Research On Human Subjects Ethics Law And Social Policy

Deviance and Decency Carl B. Klockars 1979-11

Human Subjects Research Regulation I. Glenn Cohen 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 Nuremburg 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

The Arctic Aeromedical Laboratory's Thyroid Function Study Committee on Evaluation of 1950s Air Force Human Health Testing in Alaska Using Radioactive Iodine-131 1996-02-09 During the 1950s, with the Cold War looming, military planners sought to know more about how to keep fighting forces fit and capable in the harsh Alaskan environment. In 1956 and 1957, the U.S. Air Force's former Arctic Aeromedical Laboratory conducted a study of the role of the thyroid in human acclimatization to cold. To measure thyroid function under various conditions, the researchers administered a radioactive medical trace, Iodine-131, to Alaska Natives and white military personnel; based on the study results, the researchers determined that the thyroid did not play a significant role in human acclimatization to cold. When this study of thyroid function was revisited at a 1993 conference on the Cold War legacy in the Arctic, serious questions were raised about the appropriateness of the activity--whether it posed risks to the people involved and whether the research had been conducted within the bounds of accepted guidelines for research using human participants. In particular, there was concern over the relatively large proportion of Alaska Natives used as subjects and whether they understood the nature of the study. This book evaluates the research in detail, looking at both the possible health effects of Iodine-131 administration in humans and the ethics of human subjects research. This book presents conclusions and recommendations and is a

significant addition to the nation's current reevaluation of human radiation experiments conducted during the Cold War.

Women and Health Research Institute of Medicine 1994-02-01 There is a growing perception that biomedical research has focused more on the health problems of men relative to those of women and that women have been denied access to advances in medical diagnosis and therapy as a result of being excluded from clinical studies. Women and Health Research, Volume 2, addresses issues connected with women's participation in clinical studies: ethical issues related to recruitment, retention, and the inclusion of pregnant women and other women of childbearing age; legal issues such as liability, compensation for injury, constitutional concerns, and federal regulations; and health consequences associated with exclusion or underrepresentation. The commissioned papers focus on the research participation of women from specific racial and ethnic groups and on whether women have been underrepresented in biomedical research, based on a systematic survey of clinical studies reported in a prominent medical journal.

Textbook of Research Ethics Sana Loue 2000-08-31 This textbook provides a brief history of human experimentation and reviews various theories of ethics from which the principles and rules that govern this research are derived. All relevant international documents and national regulations, policies and memoranda are referred to extensively to assist in addressing issues that regularly arise during the course of research involving human subjects. It includes case examples and exercises and is of interest to students and experienced researchers.

Federal Protection for Human Research Subjects Lee O. Jastone 2006 The Common Rule (45 CFR 46, Subpart A) governs research that is conducted on human beings if it is funded by one of 18 federal agencies. It requires a review of proposed research by an Institutional Review Board (IRB), the informed consent of research subjects, and institutional assurances of compliance with the regulations. In 1974, 45 CFR 46 was published following some cases of harm to human subjects, such as those caused by thalidomide drug trials and the United States Public Health Service syphilis study in Tuskeegee, Alabama. The regulations had their roots in numerous international agreements, such as the Nuremberg Code and the Declaration of Helsinki, and domestic policies, such as those put forth by the Department of Health, Education and Welfare (DHEW; now the Department of Health and Human Services, HHS). In 1991, 16 federal agencies adopted 45 CFR 46, Subpart A, which then became known as the Common Rule. Since the Common Rule took effect, events like the death of Jesse Gelsinger in 1999 due to his participation a clinical trial have prompted scrutiny of the Rule and its ability to protect research subjects. In order to help enhance research subject protections, in 2000 HHS removed the Office for Protection from Research Risks (OPRR) from the National Institutes of Health (NIH), and created a new office -- the Office for Human Research Protections (OHRP) -- in an elevated position in HHS. In addition, groups like the National Bioethics Advisory Commission and the National Academies raised the following policy questions: (1) Should the Common Rule be applied to non-federally funded research, social and behavioural research, international clinical trials, and research with human biological materials? (2) Do existing provisions ensure the participation and protection of children, prisoners, minorities, those with diminished capacity, pregnant women, foetuses, neonates, and people in emergency situations? (3) What should be the requirements regarding IRBs' membership, responsibilities, training, and registration? (4) How should conflicts of interest, accreditation, ongoing research, and adverse event reporting be handled? (5) How should basic and research-related medical care's cost, and IRB liability for harm be handled? (6) How should the human subjects protection system be reassessed, adequate resources ensured, and the burdens and benefits of amending regulations appropriately weighed? (7) How does 45 CFR 46 interact with the Food and Drug Administration (FDA) regulations for the protection of human subjects (21 CFR 50 and 56), and the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (45 CFR 146)?

