and addressed in gene transfer, and sketch policy options that might be explored in the nanomedicine translation arena.

King, N. M. P. 2012. "Nanomedicine First-in-Human Research: Challenges for Informed Consent." ***Journal of Law, Medicine and Ethics: A Journal of the American Society of Law, Medicine and Ethics*** **40 (4):823-830. doi: 10.1111/j.1748-720X.2012.00710.x**

Risks of harm, translational uncertainty, ambiguities in potential direct benefit, and long-term follow-up merit consideration in first-in-human research. Some nanomedical technologies have additional characteristics that should be addressed, including: defining and describing nanomedical interventions; bystander risks; the therapeutic misconception; and a decision-making context that includes both common use of nanomaterials outside medicine and persistent unknowns about the effects of nanosize. This paper considers how to address these issues in informed consent to first-in-human nanomedicine research.

Kishore, R.R. 2006. “Biomedical Research and the Mining of the Poor: The Need for their Exclusion.” *Science and Engineering Ethics*. 12(1): 175-183.
This article looks at the adequacy of international guidelines on the use of human subjects in research, and their adequacy in protecting the poor against exploitation. The author concludes that given failure of ethical guidelines in protecting the extreme vulnerability of this population, they should be excluded from being enrolled as research subjects.

Kleinsman, J., and S. Buckley. 2015. "Facebook Study: A Little Bit Unethical but Worth It?" *Journal of Bioethical Inquiry* 12 (2):179-182. doi: 10.1007/s11673-015-9621-0
Human research involving the use social media raises many of the same issues as medical research. The publication of a paper in June 2014 investigating "emotional contagion" received extensive publicity recently because of the methods used. The approach involved manipulating the "News Feeds" of Facebook users, but the participants were not informed of their involvement in the research and had no opportunity to consent or opt out. Some commentators have argued that although it would have been preferable to obtain informed consent, it was not strictly required because the research was unlikely to cause significant harm and was important. This paper argues that the research was unethical because (i) it should have been overseen by an independent ethics committee or review board and (ii) informed consent could and should have been obtained. Regardless of the importance of any research and irrespective of its likelihood to cause harm, the ethical principles that have evolved since the 1940s should be followed in all instances when experimental research is being carried out on human participants.

Koepsell, D., W.P. Brinkman, and S. Pont. 2014. "Human research ethics committees in technical universities." *Journal of Empirical Research on Human Research Ethics* 9 (3):67-73. doi: *10.1177/1556264614540596*
Human participants, however, are used in a much broader range of research than ethics committees oversee, including both basic and applied research at technical universities. Although mandated in the United States, the United Kingdom, Canada, and Australia, non-medical research involving humans need not receive ethics review in much of Europe, Asia, Latin America, and Africa. The authors’ survey of the top 50 technical universities in the world shows that, where not specifically mandated by law, most technical universities do not employ ethics committees to review human studies.

Kottow, M. 2004. "The Battering of Informed Consent." *Journal of Medical Ethics* 30(6): 565-569.
The author argues that thought autonomy has been hailed as the foremost principle of bioethics, the voluntary participation of research participants is being subject to frequent restrictions, often in the form of paternalism by doctors. The author discusses why this is a major problem in clinical research, and why bioethics should insist on reinforcing autonomy in these settings.

Kristinsson, S. 2007. "Autonomy and Informed Consent: A Mistaken Association?" *Medicine, Healthcare and Philosophy* 10(3): 253-264.
This essay explores the importance of informed consent in efforts to improve regulatory frameworks for research ethics, and explores reasons why informed consent is so important in the responsible conduct of research involving human subjects. The author uses ethical theory to explore informed consent, and concludes that the justification for informed consent should be along the lines of Kantian autonomy and not individual autonomy.

Levine, C. R. Faden and C.Grady. 2004. "The Limitations of 'Vulnerability' as a Protection for Human Research Subjects." *American Journal of Bioethics* 4(3): 44-86.
This article examines the concept of vulnerability in research ethics, and discusses how different regulations and policy documents have dealt with the concept of vulnerability, either as an inability to give informed consent or emphasizing unequal power relationships between politically and economically disadvantaged groups and investigators or sponsors. Because so many groups are now considered to be vulnerable, the term has lost its force, and it may not adequately protect certain subjects from harm. The author calls for the use of regulation to protect these groups, but also for researchers to pay attention to characteristics of the research protocol and environment that present ethical challenges.

