

RESPONSIBLE RESEARCH



**A Systems
Approach to
Protecting
Research
Participants**

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Responsible Research A Systems Approach To Protecting Research Participants

Nita Farahany



Responsible Research A Systems Approach To Protecting Research Participants:

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

Standing on Principles Tom L. Beauchamp, 2010-04-28 Tom L Beauchamp of Georgetown is one of the founding fathers of contemporary bioethics and is particularly influential as one of the co authors with James Childress of PRINCIPLES OF BIOMEDICAL ETHICS first published by OUP over 25 years ago and a true cornerstone of contemporary bioethics This volume is both an introductory textbook as well as a definitive expression of what is known as the dominant principlist approach which views bioethical reasoning developing out of four key principles respect for autonomy nonmaleficence beneficence and justice This view has been highly influential over the last two decades and has set the agenda for the field This volume will collect Tom Beauchamp s 15 most important published articles in bioethics most of which were published over the last 25 years and most of which have a strong connection to the principlist approach Most of the essays included here augment develop or defend various themes positions and arguments in that earlier book both adding depth as well as taking off in new directions Among the topic discussed are the historical origins of modern research ethics to moral principles and methodological concerns Beauchamp will include a new introduction to explain the history of the essays and their relationship to the principlist theory

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

Professional Nursing Concepts Anita Ward Finkelman, 2013 takes a patient centered traditional approach to the topic of nursing education and professional development This dynamic text engages students in recognizing the critical role that nurses play in health care delivery and focuses on the five core competencies for health professions as determined by the Institute of Medicine IOM Back cover

Health Care Regulation in America Robert I. Field, 2007 Regulation shapes all aspects of America's fragmented health care industry While the health and lives of patients as well as almost one sixth of the national economy depend on its effectiveness health care regulation in America is bewilderingly complex Health Care Regulation in America is a guide to this regulatory maze

Case Studies in Ethics and HIV Research Sana Loue, Earl C. Pike, 2007-10-05 This book represents the compilation of efforts by researchers across the country each of whom is dedicated not only to the prevention and elimination of HIV infection but also to the conduct of research according to the highest ethical principles The authors of the case studies have graciously agreed to share their experiences in conducting research which raised questions for them and will motivate us to further inquiry and examination The views that are presented in this text are diverse and readers may or may not agree with the analyses of the editor authors or the authors of the case studies We do not aim for agreement among readers but rather the studied analysis of the ethical issues raised in the conduct of HIV research We clearly emphasize the protection of the individuals participating in such research as well as their communities and view research not as an enterprise undertaken by researchers but rather as a negotiated exchange between researchers participants and communities that also involves interplay with funding sources ancillary partners and governments

The Impact of Behavioral Sciences on Criminal Law Nita Farahany, 2011-02-20 This volume is essential reading for anyone interested in the ongoing genomics and neuroscience revolution and its implications for criminal law

The SAGE Handbook of Interview Research Jaber F. Gubrium, James A. Holstein, Amir B. Marvasti, Karyn D. McKinney, 2012-02-14 The new edition of this landmark volume emphasizes the dynamic interactional and reflexive dimensions of the research interview Contributors highlight the myriad dimensions of complexity that are emerging as researchers increasingly frame the interview as a communicative opportunity as much as a data gathering format The book begins with the history and conceptual transformations of the interview which is followed by chapters that discuss the main components of interview practice Taken together the contributions to The SAGE Handbook of Interview Research The Complexity of the Craft encourage readers simultaneously to learn the frameworks and technologies of interviewing and to reflect on the epistemological foundations of the interview craft

The Oxford Textbook of Clinical Research Ethics Ezekiel J. Emanuel, Christine C. Grady, Robert A. Crouch, Reidar K. Lie, Franklin G. Miller, David D. Wendler, 2011-02 The Oxford Textbook of Clinical Research Ethics is the first comprehensive and systematic reference on clinical research ethics Under the editorship of experts from the U S National Institutes of Health of the United States the book's 73 chapters offer a wide

ranging and systematic examination of all aspects of research with human beings Considering the historical triumphs of research as well as its tragedies the textbook provides a framework for analyzing the ethical aspects of research studies with human beings Through both conceptual analysis and systematic reviews of empirical data the contributors examine issues ranging from scientific validity fair subject selection risk benefit ratio independent review and informed consent to focused consideration of international research ethics conflicts of interests and other aspects of responsible conduct of research The editors of The Oxford Textbook of Clinical Research Ethics offer a work that critically assesses and advances scholarship in the field of human subjects research Comprehensive in scope and depth this book will be a crucial resource for researchers in the medical sciences as well as teachers and students