Beyond Consent Jeffrey P. Kahn 1998 Beyond

Consent examines the concept of justice, and its application to research with human subjects, through the lenses of research populations: children, the vulnerable sick (including those seeking emergency medical care), captive and convenient populations (such as prisoners), women, people of color, and subjects in emergency and international settings. Beyond Consent will be a vital resource for students and scholars of bioethics, medicine, public health, and public policy, as well as institutional review board members, research institution administrators, and policy makers involved in regulating the process of research with human subjects.

Women and Health Research Institute of Medicine 1994-02-01 In the nineteenth century some scientists argued that women should not be educated because thinking would use energy needed by the uterus for reproduction. The proof? Educated women had a lower birth rate. Today's researchers can only shake their heads at such reasoning. Yet professional journals and the popular press are increasingly criticizing medical research for ignoring women's health issues. Women and Health Research examines the facts behind the public's perceptions about women participating as subjects in medical research. With the goal of increasing researchers' awareness of this important topic, the book explores issues related to maintaining justice (in its ethical sense) in clinical studies. Leading experts present general principles for the ethical conduct of research on womenâ€"principles that are especially important in the light of recent changes in federal policy on the inclusion of women in clinical research. Women and Health Research documents the historical shift from a paternalistic approach by researchers toward women and a disproportionate reliance on certain groups for research to one that emphasizes proper access for women as subjects in clinical studies in order to ensure that women receive the benefits of research. The book addresses present-day challenges to equity in four areas: Scientificâ€"Do practical aspects of scientific research work at cross-purposes to gender equity? Focusing on drug trials, the authors identify rationales for excluding people from research based on demographics. Social and Ethicalâ€"The authors offer compelling discussions on subjectivity in science, the evidence for male bias, and issues related to race and ethnicity, as well as the recruitment, retention, and protection of research participants. Legalâ€"Women and Health Research reviews federal research policies that affect the inclusion of women and evaluates the basis for researchers' fears about liability, citing court cases. Riskâ€"The authors focus on risks to reproduction and offspring in clinical drug trials, exploring how risks can be identified for study participants, who should make the assessment of risk and benefit for participation in a clinical study, and how legal implications could be addressed. This landmark study will be of immediate use to the research community, policymakers, women's health advocates, attorneys, and individuals.

The Ethics and Regulation of Research with Human Subjects Carl H. Coleman 2015-06

Specimen Science Holly Fernandez Lynch 2017-10-06 Advances in medicine often depend on the effective collection, storage, research use, and sharing of human biological specimens and associated data. But what about the sources of such specimens? When a blood specimen is drawn from a vein in your arm, is that specimen still you? Is it your property, intellectual or otherwise? Should you be allowed not only to consent to its use in research but also to specify under what circumstances it may be used? These and other questions are at the center of a vigorous debate over the use of human biospecimens in research. In this book, experts offer legal, regulatory, and ethical perspectives on balancing social benefit and human autonomy in biospecimen research. After discussing the background to current debates as well as several influential cases, including that of Henrietta Lacks, the contributors consider the rights, obligations, risks, and privacy of the specimen source; different types of informed consent under consideration (broad, blanket, and specific); implications for special patient and researcher communities; and the governance of biospecimen repositories and the responsibilities of investigators.

