

**Preserving Public Trust:
Accreditation and
Human Research
Participant Protection
Programs**

*Committee on Assessing the System for Protecting Human Research
Subjects*
Board on Health Sciences Policy
INSTITUTE OF MEDICINE

NATIONAL ACADEMY PRESS
Washington, D.C.

Preserving Public Trust Accreditation And Human Research Participant Protection Programs Paperback

Fay A. Rozovsky, Rodney K. Adams

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 [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 *Ethical Issues in Clinical Research* Bernard Lo, 2012-03-28 This book teaches researchers how to resolve the ethical dilemmas that can arise at any stage in clinical research In addition to explaining pertinent regulations and laws Dr Lo helps investigators understand the gaps and uncertainties in regulations as well as situations in which merely complying with the law may not fulfill ethical responsibilities Most chapters include real life examples that the author walks through discussing the salient issues and how to approach them This book can be used in courses on research ethics that are required or encouraged by major National Institutes of Health grants in academic health centers *Writing Clinical Research Protocols* Evan DeRenzo, Joel Moss, 2005-09-08 This highly engaging guide for clinical researchers provides a foundation for improving skills in the understanding of ethical requirements in the design and conduct of clinical research Writing Clinical Research Protocols includes practical information on ethical principles in clinical research designing appropriate research studies writing consent and assent documents getting protocols approved special populations confidentiality issues and the reporting of

adverse events A valuable appendix includes a listing of web resources about research ethics as well as a glossary This is an invaluable resource for basic scientists collaborating in clinical trials physician investigators clinical research fellows research nurse coordinators residents and anyone who wants a better understanding of the clinical trials process Walks investigators and trainees through identification of the ethical aspects of each section of a clinical research protocol Includes a chapter containing Case Histories Contains information on conducting clinical research within the pharmaceutical industry An appendix includes internet resources and world wide web addresses for important research ethics documents and regulations Chapter on Study Design and Methodology purposely expanded to explicitly address biostatistical considerations

Responsible Research Institute of Medicine, Committee on Assessing the System for Protecting Human Research Participants, 2003-01-06 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 sponsors but also including volunteers who may agree to serve as research participants

Books in Print Supplement, 2002 **Whitaker's Books in Print**, 1998 *Who's Who in America* Marquis Who's Who, Inc, 2002 **Human Research Protections** Patricia H. Arford, Ph.d., Ph D R N Arford, Patricia, 2015-11-21 The process of human research is an increasingly complex endeavor with a multitude of occasions to potentially cause harm to subjects violate federal regulations intended to protect human subjects abuse Protected Health Information and corrupt data Human research in the United States is highly regulated and an Institutional Review Board for Human Research IRB is the local enforcer Out of necessity IRBs have multiple requirements policies and forms designed to ensure compliance with federal regulations and state laws governing human research These mandates represent an ethical process used to protect human subjects investigators and organizations This book is a comprehensive practical guide to assist investigators their study teams and healthcare graduate students to effectively and efficiently interact with IRBs Also both experienced and novice IRB members will find this book provides a clear foundation for their decision making The

author has condensed the available human research protections conceptual and legalistic information into a basic concise functional guide that those involved in human research readily can apply to their own research questions settings and populations The researcher will be able to quickly find help to complete one task such as writing an informed consent document or constructing all the required elements of a human subject protection plan Practicing clinical and basic healthcare scientists human research support staff members of IRBs healthcare graduate students required to conduct human research to earn their degrees and faculty in academic healthcare settings will find this book useful Among the topics included are levels of IRB review preparing an approval application for the IRB the informed consent process and document and special issues such as vulnerable populations use of biospecimens and de identification of Protected Health Information

