

# Human Subjects Research

Research involving a living individual about whom data or biospecimens are obtained/used/studied/analyzed through interaction/intervention, or identifiable, private information is used/studied/analyzed/generated

**Examples of human subjects research include:**

- Collecting blood
- Administering medicine
- Collecting data
- Conducting a survey
- Interviewing
- Conducting a focus group
- Changing participants' environment
- Administering a psychological test
- Testing a new educational technique

**Included in the NIH application:**

- ✓ Protection of Human Subjects attachment

**If funded, grantees will need:**

- ✓ An Institutional Federal-Wide Assurance (FWA) with OHRP
- ✓ IRB approval or determination of exemption

# Research On Human Subjects

**Nancy M. P. King, Gail E.  
Henderson, Jane Stein**



## **Research On Human Subjects:**

*Twentieth century ethics of human subjects research* Volker Roelcke, Giovanni Maio, 2004 Debates on the ethics of human subjects research meet with an increasing interest both within the medical profession and the broader public Frequently historical arguments are used to propagate or attack certain positions within these debates However there is a tendency to oversimplify the complexities of the past for present day purposes and at the same time a lack of awareness of the historical dimension implicit in today's value preferences *Twentieth Century Ethics of Human Subjects Research* brings together leading historians of medicine to reconstruct and analyse the history of actual experimental practices the debates on human subjects research and the attempts to regulate such research during the twentieth century The volume addresses cases of medical research in France Britain Israel the United States and Germany including the Nazi period the major developments of ethical debates in these and further national contexts such as the Soviet Union the Czech Republic and Japan It also explores religious views Catholic Jewish on human experimentation and the origins and contexts of international codes and declarations Volker Roelckes *Überblick über die Geschichte der Menschenversuche im Dritten Reich* sei jedem empfohlen der sich kurz und prägnant über dieses düstere Kapitel deutscher Geschichte informieren möchte FAZ [The Ethics of Research with Human Subjects](#) David B. Resnik, 2018-01-09 This book provides a framework for approaching ethical and policy dilemmas in research with human subjects from the perspective of trust It explains how trust is important not only between investigators and subjects but also between and among other stakeholders involved in the research enterprise including research staff sponsors institutions communities oversight committees government agencies and the general public The book argues that trust should be viewed as a distinct ethical principle for research with human subjects that complements other principles such as autonomy beneficence non maleficence and justice The book applies the principle of trust to numerous issues including informed consent confidentiality risk minimization risks and benefits protection of vulnerable subjects experimental design research integrity and research oversight This work also includes discussions of the history of research involving human subjects moral theories and principles contemporary cases and proposed regulatory reforms The book is useful for undergraduate and graduate students studying ethical policy issues related to research with human subjects as well as for scientists and scholars who are interested in thinking about this topic from the perspective of trust **The Ethics of Research Involving Human Subjects** Harold Y. Vanderpool, 1996 **Ethics of the Use of Human Subjects in Research** Adil Shamoo, Felix A. Khin-Maung-Gyi, 2021-03-05 Media headlines about research misconduct in American Universities have focused public attention on the dramatic ethical problems that can arise during the conduct of research In the current atmosphere of accountability scientific research on humans is now under increased scrutiny by the media Congress and the public *Ethics of the Use of Human Subjects in Research* fills the need for learning materials and strategies providing support for training programs related to the ethics of the use of human subjects in

research It presents a practical introduction to the ethical issues at stake in the conduct of research with human subjects Beginning with a chapter on research ethics a total of 10 chapters range in scope from the development of a protocol for ethical decision making to how to obtain IRB approval with an emphasis on ethical factors underpinning the IRB process

**Research on Human Subjects** Bernard Barber, 1973-03 Confronts the ethical questions that arise in the area of scientific experimentation with human beings Data are presented here on two key issues informed consent and risk benefit ratios The authors discuss the mechanism of such experiments and the difference of approach within the field They also examine the role of medical schools in creating ethical awareness in students as well as the peer group reviews which screen research on human subjects The authors offer recommendations of policy change and reform for the bio medical profession