Louis, Renee. P. 2007. "Can You Hear us Now? Voices from the Margin: Using Indigenous Methodologies in Geographic Research." *Geographical Research*, 45: 130–139. doi:10.1111/j.1745-5871.2007.00443.x
Indigenous methodologies are an alternative way of thinking about research processes. Although these methodologies vary according to the ways in which different Indigenous communities express their own unique knowledge systems, they do have common traits. This article argues that research on Indigenous issues should be carried out in a manner which is respectful and ethically sound from an

Indigenous perspective.

Mandava, A., and J. Millum. 2013. "Manipulation in the Enrollment of Research Participants." *Hastings Center Report* 43 (2):38-47. doi: 10.1002/hast.144

Researchers can design recruitment and consent processes so that potential participants are more likely to decide to enroll. These strategies work by subtly manipulating the participants. But how much manipulation is acceptable?

McLaughlin, R.H., and T. Alfaro-Velcamp. 2015. "The Vulnerability of Immigrants in Research: Enhancing Protocol Development and Ethics Review." *Journal of Academic Ethics* 13 (1):27-43.

Vulnerabilities often characterize the availability of immigrant populations of interest in social behavioral science, public health, and medical research. Refugees, asylum seekers, and undocumented immigrants present unique vulnerabilities relevant to protocol development as well as ethics review procedures and criteria. This paper describes vulnerable populations in relation to the Belmont Report and US federal regulations for the protection of human subjects, both of which are commonly used in international research contexts. It argues for safeguards for immigrants comparable to protections for such populations as pregnant women, prisoners, and children. The paper further presents a two-part model for the review of protocols that involve immigrants. The model is intended to help identify the risks to immigrants associated with participation in research, and to suggest how researchers can responsibly frame studies and access to research participant immigrants through community-based, and/or non-governmental organizations that serve immigrants and immigrant communities.

Mehlman, M.J., J. W. Berg, and Eric T. Juengst. 2011. "Ethical and Legal Issues in Enhancement Research on Human Subjects." *Cambridge Quarterly of Healthcare Ethics* 20 (1):30-45. doi: 10.1017/S0963180110000605

The United States, along with other nations and international organizations, has developed an elaborate system of ethical norms and legal rules to govern biomedical research using human subjects. These policies govern research that might provide direct health benefits to participants and research in which there is no prospect for participant health benefits. There has been little discussion, however, about how well these rules would apply to research designed to improve participants' capabilities or characteristics beyond the goal of good health. When

mentioned at all in the literature, this so-called enhancement research, as opposed to research aimed at diagnosing, preventing, curing, or treating illnesses or medical conditions, is usually dismissed without explanation.

Miller, F. F., J.P. Gluck and D. Wendler. 2008. “Debriefing and Accountability in Deceptive Research.” *Kennedy Institute of Ethics Journai* 18(3):235-251.

This article discusses the importance of the debriefing requirement for human research involving the use of deception.

Muhammad, A.A.. 2014. "Issues of Research Ethics in Developing World: Ways of Improving the Scenario." *Eubios: Journal of Asian and International Bioethics* 24 (2):66-68.

Although it is a matter of fact that clinical trials and research play a very important role in the scientific and technological development, however, it also gives birth to many ethical problems and dilemmas specially when the research and trials are conducted in developing or resource poor countries. The sponsors and investigators could prefer to perform research in underdeveloped countries where there is lack of basic resources; people are illiterate and are most susceptible to exploitation. This paper attempts to discuss some of these issues in detail like -- potential for exploitation of research participants, standard of care debates, quality of informed consent, therapeutic misconception and conflict of interest issues. All of them lead to the violation of very basic ethical principles of autonomy, beneficence, nonmaleficence and justice. Many interventions could be implemented and the guidelines mentioned in this paper could be followed by the research enterprise to make the studies moral and ethical.

Newton, S.K. and J. Appiah-Poku. 2007. “The Perspectives of Researchers on Obtaining Informed Consent in Developing Countries.” *Developing World Bioethics* 7(1): 19-24.

This study focuses on a series of interviews done with 12 lecturers and doctoral students who had carried out research in developing countries at a leading school of public health in the UK. The researchers found that though the concept and application of the doctrine of informed consent should have been the same regardless of place, the researchers had needed to take into consideration the setting the research was to be conducted in, the autonomy of the patient, and the need to develop innovative ways to carry out the study taking into consideration the circumstances of the environment.