The Censor's Hand Carl E. Schneider 2015-04-24 An argument that the system of boards that license human-subject research is so

fundamentally misconceived that it inevitably does more harm than good. Medical and social progress depend on research with human subjects. When that research is done in institutions getting federal money, it is regulated (often minutely) by federally required and supervised bureaucracies called “institutional review boards” (IRBs). Do—can—these IRBs do more harm than good? In The Censor's Hand, Schneider addresses this crucial but long-unasked question. Schneider answers the question by consulting a critical but ignored experience—the law's learning about regulation—and by amassing empirical evidence that is scattered around many literatures. He concludes that IRBs were fundamentally misconceived. Their usefulness to human subjects is doubtful, but they clearly delay, distort, and deter research that can save people's lives, soothe their suffering, and enhance their welfare. IRBs demonstrably make decisions poorly. They cannot be expected to make decisions well, for they lack the expertise, ethical principles, legal rules, effective procedures, and accountability essential to good regulation. And IRBs are censors in the place censorship is most damaging—universities. In sum, Schneider argues that IRBs are bad regulation that inescapably do more harm than good. They were an irreparable mistake that should be abandoned so that research can be conducted properly and regulated sensibly.

Research Ethics for Social Scientists Mark Israel 2006-06-15 `This is an excellent book which can be recommended both to the professional ethicist seeking to situate research ethics for a social scientific audience and to social scientists seeking an overview of the current ethical landscape of their discipline' - Research Ethics Review Ethics is becoming an increasingly prominent issue for all researchers across the western world. This comprehensive and accessible guide introduces students to the field and encourages knowledge of research ethics in practice. Research Ethics for Social Scientists sets out to do four things: The first is to demonstrate the practical value of thinking seriously and systematically about what constitutes ethical conduct in social science research. Secondly, the text identifies how and why current regulatory regimes have emerged. Thirdly, it seeks to reveal those practices that have contributed to the adversarial relationships between researchers and regulators. Finally, the book hopes to encourage both parties to develop shared solutions to ethical and regulatory problems. Research Ethics for Social Scientists is an excellent introductory text for students as it: - introduces students to ethical theory and philosophy; - provides practical guidance on what ethical theory means for research practice; - provides case studies to give real examples of ethics in research action. The result is an informative, accessible and practical guide to research ethics for any student or researcher in the social sciences.

Ethics in Research with Human Participants Bruce Dennis Sales 2000-01-01 The American Psychological Association offers this book to help researchers understand ethical conflicts. The examples and analyses help researchers in identifying conflicts of interest and solving ethical dilemmas, planning research, recruiting participants, training researchers, managing matters of informed consent and confidentiality, dealing with intellectual property issues, working with special populations, and updating protocols for institutional review boards.

Research Ethics and Integrity for Social Scientists Mark Israel 2014-10-20 Ethics and integrity in research are increasingly important for social scientists around the world. We are tackling more complex problems in the face of expanding and not always sympathetic regulation. This book surveys the recent developments and debates around researching ethically and with integrity and complying with ethical requirements. The new edition pushes beyond the work of the first edition through updated and extended coverage of issues relating to international, indigenous, interdisciplinary and internet research. Through case studies and examples drawn from all continents and from across the social science disciplines, the book: demonstrates the practical value of thinking seriously and systematically about ethical conduct in social science research identifies how and why current regulatory regimes have emerged reveals those practices that have contributed to the adversarial relationships between researchers and regulators encourages all parties to develop

shared solutions to ethical and regulatory problems.