**Research with Human Subjects** Duke University. Committee for the Protection of Human Subjects in Non-Medical Research, 1999

**Human Subjects Research** Robert A. Greenwald, 2013-11-11 For an increasing number of hospitals and universities the institutional review board IRB has become a way of life Spurred into existence by public outcries about the unethical nature of certain modern scientific experiments the IRB represents the most visible evidence of institutional commitment to ethical review of clinical research However this exponential growth of IRB activities has not occurred without growing pains Like the Environmental Protection Agency IRBs have had to develop procedures and standards without a clear consensus as to what would be optimal for science and society Each IRB has perforce devised its own modus operandi subject to general principles and guidelines laid down by others but still relatively free to stipulate the details of its functioning Thus one can applaud the general idea as well as the overall performance of IRBs without asserting that the millennium has arrived The composition philosophy efficiency responsibilities and powers of IRBs remain topics suit able for debate It is still possible and appropriate for IRB members to worry both about the propriety of their decisions and the personal costs of their service

*Human Subjects Research Regulation* I. Glenn Cohen, Holly Fernandez Lynch, 2014-07-11 Experts from different disciplines offer novel ideas for improving research oversight and protection of human subjects The current framework for the regulation of human subjects research emerged largely in reaction to the horrors of Nazi human experimentation revealed at the Nuremberg trials and the Tuskegee syphilis study conducted by U S government researchers from 1932 to 1972 This framework combining elements of paternalism with efforts to preserve individual autonomy has remained fundamentally unchanged for decades Yet as this book documents it has significant flaws including its potential to burden important research overprotect some subjects and inadequately protect others generate inconsistent results and lag behind developments in how research is conducted Invigorated by the U S government's first steps toward change in over twenty years Human Subjects Research Regulation brings together the leading thinkers in this field from ethics law medicine and public policy to discuss how to make the system better The result is a collection of novel ideas some incremental some radical for the future of research oversight and human subject protection After reviewing the history of U S research

regulations the contributors consider such topics as risk based regulation research involving vulnerable populations including military personnel children and prisoners the relationships among subjects investigators sponsors and institutional review boards privacy especially regarding biospecimens and tissue banking and the possibility of fundamental paradigm shifts Contributors Adam Braddock Alexander Morgan Capron Ellen Wright Clayton I Glenn Cohen Susan Cox Amy L Davis Hilary Eckert Barbara J Evans Nir Eyal Heidi Li Feldman Benjamin Fombonne Elisa A Hurley Ana S Iltis Gail H Javitt Greg Koski Nicole Lockhart Holly Fernandez Lynch Michael McDonald Michelle N Meyer Osagie K Obasogie Efthimios Parasidis Govind Persad Rosamond Rhodes Suzanne M Rivera Zachary M Schrag Seema K Shah Jeffrey Skopek Laura Stark Patrick Taylor Anne Townsend Carol Weil Brett A Williams Leslie E Wolf      **Research on Human Subjects** D.N.

Weisstub,1998-10-23 There have been serious controversies in the latter part of the 20th century about the roles and functions of scientific and medical research In whose interests are medical and biomedical experiments conducted and what are the ethical implications of experimentation on subjects unable to give competent consent From the decades following the Second World War and calls for the global banning of medical research to the cautious return to the notion that in controlled circumstances medical research on human subjects is in the best interest of the given individual and the broader population this book addresses the key implications of experimentation on humans This volume covers major ethical themes within biomedical research providing historical philosophical legal and policy reflections on the literature and specific issues in the field of research on human subjects Focusing on special populations the elderly children prisoners and the cognitively impaired it represents the most up to date review of the special ethical and legal conflicts that arise with relation to experimentation on subjects from these groups In the light of current initiatives for law reform pertaining to research ethics the world over this volume provides a timely comprehensive and provocative exploration of the field The volume has been carefully organized to present important philosophical perspectives on organizing principles that should underlie any practical application A forward looking historical review of the regulatory regimes of principal jurisdictions including of the legal controls already in place provides the backdrop for future policy initiatives Additionally in the light of global restructuring of health care systems several chapters have been devoted to epidemiological research and related issues