Ngui, E. M., T. D. Warner, and Laura Weiss Roberts. 2015. "Ethical Responsibilities and Perceptions of Stakeholders of Genetic Research Involving Racial/Ethnic Minority Participants." *AJOB Empirical Bioethics* 6 (3):15-27. doi: 10.1080/23294515.2014.978414

Genetic research involving racial/ethnic populations has novel ethical implications for various stakeholders, but ethical acceptability among stakeholders regarding such research is not clear. As part of a multifaceted National Institute of Mental Health (NIMH)/National Human Genome Research Institute (NHGRI) funded survey, the authors looked at the perspectives of institutional review board (IRB) chairs, investigators, and community members on the ethical acceptability of participating in and reporting of psychiatric genetic research focused on racial/ethnic minority groups. Findings show community and professional stakeholders support participation in genetic research focused on specific racial/ethnic groups but recognize that the results of such studies may contribute to discrimination or stigmatization. Stakeholders differed in their perspectives of investigators and editors in balancing ethical issues intrinsic to advancing science versus minimizing harm to potentially vulnerable populations.

O'Connor, D.. 2013. "The Apomediated World: Regulating Research When Social Media Has Changed Research." *Journal of Law, Medicine and Ethics: A Journal of the American Society of Law, Medicine and Ethics* 41 (2):470-483. doi: 10.1111/jlme.12056

Social Media, like Facebook and Twitter, are having a profound effect on the way that human subjects research is being conducted. In light of the changes proposed in ANPRM, in this article I argue that traditional research ethics and regulations may not easily translate to the use of social media in human subjects research. Using the conceptual model of apomediation, which describes the peer-to-peer way in which health information is shared via social media, I suggest that we may need to think again about the suitability of current regulations to deal with social media research.

Pieper, I. J., and C. J. H. Thomson. 2014. "The Value of Respect in Human Research Ethics: A Conceptual Analysis and a Practical Guide." *Monash Bioethics Review* 32 (3-4):232-253. doi: 10.1007/s40592-014-0016-5

In order to continue to maintain public trust and confidence in human research, participants must be treated with respect. Researchers and Human Research Ethics Committee members need to be aware that modern considerations of this value include: the need for a valid consenting process, the protection of participants who

have their capacity for consent compromised; the promotion of dignity for participants; and the effects that human research may have on cultures and communities. This paper explains the prominence of respect as a value when considering the ethics of human research and provides practical advice for both researchers and Human Research Ethics Committee members in developing respectful research practices.

Pittaway, Eileen, Linda Bartolomei, and Richard Hugman. 2010. "'Stop Stealing Our Stories': The Ethics of Research with Vulnerable Groups." *Journal of Human Rights Practice* 2 (2):229-251. doi: 10.1093/jhuman/huq004.

The article discusses the challenges and opportunities faced when integrating participatory methods into human rights-based research. It describes the development of a participatory action research approach designed to fulfil the aim of undertaking advocacy-focused research grounded in human rights and community participation. It reflects the principles of anti-oppressive social work and the ethics of undertaking research with vulnerable populations.

Ploug, T., and S. Holm. 2015. "Going Beyond the False Dichotomy of Broad or Specific Consent: A Meta-perspective on Participant Choice in Research Using Human Tissue." *American Journal of Bioethics* 15 (9):44-46. doi: 10.1080/15265161.2015.1062178

Recognising that there are strong reasons for requiring consent for collecting and conducting research on biological samples, we argue (1) that neither empirical studies nor general considerations favor broad consent, (2) that broad consent may fail to act in the interests both of research and of the individual and his/her autonomy, (3) that positing a choice between broad and specific consent as the only options presents a false dichotomy, and (4) that our recently proposed model of consent -- metaconsent -- is better suited to safeguarding both research and the individual's interests and autonomy.

Quigley, D. 2015. "Promoting Human Subjects Training for Place-Based Communities and Cultural Groups in Environmental Research: Curriculum Approaches for Graduate Student/Faculty Training." *Science and Engineering Ethics* 21 (1):209-226. doi: 10.1007/s11948-013-9508-6

A collaborative team of environmental sociologists, community psychologists, religious studies scholars, environmental studies/science researchers and engineers has been working together to design and implement new training in research ethics,

culture and community-based approaches for place-based communities and cultural groups. The training is designed for short and semester-long graduate courses at several universities in the northeastern US. The team received a 3 year grant from the US National Science Foundation's Ethics Education in Science and Engineering in 2010. This manuscript details the curriculum topics developed that incorporate ethical principles, particularly for group protections/benefits within the field practices of environmental/engineering researchers.