Social Science Research Ethics for a Globalizing World Keerty Nakray 2015-10-14 Research in the humanities and social sciences thrives on critical reflections that unfold with each research project, not only in terms of knowledge created, but in whether chosen methodologies served their purpose. Ethics forms the bulwark of any social science research methodology and it requires continuous engagement and reengagement for the greater advancement of knowledge. Each chapter in this book will draw from the empirical knowledge created through intensive fieldwork and provide an account of ethical questions faced by the contributors, placing them in the context of contemporary debates surrounding the theory and practice of ethics. The chapters have been thematically organized into five sections: Feminist Ethics: Cross-Cultural Reflections and Its Implications for Change; Researching Physical and Sexual Violence in Non-Academic Settings: A Need for Ethical Protocols; Human Agency, Reciprocity, Participation and Activism: Meanings for Social Science Research Ethics; Emotions, Conflict and Dangerous Fields: Issues of "Safety" and Reflective Research; and Social Science Education: Training in Ethics or "Ethical Training" and "Ethical Publicizing." This inter-disciplinary volume will interest students and researchers in academic and non-academic settings in core disciplines of Anthropology, Sociology, Law, Political Science, International Relations, Geography, or inter-disciplinary degrees in Development Studies, Health Studies, Public Health Policy, Social Policy, Health Policy, Psychology, Peace and Conflict studies, and Gender Studies. The book features a foreword by His Holiness The Dalai Lama.

The Immortal Life of Henrietta Lacks Rebecca Skloot 2010-02-02 #1 NEW YORK TIMES BESTSELLER • "The story of modern medicine and bioethics—and, indeed, race relations—is refracted beautifully, and movingly."—Entertainment Weekly NOW A MAJOR MOTION PICTURE FROM HBO® STARRING OPRAH WINFREY AND ROSE BYRNE • ONE OF THE "MOST INFLUENTIAL" (CNN), "DEFINING" (LITHUB), AND "BEST" (THE PHILADELPHIA INQUIRER) BOOKS OF THE DECADE • ONE OF ESSENCE'S 50 MOST IMPACTFUL BLACK BOOKS OF THE PAST 50 YEARS • WINNER OF THE CHICAGO TRIBUNE HEARTLAND PRIZE FOR NONFICTION NAMED ONE OF THE BEST BOOKS OF THE YEAR BY The New York Times Book Review • Entertainment Weekly • O: The Oprah Magazine • NPR • Financial Times • New York • Independent (U.K.) • Times (U.K.) • Publishers Weekly • Library Journal • Kirkus Reviews • Booklist • Globe and Mail Her name was Henrietta Lacks, but scientists know her as HeLa. She was a poor Southern tobacco farmer who worked the same land as her slave ancestors, yet her cells—taken without her knowledge—became one of the most important tools in medicine: The first "immortal" human cells grown in culture, which are still alive today, though she has been dead for more than sixty years. HeLa cells were vital for developing the polio vaccine; uncovered secrets of cancer, viruses, and the atom bomb's effects; helped lead to important advances like in vitro fertilization, cloning, and gene mapping; and have been bought and sold by the billions. Yet Henrietta Lacks remains virtually unknown, buried in an unmarked grave. Henrietta's family did not learn of her "immortality" until more than twenty years after her death, when scientists investigating HeLa began using her husband and children in research without informed consent. And though the cells had launched a multimillion-dollar industry that sells human biological materials, her family never saw any of the profits. As Rebecca Skloot so brilliantly shows, the story of the Lacks family—past and present—is inextricably connected to the dark history of experimentation on African Americans, the birth of bioethics, and the legal battles over whether we control the stuff we are made of. Over the decade it took to uncover this story, Rebecca became enmeshed in the lives of the Lacks family—especially Henrietta's daughter Deborah. Deborah was consumed with questions: Had scientists cloned her mother? Had they killed her to harvest her cells? And if her mother was so important to medicine, why couldn't her children afford health insurance? Intimate in feeling, astonishing in scope, and impossible to put down, The Immortal Life of Henrietta Lacks

captures the beauty and drama of scientific discovery, as well as its human consequences.