*The Belmont Report* United States. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research,1978      Guidelines for Research Involving Human Subjects State University of New York at Stony Brook. Committee on Research Involving Human Subjects,1981      **The Use of Human Beings in Research** S.F. Spicker,I. Alon,A. de Vries,H. Tristram Engelhardt Jr.,2012-12-06 This volume which has developed from the Fourteenth Trans Disciplinary Symposium on Philosophy and Medicine September 5 8 1982 at Tel Aviv University Israel contains the contributions of a group of distinguished scholars who together examine the ethical issues raised by the advance of biomedical science and technology We are of course still at the beginning of a revolution in our understanding of human

biology scientific medicine and clinical research are scarcely one hundred years old Both the sciences and the technology of medicine until ten or fifteen years ago had the feeling of the 19th century about them we sense that they belonged to an older time that era is ending The next twenty five to fifty years of investigative work belong to neurobiology genetics and reproductive biology The technologies of information processing and imaging will make diagnosis and treatment almost incomprehensible by my generation of physicians Our science and technology will become so powerful that we shall require all of the art and wisdom we can muster to be sure that they remain dedicated as Francis Bacon hoped four centuries ago to the uses of life It is well that as philosophers and physicians we grapple with the issues now when they are relatively simple and while the pace of change is relatively slow We require a strategy for the future that strategy must be worked out by scientists philosophers physicians lawyers theologians and I should like to add artists and poets     *The Ethics and Regulation of Research with Human Subjects* Carl H. Coleman, 2005 This new book provides a set of teaching materials that could be used in an academic course on human subject research in a broad range of professional school settings In developing these materials the authors were mindful that their readers would include tomorrow s advisers managers and regulators of researchers and research institutions If students are to be effective in these roles they must not only understand the history of human subject protection and the relevant ethical and regulatory issues they must begin to think critically about the existing regulatory system and to consider the desirability of policy reform *The Ethics and Regulation of Research with Human Subjects* is largely comprised of primary source documents including governmental regulations guidance statements and court decisions and excerpts from the voluminous commentary produced by scholars advisory commissions and others These materials are accompanied by extensive notes and questions which expand on some of the issues raised in the primary readings and ask the reader to think about the gaps ambiguities and conflicts those materials raise     **Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences** National Research Council, Division of Behavioral and Social Sciences and Education, Committee on Population, Committee on National Statistics, Board on Behavioral, Cognitive, and Sensory Sciences, Committee on Revisions to the Common Rule for the Protection of Human Subjects in Research in the Behavioral and Social Sciences, 2014-03-31 *Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences* examines how to update human subjects protections regulations so that they effectively respond to current research contexts and methods With a specific focus on social and behavioral sciences this consensus report aims to address the dramatic alterations in the research landscapes that institutional review boards IRBs have come to inhabit during the past 40 years The report aims to balance respect for the individual persons whose consent to participate makes research possible and respect for the social benefits that productive research communities make possible The ethics of human subjects research has captured scientific and regulatory attention for half a century To keep abreast of the universe of changes that factor into

the ethical conduct of research today the Department of Health and Human Services published an Advance Notice of Proposed Rulemaking ANPRM in July 2011 Recognizing that widespread technological and societal transformations have occurred in the contexts for and conduct of human research since the passage of the National Research Act of 1974 the ANPRM revisits the regulations mandated by the Act in a correspondingly comprehensive manner Its proposals aim to modernize the Common Rule and to improve the efficiency of the work conducted under its auspices Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences identifies issues raised in the ANPRM that are critical and feasible for the federal government to address for the protection of participants and for the advancement of the social and behavioral sciences For each identified issue this report provides guidance for IRBs on techniques to address it with specific examples and best practice models to illustrate how the techniques would be applied to different behavioral and social sciences research procedures

