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**Accreditation and
Human Research
Participant Protection
Programs**

INSTITUTE OF MEDICINE

Preserving Public Trust Accreditation And Human Research Participant Protection Programs Paperback

Gary E. Marchant, Wendell Wallach



Preserving Public Trust Accreditation And Human Research Participant Protection Programs Paperback:

Preserving Public Trust Institute of Medicine, Board on Health Sciences Policy, Committee on Assessing the System for Protecting Human Research Subjects, 2001-08-02 Amid increasing concern for patient safety and the shutdown of prominent research operations the need to improve protections for individuals who volunteer to participate in research has become critical Preserving Public Trust Accreditation and Human Research Participant Protection Programs considers the possible impact of creating an accreditation system to raise the performance of local protection mechanisms In the United States the system for human research participant protections has centered on the Institutional Review Board IRB however this report envisions a broader system with multiple functional elements In this context two draft sets of accreditation standards are reviewed authored by Public Responsibility in Medicine Research and the National Committee for Quality Assurance for their specific content in core areas as well as their objectivity and validity as measurement tools The recommendations in the report support the concept of accreditation as a quality improvement strategy suggesting that the model should be initially pursued through pilot testing of the proposed accreditation programs

Preserving Public Trust Institute of Medicine (U, 2001) *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 Tuskegee 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 in 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 fetuses 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

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 Ethics, Law, And Aging Review, Volume 8 Marshall B. Kapp, JD, MPH, FCLM, 2002-07-31 Perplexing ethical questions emerge when conducting research involving older adult participants Fundamental ethical concerns often grappled with include the ability to obtain truly voluntary and competent informed consent the proper role of surrogate decision making in the research context and the equitable selection of research subjects This volume brings to the forefront a discussion of how to encourage essential research specifically designed to benefit older persons while protecting the legal and ethical rights of actual and potential older research participants Highly qualified and diverse contributors analyze and explain some of the most salient and legal conundrums implicated in the design conduct interpretation and application of research protocols that touch on these problems of aging and the aged

The Handbook of Social Research Ethics Donna M. Mertens, Pauline E. Ginsberg, 2009 Brings together international scholars across the social and behavioural sciences and education to address those ethical issues that arise in the theory and practice of research within the technologically advancing and culturally complex world in which we live

Principles and Practice of Clinical Research John I. Gallin, Frederick P Ognibene, Laura Lee Johnson, 2017-11-17 Principles and Practice of Clinical Research Fourth Edition has been thoroughly revised to provide a comprehensive look at both the fundamental principles and expanding practice of clinical research New to this edition of this highly regarded reference authors have focused on examples that broadly reflect clinical research on a global scale while including a discussion of international regulations studies and implications In addition to key topics such as bioethics clinical outcome data cultural diversity protocol guidelines and omic platforms this edition contains new chapters devoted to electronic health records and information resources for clinical researchers as well as the many opportunities associated with big data Covering a vast number of topics and practical advice for both novice and advanced clinical investigators this book is a highly relevant and essential resource for all those involved in conducting research Features input from experts in the field dedicated to translating scientific research from bench to bedside and back Provides expanded coverage of global clinical research Contains hands on practical suggestions illustrations and examples throughout Includes new chapters on the international regulation of drugs and biologics the emergence of the important role of comparative effectiveness research and how to identify clinical risks

and manage patient safety in a clinical research setting

Intentional Human Dosing Studies for EPA Regulatory

Purposes National Research Council, Policy and Global Affairs, Science, Technology, and Law Program, Committee on the Use of Third Party Toxicity Research with Human Research Participants, 2004-06-04 The EPA commissioned The National Academies to provide advice on the vexing question of whether and if so under what circumstances EPA should accept and consider intentional human dosing studies conducted by companies or other sources outside the agency so called third parties to gather evidence relating to the risks of a chemical or the conditions under which exposure to it could be judged safe This report recommends that such studies be conducted and used for regulatory purposes only if all of several strict conditions are met including the following The study is necessary and scientifically valid meaning that it addresses an important regulatory question that can't be answered with animal studies or nondosing human studies The societal benefits of the study outweigh any anticipated risks to participants At no time even when benefits beyond improved regulation exist can a human dosing study be justified that is anticipated to cause lasting harm to study participants and All recognized ethical standards and procedures for protecting the interests of study participants are observed In addition EPA should establish a Human Studies Review Board HSRB to evaluate all human dosing studies both at the beginning and upon completion of the experiments if they are carried out with the intent of affecting the agency's policy making

