



Ethics and Regulation of Human Subjects Research

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The Ethics And Regulation Of Research With Human Subjects

Carl H. Coleman



The Ethics And Regulation Of Research With Human Subjects:

The Ethics and Regulation of Research with Human Subjects Carl H. Coleman, 2005 This 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 This book 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

Ethics and Regulation of Clinical Research Robert J. Levine, 1988-01-01 The use of human subjects in medical and scientific research has given rise to troubling ethical questions How should human subjects be selected for experiments What should they be told about the research in which they are involved How can their privacy be protected When is it permissible to deceive them How do we deal with subjects such as children fetuses and the mentally infirm for whom informed consent is impossible In this book Dr Robert J Levine reviews federal regulations ethical analysis and case studies in an attempt to answer these questions His book is an essential reference for everyone members of institutional review boards scientists philosophers lawyers addressing the ethical issues involved Levine's experience as a clinician IRB chairman writer and editor of a journal devoted exclusively to issues faced by IRBS makes him uniquely qualified to bring together the legal ethical and practical dimensions The book is sophisticated but readable and should be on every IRB administrator's desk and in every medical ethics library

Norman Fost M D The New England Journal of Medicine Levine is one of the foremost historians of contemporary clinical science His book is at once a guide to primary sources for the history of clinical research in the late twentieth century and a pioneering secondary source about that history Daniel M Fox Bulletin of the History of Medicine You will be charmed by the book's elegance and lucidity and persuaded of its relevance to doctors in any country Alex Paton British Medical Journal Should be of wide interest to those keen to see advances in medical research brought into general medical practice Gilbert Omenn Issues in Science and Technology

The Ethics of Research Involving Human Subjects Harold Y. Vanderpool, 1996

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

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

The Ethics of Research with Human Subjects David B. Resnik, 2025-02-27 In The Ethics of Research with Human Subjects David B Resnik PhD JD develops and defends an approach to thinking about ethical and policy dilemmas in research with human subjects based on the notion of trust The book explains why trust is important not only between investigators and research 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 public Dr Resnik argues that trust should be viewed as a distinct ethical principle for research with human subjects that complements other principles such as respect for human dignity beneficence non maleficence and justice The book applies the principle of trust to numerous issues including informed consent confidentiality privacy risk minimization risk benefit assessment payments for participation protection of vulnerable subjects experimental design research integrity and research oversight The book also includes discussions of the history of research involving human subjects moral theories and principles contemporary cases and proposed regulatory reforms This second edition of The Ethics of Research with Human Subjects expands upon and clarifies arguments and ideas discussed in the first edition and includes new material on emerging issues in human research ethics including community based research citizen science research challenge studies including COVID 19 experiments public health research genomics research social and behavioral research xenotransplantation experiments alternative study

designs and research with people with compromised decisional capacity employees and students The book is of interest to undergraduate and graduate students who are studying ethical and policy issues related to research with human subjects as well as scientists and scholars who are interested learning more about the issues and thinking about what it means to promote integrity and trust in research with human subjects *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

Legal and Ethical Regulation of Biomedical Research in Developing Countries Remigius N. Nwabueze,2016-04-22 There has been a rapid increase in the pace and scope of international collaborative research in developing countries in recent years This study argues that whilst ethical regulation of biomedical research in Africa and other developing countries has attracted global attention legal liability issues such as the application of common law rules and the development of legally enforceable regulations have been neglected It examines some of the major research scandals in Africa and suggests a new ethical framework against which clinical trials could be conducted The development of research guidelines in Uganda Tanzania Malawi and Nigeria are also examined as well as the role of ethics committees Providing a detailed analysis of the law of negligence and its application to research ethics committees and their members common law and constitutional forms of action and potential negligence claims the book concludes by suggesting new protocols and frameworks improved regulation and litigation This book will be a valuable guide for students researchers and policy makers with an interest in medical law and ethics bioethics customary law in Africa and regulation in developing countries *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

Ethical Research Ulf Schmidt,Andreas Frewer,Dominique Sprumont,2020-04-17 Ethical Research is a new and important book focusing on the centrality of the Declaration of Helsinki to the protection of human subjects involved in human experimentation The text illuminates the history nature scope context and controversies that challenge modern research ethics The editors and authors are international experts in their fields of study and each approaches the subject in a scholarly and accessible dialogue