Rothwell, E., Karen J. Maschke, J. R. Botkin, Aaron Goldenberc, T. H. Murray, and S. M. RlVera. 2015. "Biobanking Research and Human Subjects Protections: Perspectives o f IRB Leaders." *IRB: Ethics & Human Research* 37 (2):8-13.

Discusses the unique ethical issues raised by the biobanking of genetic material and other human biospecimens and relates the results of a study of IRB policies on collecting, storing and sharing biospecimens and associated data.

Rózynska, J. 2015. "On the Alleged Right to Participate in High-Risk Research." *Bioethics* 29 (7):451-461. doi: 10.1111/bioe.1214

Reigning regulatory frameworks for biomedical research impose on researchers and research ethics committees an obligation to protect research participants from risks that are unnecessary, disproportionate to potential research benefits, and non-minimized. Where the research has no potential to produce results of direct benefit to the subjects and the subjects are unable to give consent, these requirements are strengthened by an additional condition, that risks should not exceed a certain minimal threshold. In this article, the author addresses s the question of whether there should be limits of permissible risks in non-therapeutic research involving competent and healthy subjects.

Satalkar, P., and D. Shaw. 2015. "Not Fit for Purpose: The Ethical Guidelines of the Indian Council of Medical Research." *Developing World Bioethics* 15 (1):40-47.

In 2006, the Indian Council of Medical Research (ICMR) published its 'Ethical guidelines for Biomedical Research on human participants'. The intention was to translate international ethical standards into locally and culturally appropriate norms and values to help biomedical researchers in India to conduct ethical research and thereby safeguard the interest of human subjects. Unfortunately, it is apparent that the guideline is not fit for purpose. In addition to problems with the structure and clarity of the guidelines, there are several serious

omissions and contradictions in the recommendations. In this paper, the authors take a close look at the two key chapters and highlight some of the striking flaws in this important document. We conclude that ethics committees and national authorities should not lose sight of international ethical standards while incorporating local reality and cultural and social values, as focusing too much on the local context could compromise the safety of human subjects in biomedical research, particularly in India.

Schonfeld, T., J. S. Brown, and N. Jean Amoura. 2011. "'You Don't Know Me, but … ': Access to Patient Data and Subject Recruitment in Human Subjects Research." *American Journal of Bioethics* 11 (11):31-38. doi: 10.1080/15265161.2011.603794.

The authors argue that maintaining a patient's right to privacy is the key notion in determining who has legitimate access to patient information for research purposes. Limiting research access to those with legitimate access to patient clinical information minimizes the likelihood that there will be an expansion in the number of people who know private patient information, minimizing harm to patients. They also make an analogy between waiving informed consent and an increase in ethical access to private information for information that presents no greater than a minimal risk to subjects should it be released. These are part of the pragmatic considerations we offer to facilitate the conduct of research while safeguarding patients' rights to determine who has access to their private information.

Sharpe, R. R. and M.W. Foster. 2007. “Grappling with groups: protecting collective interests in biomedical research.” *Journal of Medicine and Philosophy* 32(4):321-337.

This article looks at strategies for protecting historically disadvantaged groups in the context of genetic research, and discusses the benefits and drawbacks of these strategies.

Sheehan, M.. 2014. "Ethical Review of Research on Human Subjects at Unilever: Reflections on Governance." *Bioethics* 28 (6):284-292. doi: 10.1111/bioe.12040

This article considers the process of ethical review of research on human subjects at a very large multinational consumer products company. The commercial context of this research throws up unique challenges and opportunities that make the ethics of the process of oversight distinct from mainstream medical research. Reflection on the justification of governance processes sheds important, contrasting light on the

ethics of governance of other forms and context of research.