Assessing Social Science Research Ethics and Integrity Harry Perlstadt, 2024-01-19 This book discusses the development of key issues in research ethics relevant for clinical sociologists concerning client rights to confidentiality privacy and informed consent It describes the US human research protection system used by clinical and applied sociologists through a history of research ethics including the landmark Belmont Report and the creation of the regulatory structure of Institutional Review Boards IRBs in the United States It also discusses ethical research systems in other nations like Canada the UK Australia and New Zealand The book provides a comprehensive account of controversial studies in the US including Milgram's Obedience to Authority Zimbardo's Stanford Prison Experiment and the US Public Health Service and the Tuskegee Syphilis Study and analyzes how ethical concerns in these studies were or were not resolved This book covers a topic of core interest to clinical and applied sociologists and other social science practitioners who do research as well as students and teachers in research ethics courses in anthropology psychology political science sociology and philosophy thereby broadening an awareness of clinical sociology

Professionalism and Ethics in Medicine Laura Weiss Roberts, MD, MA, Daryn Reicherter, MD, 2014-12-08 Professionalism and Ethics in Medicine A Study Guide for Physicians and Physicians in Training is a unique self study guide for practitioners and trainees covering the core competency areas of professionalism ethics and cultural sensitivity This novel title presents real world dilemmas encountered across the specialties of medicine offering guidance and relevant information to assist physicians residents and medical students in their decision making The text is divided into two parts Foundations and Questions with Answers The first part provides a substantive foundation of knowledge in the

principles scholarship policy guidelines and decision making strategies of the modern health professions The second part assists practitioners and trainees in preparing for the complex issues that arise each day in the settings where health professionals work and train clinics research centers educational contexts and communities Developed by renowned leaders in a broad range of clinical fields Professionalism and Ethics in Medicine A Study Guide for Physicians and Physicians in Training is a major invaluable contribution to the literature and an indispensable reference for clinicians at all levels

Everyday Practice of Science Frederick Grinnell,2011-05-12 Presents an overview of the scientific process for those curious about science practice in today s society and especially for those considering making a career of science Children in Medical Research Lainie Friedman Ross,2006-02-09 Lainie Ross presents a rigorous critical investigation of the development of policy governing the involvement of children in medical research She examines the shift in focus from protection of medical research subjects enshrined in post World War II legislation to the current era in which access is assuming greater precedence Infamous studies such as Willowbrook where mentally retarded children were infected with hepatitis are evidence that before the policy shift protection was not always adequate even for the most vulnerable groups Additional safeguards for children were first implemented in many countries in the 1970s and 1980s more recent policies and guidelines are trying to promote greater participation Ross considers whether the safeguards work whether they are fair and how they apply in actual research practice She goes on to offer specific recommendations to modify current policies and guidelines Ross examines the regulatory structures e g federal regulations and institutional review boards the ad hoc policies e g payment in pediatric research and the role of schools as research venues the actual practices of researchers e g the race ethnicity of enrolled research subjects or the decision to enroll newborns as well as the decision making process both parental permission and the child s assent in order to provide a broad critique Some of her recommendations will break down current barriers to the enrolment of children e g permitting the payment of child research subjects allowing healthy children to be exposed to research that entails more than minimal risk without requiring recourse to 407 panels whereas other recommendations may create new restrictions e g the need for greater protection for research performed in schools restrictions on what research should be done in the newborn nursery The goal is to ensure that medical research is done in a way that promotes the health of current and future children without threatening to use the words of Hans Jonas the erosion of those moral values whose loss would make its most dazzling triumphs not worth having *Challenges and Opportunities for Education About Dual Use Issues in the Life Sciences* National Research Council,Division on Earth and Life Studies,Board on Life Sciences,Committee on Education on Dual Use Issues in the Life Sciences,2011-01-16 The Challenges and Opportunities for Education About Dual Use Issues in the Life Sciences workshop was held to engage the life sciences community on the particular security issues related to research with dual use potential More than 60 participants from almost 30 countries took part and included practicing life scientists bioethics and biosecurity practitioners and experts in the

