Online Ethics Center
FOR ENGINEERING AND SCIENCE

Human Subjects Research Subject Aid

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Description

A short guide to some key resources and readings on the topic of human subjects in research.

Body

Human subjects research is any research or clinical investigation that involves human subjects. Investigators conducting human subjects research must satisfy DHHS regulations [45 CFR Part 46] and FDA regulations [21 CFR Part 50 and 56] regarding the protection of human subjects research, as applicable.

Subject Overviews

“Human Participants and Animal Subjects in Research.” in *On Being A Scientist: A Guide to Responsible Conduct in Research* National Academies. Committee on Science Engineering and Public Policy. 2009. 3rd ed. 4-7. Washington, D.C.: National Academies Press.
http://www.nap.edu/read/12192/chapter/8

An excellent guide to ethical issues faced by practicing researchers. Includes a good summary of U.S. federal regulations governing the use of human subjects in research, as well as a number of case studies. See specifically pages 24-27, 29-34.

National Institutes of Health, NIH Office of Extramural Research. 2015. "Protecting Human Research Participants." Accessed 20 July 2016. https://phrp.nihtraining.com/users/login.php

This is a free, online education module that is used by many institutions to certify that researchers are familiar with federal guidelines and regulations governing research involving human subjects. Users need to register to take the course, and it takes about an hour or more to complete.

Steneck, Nicholas. 2007. "Chapter 3. The Protection of Human Subjects," in *ORI Introduction to RCR*, Nicholas Steneck, 117-128. Office of Research Integrity. http://ori.hhs.gov/chapter-3-The-Protection-of-Human-Subjects-introduction

This booklet introduces the reader to the nine RCR core instructional areas in four sections that follows research from inception to planning, conducting, reporting, and reviewing research. The publication features case studies, text-box inserts, discussion questions, and electronic and printed resources. See specifically pages 35-45.

Weijer, C.M. and E.J. Emanuel. 2000. "Protecting Communities in Biomedical Research." *Science* 289 142-44. doi: 10.1126/science.289.5482.1142 http://science.sciencemag.org/content/289/5482/1142.full

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.

Policy and Guidance

Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS). 2000. "Guidelines for Ethical Research in Indigenous Studies."

Australia: Australian Institute of Aboriginal and Torres Strait Islander Studies.
http://www.wipo.int/export/sites/www/tk/en/databases/creative_heritage/docs/aiats

In this document, the Australian Institute of Aboriginal and Torres Strait Islander Studies draw on the principles of Indigenous self-determination and the right to control and maintain their culture and heritage to promote a practice of ethical research. The Institute offers 11 general guidelines and advice on about their implementation. The 11 points fall under these three broad categories: (1) consultation, negotiation, and mutual understanding; (2) respect, recognition, and involvement; and (3) benefits, outcomes, and agreement.

Council for International Organizations of Medical Sciences. 2016. "International Ethical Guidelines for Biomedical Research Involving Human Subjects. Accessed November 28, 2016. http://www.cioms.ch/ethical-guidelines-2016/

Developed in collaboration with the World Health Organization, these guidelines seek to effectively apply the ethical standards set forth in the Declaration of Helsinki, especially in developing countries with different socioeconomic circumstances, laws, and regulations.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. 1979. "Belmont Report." in *Office for Human Research Protections.* Accessed 20 July 2016
http://www.hhs.gov/ohrp/policy/belmont.html

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.

Office for Human Research Protections. 2016. "Regulations and Policy" Accessed 20 July 2016. http://www.hhs.gov/ohrp/regulations-and-policy/index.html

An excellent collection of statutes, regulations and other documents outlining U.S. regulations on the use of human participants in research.

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. https://www.nap.edu/catalog/18383/proposed-revisions-to-the-common-rule-perspectives-of-social-and

> 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. https://www.nap.edu/catalog/12942/conducting-biosocial-surveys-collecting-storing-accessing-and-protecting-biospecimens-and

> 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. https://www.nap.edu/catalog/11692/ethical-considerations-for-research-involving-prisoners

> 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. https://www.nap.edu/catalog/10958/ethical-conduct-of-clinical-research-involving-children

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*. 2002. Washington DC: National Academies Press. https://www.nap.edu/catalog/10481/research-ethics-in-complex-humanitarian-emergencies-summary-of-a-workshop

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.

World Health Organization. 2013. “Declaration of Helsinki.” Accessed 20 July 2016. http://www.wma.net/en/20activities/10ethics/10helsinki/index.html

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

Bibliography

“Human Subjects and Informed Consent Bibliography.” In Online Center for Engineering and Science. Last updated June 2016.
https://onlineethics.org/cases/human-subjects-informed-consent-bibliography

An annotated collection of links, books, and journal articles addressing issues in research using human subjects. Also includes links to online training programs.

Notes

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Rights

Resource Type

Bibliography

Parent Collection

OEC Subject Aids

Topics

Human Subjects Research

Discipline(s)

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