The Oxford Handbook of Research Ethics Ana S. Iltis,Douglas MacKay,2024 The development of new pharmaceutical products and behavioral interventions aimed at improving people s health as well as research that assesses the efficacy and cost effectiveness of public policies such as policies designed to improve children s education or reduce poverty depends on research conducted with human participants It is imperative that research with human subjects is conducted in accordance with sound ethical principles and regulatory requirements Featuring 45 original essays by leading research ethicists The Oxford Handbook of Research Ethics offers a critical overview of the ethics of human subjects research within multiple disciplines and fields including biomedicine public health psychiatry sociology political science and public policy

Ethics and Law in Biomedicine and Genetics: an Overview of National Regulations in the Arab States ,2011

On the Dual Uses of Science and Ethics Michael J. Selgelid,Brian Rappert,2013-12-19 Claims about the transformations enabled by modern science and medicine have been accompanied by an unsettling question in recent years might the knowledge being produced undermine rather than further human and animal well being On the Dual Uses of Science and Ethics examines the potential for the skills know how information and techniques associated with modern biology to serve contrasting ends In recognition of the moral ambiguity of science and technology each chapter considers steps that might be undertaken to prevent the deliberate spread of disease Central to achieving this aim is the consideration of what role ethics might serve To date the ethical analysis of the themes of this

volume has been limited This book remedies this situation by bringing together contributors from a broad range of backgrounds to address a highly important ethical issue confronting humanity during the 21st century

The Ethical Challenges of Human Research Franklin G. Miller, 2012-11-15 This book contains 22 essays on the ethics of research involving human subjects written over a 15 year period Topics addressed include the ethics of clinical trials controversial study designs and informed consent

Handbook Of Health Research Methods: Investigation, Measurement And Analysis Bowling, Ann, Ebrahim, Shah, 2005-06-01 Handbook of Health Research Methods is an essential tool for researchers and postgraduate students taking masters courses or undertaking doctoral programmes in health services evaluation health sciences health management public health nursing sociology socio biology medicine and epidemiology However the book also appeals to health professionals who wish to broaden their knowledge of research methods in order to make effective policy and practice decisions

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 **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 **Ethical Challenges in Genomics Research** Paula

Boddington, 2012-03-12 New developments in science and technology have resulted in shifting ethical challenges in many areas including in genomics research This book enables those who are involved in genomics research whether as researcher participant or policy maker to understand the ethical issues currently developing in this field and to participate actively in these important debates A clear account is given of how science and technology are outstripping the capacity of previous ethical regulations to cope with current issues together with practical illustrations of possible ways forward Key ethical ideas are presented drawing on the history of research regulation and on an account of the particular challenges arising in the field of genomics The book uses a grounded practical approach to explaining ethical concepts and issues which is geared to enhancing interdisciplinary dialogue Its broad approach to ethical issues includes relevant considerations from social psychology and there is a particular emphasis on understanding the problems of ethical regulations and practice in the institutional and social context of research A glossary and numerous text boxes explaining relevant terms and key ideas help to make the work an invaluable resource for both beginners and experts in the field **Revival: Human Experimentation and Research (2003)** George F. Tomossy, David N. Weisstub, 2017-07-12 This title was first published in 2003 As new

medical technologies and treatments develop with increasing momentum the legal and ethical implications of research involving human participants are being called into question as never before Human Experimentation and Research explores the philosophical foundations of research ethics ongoing regulatory dilemmas and future challenges raised by the rapid globalisation and corporatisation of the research endeavour This volume brings together some of the most significant published essays in the field The editors also provide an informative introduction summarizing the area and the relevance of the articles chosen **The Oxford Handbook of Professional Economic Ethics** George DeMartino, Deirdre N.

McCloskey, 2016 This volume brings together leading figures in economics professional ethics and other relevant fields to explore questions related to the nature of ethical economic practice and the adoption and content of professional economic ethics It explores current thinking that has emerged in these areas while widening substantially the terrain of inquiry into economic ethics There has never been a volume that poses so directly and intensively the question of the need for and content of professional ethics for economics The Handbook incorporates the work of a wide array of scholars including

economists from various theoretical traditions economists from academia economists from other fields where practicing economists have a large social impact and professional ethicists from fields that have addressed the nature of professionalism and its implications for ethical practice

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