Sofaer, N.. 2014. "Reciprocity-Based Reasons for Benefiting Research Participants: Most Fail, the Most Plausible Is Problematic." *Bioethics* 28 (9):456-471. doi: 10.1111/bioe.12039

A common reason for giving research participants post-trial access (PTA) to the trial intervention appeals to reciprocity, the principle, stated most generally, that if one person benefits a second, the second should reciprocate: benefit the first in return. Many authors consider it obvious that reciprocity supports PTA. Yet their reciprocity principles differ, with many authors apparently unaware of alternative versions. This article is the first to gather the range of reciprocity principles. It finds that: (1) most are false. (2) The most plausible principle, which is also problematic, applies only when participants experience significant net risks or burdens. (3) Seldom does reciprocity support PTA for participants or give researchers stronger reason to benefit participants than equally needy non-participants. (4) Reciprocity fails to explain the common view that it is bad when participants in a successful trial have benefited from the trial intervention but lack PTA to it.

Shrag, Brian. 2006. “Research with Groups, Group Consent and Collaborative Research”. *Science and Engineering Ethics* 12 (3):511-521

Discusses the importance of group consent for social science researchers working with indigenous and other communities.

Van Assche, K., L. Capitaine, and G. Pennings. 2015. "Governing the Postmortem Procurement of Human Body Material for Research." *Kennedy Institute of Ethics Journal* 25 (1):67-88. doi: 10.1353/ken.2015.0000.

Human body material removed post mortem is a particularly valuable resource for research. Considering the efforts that are currently being made to study the biochemical processes and possible genetic causes that underlie cancer and cardiovascular and neurodegenerative diseases, it is likely that this type of research will continue to gain in importance. However, post mortem procurement of human body material for research raises specific ethical concerns, more in particular with regard to the consent of the research participant. In this paper, the authors attempt to determine which consent regime should govern the post mortem procurement of body material for research. In order to do so, we assess the various arguments that could be put forward in support of a duty to make body material available for research purposes after death. We argue that this duty does in practice not support conscription but is sufficiently strong to defend a policy of presumed rather than

explicit consent.

Weijer, C.M. 2001. "The Ethical Analysis of Risks and Potential Benefits in Human Subjects Research: History, Theory, and Implications for U.S. Regulation." ***Ethical and Policy Issues in Research Involving Human Participants*****. Volume II: Commissioned Papers. P1 – P29. Washington, D.C.: National Bioethics Advisory Commission.**

This paper addresses three questions central to the ethical analysis of risks and potential benefits in human subjects research: 1. How was the ethical analysis of risk understood by the members of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission)? 2. What conceptual framework should guide the ethical analysis of risk? 3. What changes to U.S. regulations would the implementation of such a framework require?

Weijer, C. M. 1999. "Research Involving the Vulnerable Sick." ***Accountability in Research*** **7: 21–36.**

Discusses challenges associated with research involving the vulnerable sick, including deciding who among the ill count as vulnerable, and the need to include protections, including enrolling subjects in a study only with a strong justification, ensuring that consent is free and comprehending, and setting limits on the risk to which they may be asked to endure.

Weijer, C.M. and E.J. Emanuel. 2000. "Protecting Communities in Biomedical Research." ***Science*** **289 142-44.** . doi: 10.1126/science.289.5482.1142

Authors discuss the need to establish standards for the protection of communities involved in biomedical and genetics research, and lays out a five-step plan for designing these sorts of protections.

Wendler, D. 1998. "When Should 'Riskier' Subjects Be Excluded from Research Participation?" ***Kennedy Institute of Ethics Journal*** **8(3): 307-327.**

The exclusion of potential subjects based on increased risks is a common practice in human subjects research. However, there are no guidelines to ensure that this practice is conducted in a systematic and fair way. This article seeks to fill this gap by giving a a specific account of a "condition on inclusion risks" (CIR), a condition under which potential subjects should be excluded from research on the basis of increased risks. This account provides a general framework for assessing standard exclusions as well as more controversial ones such as the exclusion of pregnant

women and women of childbearing potential from certain types of research.

Wendler, D. 2013. "What Should Be Disclosed to Research Participants?" *American Journal of Bioethics* 13 (12):3-8. doi: 10.1080/15265161.2013.851578

Debate surrounding the SUPPORT study highlights the absence of consensus regarding what information should be disclosed to potential research participants. Some commentators endorse the view that clinical research should be subject to high disclosure standards, even when it is testing standard-of-care interventions. Others argue that trials assessing standard-of-care interventions need to disclose only the information that is disclosed in the clinical care setting. To resolve this debate, it is important to identify the ethical concerns raised by clinical research and determine what consent process is needed to address them.