design of educational programs The workshop sought to identify a baseline about 1 the extent to which dual use issues are currently being included in postsecondary education undergraduate and postgraduate in the life sciences 2 in what contexts that education is occurring e g in formal coursework informal settings as stand alone subjects or part of more general training and in what fields and 3 what online educational materials addressing research in the life sciences with dual use potential already exist *Ethics, Medicine, and Information Technology* Kenneth W. Goodman, 2016-01-14 Information technology is transforming the practices of medicine nursing and biomedical research Computers can now render diagnoses and prognoses more accurately than humans The concepts of privacy and confidentiality are evolving as data moves from paper to silicon to clouds Big data promises financial wealth as well as riches of information and benefits to science and public health Online access and mobile apps provide patients with an unprecedented connection to their health and health records This transformation is as unsettling as it is exhilarating This unique new book is essential for anyone who uses computers in health care biomedical research or public health and cares about the ethical issues that arise in their work With chapters spanning issues from professionalism and quality to mobile health and bioinformatics it establishes what will become the core curriculum in ethics and health informatics a growing field which encourages truly inter and multidisciplinary inquiry **Emerging Technologies** Gary E. Marchant, Wendell Wallach, 2020-07-26 Emerging technologies present a challenging but fascinating set of ethical legal and regulatory issues The articles selected for this volume provide a broad overview of the most influential historical and current thinking in this area and show that existing frameworks are often inadequate to address new technologies such as biotechnology nanotechnology synthetic biology and robotics and innovative new models are needed This collection brings together invaluable innovative and often complementary approaches for overcoming the unique challenges of emerging technology ethics and governance

Institutional Review Board: Management and Function Public Responsibility in Medicine & Research (PRIM&R), Elizabeth A. Bankert, Bruce G. Gordon, Elisa A. Hurley, 2021-03-01 Institutional Review Board IRB members and oversight personnel face challenges with research involving new technology management of big data globalization of research and more complex federal regulations Institutional Review Board Management and Function Third Edition provides everything IRBs and administrators need to know about efficiently managing and effectively operating a modern and compliant system of protecting human research subjects This trusted reference manual has been extensively updated to reflect the 2018 revisions to the Federal Policy for the Protection of Human Subjects Common Rule An essential resource for both seasoned and novice IRB administrators and members Institutional Review Board Management and Function provides comprehensive and understandable interpretations of the regulations clear descriptions of the ethical principles on which the regulations are based and practical step by step guidance for effectively implementing regulatory oversight **Scientific and Medical Aspects of Human Reproductive Cloning** National Research Council, Division on Earth and Life

Studies, Board on Life Sciences, Policy and Global Affairs, Committee on Science, Engineering, and Public Policy, 2002-06-17

Human reproductive cloning is an assisted reproductive technology that would be carried out with the goal of creating a newborn genetically identical to another human being. It is currently the subject of much debate around the world involving a variety of ethical, religious, societal, scientific, and medical issues. Scientific and Medical Aspects of Human Reproductive Cloning considers the scientific and medical sides of this issue plus ethical issues that pertain to human subjects research. Based on experience with reproductive cloning in animals, the report concludes that human reproductive cloning would be dangerous for the woman, fetus, and newborn and is likely to fail. The study panel did not address the issue of whether human reproductive cloning, even if it were found to be medically safe, would be or would not be acceptable to individuals or society.

The Journal of Health Care Law & Policy, 2004 *Clinical and Translational Science* David Robertson, Gordon H. Williams, 2016-11-25. *Clinical and Translational Science: Principles of Human Research*, Second Edition is the most authoritative and timely resource for the broad range of investigators taking on the challenge of clinical and translational science, a field that is devoted to investigating human health and disease interventions and outcomes for the purposes of developing new treatment approaches, devices, and modalities to improve health. This updated second edition has been prepared with an international perspective, beginning with fundamental principles, experimental design, epidemiology, traditional and new biostatistical approaches, and investigative tools. It presents complete instruction and guidance from fundamental principles, approaches, and infrastructure, especially for human genetics and genomics, human pharmacology, research in special populations, the societal context of human research, and the future of human research. The book moves on to discuss legal, social, and ethical issues and concludes with a discussion of future prospects, providing readers with a comprehensive view of this rapidly developing area of science. Introduces novel physiological and therapeutic strategies for engaging the fastest growing scientific field in both the private sector and academic medicine. Brings insights from international leaders into the discipline of clinical and translational science. Addresses drug discovery, drug repurposing, and development, innovative and improved approaches to go/no-go decisions in drug development, and traditional and innovative clinical trial designs. **Ethical Health Care** Patricia Illingworth, Wendy E. Parmet, 2006. **KEY BENEFIT** *Ethical Health Care* provides an interdisciplinary perspective to bioethics, relying heavily upon the teachings of economics, law, and public health. **KEY TOPICS** The book explores with care and context the nature of the relationship between patients and clinicians, health care providers and the societies in which they live, and finally the relationship between the health care enterprise and the international community. **MARKET** For clinicians and other health care providers.

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Introduction

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