Promoting Ethical Research with Humans Task Force for the Development of an Accreditation System for Human Resource Protection Programs (Canada), Davey, K.G. (Kenneth George), Owen, Michael, 2006 **Protecting Participants and Facilitating Social and Behavioral Sciences Research** National Research Council, Division on Behavioral and Social Sciences and Education, Board on Behavioral, Cognitive, and Sensory Sciences, Committee on National Statistics, Panel on Institutional Review Boards, Surveys, and Social Science Research, 2003-07-26 Institutional review boards IRBs are the linchpins of the protection systems that govern human participation in research In recent years high profile cases have focused attention on the weaknesses of the procedures for protecting participants in medical research The issues surrounding participants protection in the social behavioral and economic sciences may be less visible to the public eye but they are no less important in ensuring ethical and responsible research This report examines three key issues related to human participation in social behavioral and economic sciences research 1 obtaining informed voluntary consent from prospective participants 2 guaranteeing the confidentiality of information collected from participants which is a particularly challenging problem in social sciences research and 3 using appropriate review procedures for minimal risk research Protecting Participants and Facilitating Social and Behavioral Sciences Research will be important to policy makers research administrators research sponsors IRB members and investigators More generally it contains important information for all who want to ensure the best protection for participants and researchers alike in the social behavioral and economic sciences

Protecting Subjects, Preserving Trust, Promoting Progress Association of American Medical Colleges, AAMC Task Force on Financial Conflicts of Interest in Clinical Research, 2001 Protecting Subjects, Preserving Trust, Promoting Progress II, 2002 **Accreditation Standards for Human Research Protection and Independent Review Boards**, 2003-01-01

Institutional Review Board for the Protection of Human Subjects in Research Xavier University (Cincinnati, Ohio). Institutional Review Board for the Protection of Human Subjects in Research, 1996 **Protecting Human Research Subjects** Robin Levin Penslar, 1993 2d edition Issued in looseleaf form with index dividers and a spinelabel Prepared under contract by Robin Levin Penslar at Indiana University Poynter Center for the Study of Ethics and American Institutions

Includes sections on institutional administration of the Institutional Review Board the IRB regulations and policies biomedical and behavioral research an overview special classes of subjects such as fetuses women children prisoners comatose patients and volunteers bibliography glossary texts of international human rights documents Nuremberg Helsinki and Belmont lists of contacts Federal regulations and other information Final Report of the Task Force Established by the National Council on Ethics in Human Research To Study Models of Accreditation for Human Research Protection Programs in Canada Task Force Established by the National Council on Ethics in Human Research To Study Models of Accreditation for Human Research Protection Programs in Canada, National Council on Ethics in Human Research, 2002 **Protection of Human Research Subjects** D.M. Maloney, 2012-12-06 Regulations on human subjects research have evolved over a 20 year period and now provide a formal set of requirements for the conduct of federally sponsored studies Over time government regulations like taboos in primitive societies develop a life of their own seemingly dissociated from their origins and justifications When the investigator suffers the burdens of trying to comply with complex rules it is easy for him or her to lapse into a frustration that can be eased by being informed or reminded of why the rules were created in the first place and what they were designed to accomplish Dennis Maloney's work provides a handy historical record of the processes by which the regulations were created and modified He also recounts his own experience with research at Boys Town and provides instructions on how to cope with the system It is difficult to find in one place the current status and appropriate citations for regulations as well as the contacts and know how to obtain more information on the subject In this respect by providing a history and guide to interpretation and compliance Protection of Human Subjects is a reference of importance and utility to the investigator entering into or working in the field of biomedical or behavioral research involving human subjects

Clinical Trials and Human Research Fay A. Rozovsky, Rodney K. Adams, 2003-06-10 This easy to read reference book provides a practical approach for dealing with the legal and regulatory compliance issues involved in human research Covering a broad range of topics such as consent confidentiality subject recruitment and selection the role of the investigator and Institutional Review Board it offers timely and useful strategies for achieving regulatory compliance while reducing liability In addition insurance quality management accreditation and risk management are topics examined in the book The practical insights found in this volume are not found in other books on the subject Clinical Trials and Human Research is a practical tool to help anyone involved in clinical research

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