**Silent Partners** Rebecca Dresser, 2017 The research ethics system was created without the help of people who know what it is like to be a research subject This is a serious omission Experts have overlooked ethical issues that matter to subjects Silent Partners moves subjects to the forefront giving them a voice in research ethics

*Beyond Regulations* Nancy M. P. King, Gail E. Henderson, Jane Stein, 2005-10-12 Across a broad range of disciplines in medicine social science and the humanities researchers scholars teachers and administrators increasingly are looking for new ways to approach ethical issues in research with human subjects Questions about how relationships between funders and researchers should affect research design for example or whether the potential benefits of research can outweigh the importance of its subjects interests are inadequately addressed by the prevailing regulation based research ethics paradigm This book constitutes a reexamination of research ethics It combines case studies and commentaries by a multidisciplinary group of scholars and researchers to explore such topics as informed consent conflict of interest confidentiality and research on illegal behavior All human subjects research takes place within complex social cultural and political contexts the contributors argue Increased consideration of the relationships between researchers and their subjects funders and institutions within these contexts will facilitate research that is sensitive and responsible as well as scientifically fruitful Beyond Regulations features a keynote essay by Ruth Macklin Other contributors are Marcela Aracena Alvarez Jorge Balan B Susan Bauer Alan F Benjamin Lynn Blanchard Allan M Brandt J Pat Browder Barbara Entwisle Sue E Estroff Renee C Fox Lara Freidenfelds Gail E Henderson Nancy M P King Loretta M Kopelman Ernest N Kraybill Barry M Popkin Silvina Ramos Desmond K Runyan Jane Stein Ronald P Strauss Keith A Wailoo and Cynthia Waszak Across a broad range of disciplines in biomedicine the social sciences and the humanities researchers scholars administrators and teachers increasingly struggle with questions of ethics in research with human subjects All research takes place in complex social cultural political and economic contexts yet the prevailing principle based research ethics paradigm does not adequately account for them This book reexamines research ethics using a new relationships paradigm Through in depth cases

commentaries and essays a multidisciplinary group of scholars and researchers addresses informed consent conflict of interest confidentiality and other issues considering questions like What relationships should researchers have with their subjects communities When researchers and subjects have different views about research who should have control How should relationships between funders and researchers affect research design Can research be so potentially beneficial that its importance outweighs the interests of subjects Examining the relationships between researchers and subjects communities funders and institutions including considerations of authority and voice can facilitate human subjects research that is morally sensitive and responsible as well as scientifically fruitful      Human Subjects Research Guidance Springfield Committee for Research Involving Human Subjects,Southern Illinois University School of Medicine's institutional review board (IRB),2018 This manual provides extensive guidance information for Investigators and Study Staff conducting human subjects research at Southern Illinois University School of Medicine It is very important to remember that guidance should not be interrupted as regulation or policy      *Conducting Research with Human Participants* Nathan Durdella,2022-02-15 Conducting Research with Human Participants An IRB Guide for Students and Faculty by Nathan Durdella is the only guidebook students and faculty will need to navigate the IRB process and secure swift approval of research protocols This book serves as an advisor to walk researchers through all the details of drafting submission and revision of materials for Institutional Review Boards so they can complete their research projects or dissertations faster This text walks readers through the history of Institutional Review Boards the contemporary context of ethical research strategies to effectively draft submit and revise an IRB protocol and guidance on working with an approved protocol in the field The latest updates to the Common Rule and other regulatory frameworks including special protections for working with vulnerable groups are covered throughout the text Not every research project goes according to plan so adverse events and reporting receive special coverage A final chapter on ethical research practices beyond IRB compliance encourages researchers to think through how to exit the field of research and ensure their research benefits the individuals families and communities in which they work Take the guesswork out of the IRB process from start to finish with this handy guide      *The Protection of Human Subjects in Research Conducted Or Supported by Federal Agencies* United States. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research,1978      **Issues in Research with Human Subjects** ,1980



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