Ethics in Social Research Robert T. Bower 1978

Tearoom Trade Laud Humphreys 2017-07-12 From the time of its first publication, 'Tearoom Trade' engendered controversy. It was also accorded an unusual amount of praise for a first book on a marginal, intentionally self-effacing population by a previously unknown sociologist. The book was quickly recognized as an important, imaginative, and useful contribution to our understanding of "deviant" sexual activity. Describing impersonal, anonymous sexual encounters in public restrooms—"tearooms" in the argot—the book explored the behavior of men whose closet homosexuality was kept from their families and neighbors. By posing as an initiate, the author was able to engage in systematic observation of homosexual acts in public settings, and later to develop a more complete picture of those involved by interviewing them in their homes, again without revealing their unwitting participation in his study. This enlarged edition of 'Tearoom Trade' includes the original text, together with a retrospect, written by Nicholas von Hoffman, Irving Louis Horowitz, Lee Rainwater, Donald P. Warwick, and Myron Glazer. The material added includes a perspective on the social scientist at work and the ethical problems to which that work may give rise, along with debate by the book's initial critics and proponents. Humphreys added a postscript and his views on the opinion expressed in the retrospect.

Beyond Regulations Nancy M. P. King 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.

Ethics in Health Services and Policy Dean M.

Harris 2011-03-03 This comprehensive textbook analyzes the ethical issues of health and health care in global perspective. Ideal for students of public health, medicine, nursing and allied health professions, public policy, and ethics, the book helps students in all these areas to develop important competencies in their chosen fields. Applying a comparative, or multicultural, approach, the book compares different perspectives on ethical issues in various countries and cultures, such as informed consent, withholding or withdrawing treatment, physician-assisted suicide, reproductive health issues, research with human subjects, the right to health care, rationing of limited resources, and health system reform. Applying a transnational, or cross-border, approach, the book analyzes ethical issues that arise from the movement of patients and health professionals across national borders, such as medical tourism and transplant tourism, ethical obligations to provide care for undocumented aliens, and the "brain drain" of health professionals from developing countries. Comprehensive in scope, the book includes selected readings which provide diverse perspectives of people from different countries and cultures in their own words. Each chapter contains an introductory section centered on a specific topic and explores the different ways in which the topic is viewed around the globe. Ethics in Health Services and Policy is designed to promote student participation and offers methods of activity-based learning, including factual scenarios for analysis and discussion of specific ethical issues.

Ethical Conduct of Clinical Research Involving Children Institute of Medicine 2004-07-09 In recent decades, advances in biomedical research have helped save or lengthen the lives of children around the world. With improved therapies, child and adolescent mortality rates have decreased significantly in the last half century. Despite these advances, pediatricians and others argue that children have not shared equally with adults in biomedical advances. Even though we want children to benefit from the dramatic and accelerating rate of progress in medical care that has been fueled by scientific research, we do not want to place children at risk of being harmed by participating in clinical studies. Ethical Conduct of Clinical Research Involving Children considers the necessities and challenges of this type of research and reviews the ethical and legal standards for conducting it. It also considers problems with the interpretation and application of these standards and conduct, concluding that while children should not be excluded from potentially beneficial clinical studies, some research that is ethically permissible for adults is not acceptable for children, who usually do not have the legal capacity or maturity to make informed decisions about research participation. The book looks at the need for appropriate pediatric expertise at all stages of the design, review, and conduct of a research project to effectively implement policies to protect children. It argues persuasively that a robust system for protecting human research participants in general is a necessary foundation for protecting child research participants in particular.

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.

Big Data, Health Law, and Bioethics I. Glenn Cohen 2018-03-08 When data from all aspects of our lives can be relevant to our health - from our habits at the grocery store and our Google searches to our FitBit data and our medical records - can we really differentiate between big data and health big data? Will health big data be used for good, such as to improve drug safety, or ill, as in insurance discrimination? Will it disrupt health care (and the health care system) as we know it? Will it be possible to protect our health privacy? What barriers will there be to collecting and utilizing health big data? What role should law play, and what ethical concerns may arise? This timely, groundbreaking volume explores these questions and more from a variety of perspectives, examining how law promotes or discourages the use of big data in the health care sphere, and also what we can learn from other sectors.

Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences Committee on Revisions to the Common Rule for the Protection of Human Subjects in Research in the Behavioral and Social Sciences 2014-12-31 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.

Ethical and Legal Issues of Social Experimentation Alice M. Rivlin 1975 Monograph comprising a revised conference report on the legal aspects and ethics issues raised by the use of social research experiments to evaluate social policies - covers the protection of the human rights of subjects, etc., with particular reference to the situation in the USA. References. Conference held in Washington 1973 September.

World Medical Association Declaration of Helsinki 2004

Beyond Consent Jeffrey P. Kahn 1998-09-03 Patients with cancer and AIDS now clamor for access to clinical trials. Federal policies governing research that once emphasized protecting subjects from dangerous research now promote access to clinical research. Have claims about justice and access to the benefits of research eclipsed concerns about consent and protection from risks? How can we make good

and fair decisions about the selection of subjects and other questions of justice in research? Beyond Consent examines the concept of justice and its application to human subject research through the different lenses of important research populations: children, the vulnerable sick, captive and convenient populations, women, people of color, and subjects in international settings. To set the stage for this examination, and introductory chapter addresses the evolution of research policies. After a look at specific subject populations, the authors discuss the concept of justice for research with human subjects in the future and analyze justice throughout the research enterprise.

Public Trust in Medical Research? Philip Cheung 2018-04-19 It has been claimed by fertility experts that embryos can be screened for 6,000 diseases, thereby the risk of x-linked diseases can be minimised by 'cherry-picking' male embryos that do not carry the abnormal gene. If medical scientists continue to strive for cures, genetic aberrance in human could be a phenomenon of the past...This challenging book explores issues of professional integrity and ethics underpinning medical research. It includes real-life case studies where public trust in medical research has been misplaced and encourages medical professionals to adhere to professional codes of conduct and be informed about their decision making process. It is vital reading for undergraduate and postgraduate students of medicine, law, sociology and social policy, philosophy, health related research and ethics. Practising researchers in medicine and the pharmaceutical industry, and their managers will find it invaluable. The text provides motivation for academics and educators with an interest in research and governance. Healthcare policy makers and shapers, patient rights groups, campaigners and the general media will find the information enlightening. "Over the last four decades, medicine has given hope to many people and saved many lives as a result of the ability of the physicians and surgeons to develop new treatments and innovative surgical techniques. While we can celebrate the success of medical science, we should also critically examine some of these developments against principles and in the light of public opinion." - Philip Cheung.

Medical Experimentation Charles Fried 2016-05-02 First published in 1974, Charles Fried's Medical Experimentation is a classic statement of the moral relationship between doctor and patient, as expressed within the concept of personal care. This concept is then tested in the context of medical experimentation and, more specifically, the randomized controlled trial (RCT). Regularly referred to as a point of departure for ethical and legal discussions of the RCT, the book has long been out of print. This new, second edition includes a general introduction by Franklin Miller and the late Alan Wertheimer, a reprint of the 1974 text, and an in-depth analysis by Harvard Law School scholars I. Glenn Cohen and D. James Greiner which discusses the extension of RTCTs to social science and public policy contexts. The volume concludes with a new essay by Charles Fried that reflects on the original text and how it applies to the contemporary landscape of medicine and medical experimentation.

Responsible Conduct of Research Adil E. Shamoo 2009-02-12 Recent scandals and controversies, such as data fabrication in federally funded science, data manipulation and distortion in private industry, and human embryonic stem cell research, illustrate the importance of ethics in science. Responsible Conduct of Research, now in a completely updated second edition, provides an introduction to the social, ethical, and legal issues facing scientists today.

Responsible Research Institute of Medicine 2003-02-06 When 18-year-old Jesse Gelsinger died in a gene transfer study at the University of Pennsylvania, the national spotlight focused on the procedures used to ensure research participants' safety and their capacity to safeguard the well-being of those who volunteer for research studies. Responsible Research outlines a three-pronged approach to ensure the protection of every participant through the establishment of effective Human Research Participant Protection Programs (HRPPPs). The approach includes: Improved research review processes, Recognition and integration of research participants' contributions to the system, and Vigilant maintenance of HRPPP performance. 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. Responsible Research will be important to anyone interested in the issues that are relevant to the practice of using human subjects as research participants, but especially so to policy makers, research administrators, investigators, and research sponsorsâ€"but also including volunteers who may agree to serve as research participants.