Wenner, D. M. 2015. "The Social Value of Knowledge and International Clinical Research." *Developing World Bioethics* 15 (2):76-84. doi: 10.1111/dewb.12037

In light of the growth in the conduct of international clinical research in developing populations, this paper seeks to explore what is owed to developing world communities who host international clinical research. Although existing paradigms for assigning and assessing benefits to host communities offer valuable insight, the author criticizes their failure to distinguish between those benefits which can justify the conduct of research in a developing world setting and those which cannot. She argues that the justification for human subjects research is fundamentally grounded in the social value of knowledge, and that this value is context-dependent in a manner which should inform our ethical evaluation of the conduct of research in specific settings. She ends by proposing a new framework for the assessment of research benefits assigned to developing world host communities, a natural implication of which is to limit the types of research projects which may permissibly be conducted in developing world settings.

Wertheimer, A.. 2015. "The Social Value Requirement Reconsidered." *Bioethics* 29 (5):301-308. doi: 10.1111/bioe.12128

It is widely assumed that it is ethical to conduct research with human subjects only if the research has social value. There are two standard arguments for this view. The allocation argument claims that public funds should not be devoted to research that lacks social value. The exploitation avoidance argument claims that subjects are exploited if research has no social value. The primary purpose of this article is to

argue that these arguments do not succeed. The allocation argument has little relevance to commercial research. Social value is not necessary to avoid exploitation if subjects benefit from participation. Although the standard arguments for a social value requirement do not succeed, that view might be justified in a different way. It might be justified by appeal to the importance of social trust or the integrity of physician investigators. It is possible but doubtful that these arguments succeed.

Westra, A.E., and I. De Beaufort. 2015. "Improving the Helsinki Declaration's Guidance on Research in Incompetent Subjects." *Journal of Medical Ethics: The Journal of the Institute of Medical Ethics* 41 (3):278-280. doi: 10.1136/medethics-2013-101496.

Research involving children or other incompetent subjects who are deemed unable to provide informed consent is complex, particularly in the case of research that does not directly benefit the research subjects themselves. The Helsinki Declaration, the World Medical Association's landmark document for research ethics, therefore states that incompetent research subjects must not be included in such research unless it entails only minimal risk and minimal burden. In this paper, the authors argue that now that research in these groups is expected to expand, this undifferentiated minimal risk and burden requirement does not suffice any more. In the upcoming revision of the Declaration, the paragraph at stake should be refined in such a way that it is not unnecessarily restrictive or more permissive than can be ethically justified.

Wilkinson, T.M. 200“Research, Informed Consent, and the Limits of Disclosure.” *Bioethics* 15(4): 341-363.

According to this paper, respect for informed consent implies that subjects should often be told a good deal more than ethical guidelines explicitly or implicitly require. This includes informing research participants about researchers' personal characteristics and views, whenever they are relevant to the research being done, as well as always being informed about who is sponsoring the research.

Wolf, L. E., Mayank J. Patel, B. A. Williams Tarver, Jeffrey L. Austin, Lauren A. Dame, and Laura M. Beskow. 2015. "Certificates of Confidentiality: Protecting Human Subject Research Data in Law and Practice." *Journal of Law, Medicine & Ethics* 43 (3):594-609. doi: 10.1111/jlme.12302.

The federal Certificate of Confidentiality plays an important role in research on sensitive topics by authorizing researchers to refuse to disclose identifiable research

data in response to subpoenas in any legal setting. However, there is little known about how effective Certificates are in practice. This article draws on our legal and empirical research on this topic to fill this information gap. It includes a description of the purpose of Certificates, their legislative and regulatory history, and a summary of the few reported and unreported cases that have dealt with Certificates.

Zimmerman, E., and E. Racine. 2012. "Ethical Issues in the Translation of Social Neuroscience: A Policy Analysis of Current Guidelines for Public Dialogue in Human Research." ***Accountability in Research: Policies and Quality Assurance*** **19 (1):27-46. doi: 10.1080/08989621.2012.650949.**
Social neuroscience and its potential implications create an interesting case study for examining human research ethics policies on the topic of public communication of research. The authors reviewed mainstream national and international human research ethics guidelines and policies on issues of public communication of research and usedn five thematic nets to capture the interactions between research and the public: public understanding, knowledge translation, public participation, social outcomes, and dual use. Coverage of these topics is sparse and inconsistent in mainstream policies and guidelines.

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