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.

The Belmont Report United States. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1978

The Law and Regulation of Clinical Research Pamela A. Andanda 2006

Ethics and Planning Research Dr Huw Thomas 2012-11-28 The consideration of ethics in social research has gained increasing prominence in the past few years, particularly research which seeks to inform public policy. This important and unique book provides a thorough examination of the issues relating to research ethics in planning for an international audience. The authors examine alternative frameworks within which ethical action can be discussed and critically describe the key institutional arrangements surrounding the management of ethical behaviour in research. Also included are highly relevant accounts of ethical challenges faced in planning research.

Ethics in Research Practice and Innovation Sandu, Antonio 2018-11-16 A particularly important component of any research project is its ethical dimensions which can refer to varied categories of practice – from the protection of human subjects involved in medical and social research to the publication of results research. More recently, with the estimation of the possible consequences of the implementation of technology, it is important for today's researchers to address the standards of scientific practice and avoid unethical behavior. Ethics in Research Practice and Innovation is an essential reference source that discusses current and historical aspects of ethical values in scientific research and technologies, as well as emerging perspectives of conducting ethical research in a variety of fields. Featuring research on topics such as clinical trials, human subjects, and informed consent, this book is ideally designed for practitioners, medical professionals, nurses, researchers, scientists, scholars, academicians, policy makers, and students seeking coverage on the ethical risks and limitations of research practice.

Medical Ethics and the Law Marc D. Hiller 1981

The Limits of Consent Oonagh Corrigan 2009-01-29 Since its inception as an international requirement to protect patients and healthy volunteers taking part in medical research, informed consent has become the primary consideration in research ethics. Despite the ubiquity of consent, however, scholars have begun to question its adequacy for contemporary biomedical research. The Limits of Consent explores this issue, reviewing the application of consent to genetic research, clinical trials, and research involving vulnerable populations. For example, in genetic research, information obtained from an autonomous research participant may have significant bearing on the interests of family members who have not consented to the study. This casts doubt on the adequacy of consent for such studies. The Limits of Consent also questions the assumptions that informed consent is essential and that it satisfactorily protects the principle of individual autonomy. It reviews recent empirical studies that challenge the possibility of truly informed consent and highlights the extent to which consent is governed by social norms and expectations. It also investigates how consent might be of secondary importance in some circumstances, for example when a research project appears to protect a public or community interest. Building on these observations, the

authors make bold attempts to outline constructive solutions to the problems identified with perspectives from medicine, law, philosophy and sociology. This fascinating and provocative exploration of the limits of informed consent will appeal to ethicists, social scientists, health lawyers, clinical researchers, research ethics committee members, policy makers, and others with an interest in bioethics.

Optimizing the Nation's Investment in Academic Research National Academies of Sciences, Engineering, and Medicine 2016-06-29 Research universities are critical contributors to our national research enterprise. They are the principal source of a world-class labor force and fundamental discoveries that enhance our lives and the lives of others around the world. These institutions help to create an educated citizenry capable of making informed and crucial choices as participants in a democratic society. However many are concerned that the unintended cumulative effect of federal regulations undercuts the productivity of the research enterprise and diminishes the return on the federal investment in research. Optimizing the Nation's Investment in Academic Research reviews the regulatory framework as it currently exists, considers specific regulations that have placed undue and often unanticipated burdens on the research enterprise, and reassesses the process by which these regulations are created, reviewed, and retired. This review is critical to strengthen the partnership between the federal government and research institutions, to maximize the creation of new knowledge and products, to provide for the effective training and education of the next generation of scholars and workers, and to optimize the return on the federal investment in research for the benefit of the American people.

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.

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