Neuroscience in the 21st Century Donald W. Pfaff, Nora D. Volkow, John L. Rubenstein, 2022-10-17 Edited and authored by a wealth of international experts in neuroscience and related disciplines this key new resource aims to offer medical students and graduate researchers around the world a comprehensive introduction and overview of modern neuroscience Neuroscience research is certain to prove a vital element in combating mental illness in its various incarnations a strategic battleground in the future of medicine as the prevalence of mental disorders is becoming better understood each year Hundreds of millions of people worldwide are affected by mental behavioral neurological and substance use disorders The World Health Organization estimated in 2002 that 154 million people globally suffer from depression and 25 million people from schizophrenia 91 million people are affected by alcohol use disorders and 15 million by drug use disorders A more recent WHO report shows that 50 million people suffer from epilepsy and 24 million from Alzheimer's and other dementias Because neuroscience takes the etiology of disease the complex interplay between biological psychological and sociocultural factors as its object of inquiry it is increasingly valuable in understanding an array of medical conditions A recent report by the United States Surgeon General cites several such diseases schizophrenia bipolar disorder early onset depression autism attention deficit hyperactivity disorder anorexia nervosa and panic disorder among many others Not only is this volume a boon to those wishing to understand the future of neuroscience it also aims to encourage the initiation of neuroscience programs in developing countries featuring as it does an appendix full of advice on how to develop such programs With broad coverage of both basic science and clinical issues comprising around 150 chapters from a diversity of international authors and including complementary video components Neuroscience in the 21st Century in its third edition serves as a comprehensive resource to students and researchers alike

Resolving Ethical Dilemmas Bernard Lo, 2013-01-25 Now in its Fifth Edition this respected reference helps readers tackle the common and often challenging ethical issues that affect patient care The book begins with a concise discussion of clinical ethics that provides the background information essential to understanding key ethical issues Readers then explore a wide range of real world ethical dilemmas each accompanied by expert guidance on salient issues and how to approach them The book's two color design improves retention of material for visual learners An accompanying website lets readers access

the full text along with features designed to reinforce understanding and test knowledge New to the Fifth Edition This edition includes new discussions of ethical issues as they relate to clinical practice guidelines and evidence based medicine electronic medical records genetic testing and opioid prescription The book also includes an increased focus on ethical issues in ambulatory care Readers will also find more detailed analysis of cases more examples of ethical reasoning more highlight pages relating clinical ethics to emergency medicine oncology palliative care and family medicine Also new are discussions of quality improvement and use of advance care planning rather than advance directives

Law and Ethics in Biomedical Research Duff William Ramus Waring,Trudo Lemmens,2006-01-01 When a young man named Jesse Gelsinger died in 1999 as a result of his participation in a gene transfer research study regulatory agencies in the United States began to take a closer look at what was happening in medical research The resulting temporary shutdown of some of the most prestigious academic research centres confirmed what various recent reports in the United States as well as Canada had claimed that the current system of regulatory oversight was in need of improvement Law and Ethics in Biomedical Research uses the Gelsinger case as a touchstone illustrating how three major aspects of that case the flaws in the regulatory system conflicts of interest and legal liability embody the major challenges in the current medical research environment Editors Trudo Lemmens and Duff R Waring along with a host of top scholars in the field demonstrate why existing models of research review and human subject protection are in need of improvement and how more stringent regulatory and legal means can be used to strengthen the protection of research subjects and the integrity of research The contributors also address conflicts of interest paying particular attention to the growing commercialization of medical research as well as the legal liability of scientific investigators research institutions and governmental agencies Legal liability is a growing concern in medical research and this fascinating study is in the international context one of the first to explore the liability of various parties involved in the research enterprise

Prisoners' Rights John Kleinig,2017-07-05 This volume brings together a selection of the most important published research articles from the ongoing debate about the moral rights of prisoners The articles consider the moral underpinnings of the debate and include framework discussions for a theory of prisoners rights as well as several international documents which detail the rights of prisoners including women prisoners Finally detailed analysis of the moral bases for particular rights relating to prison conditions covers areas such as health solitary confinement recreation work religious observance library access the use of prisoners in research and the disenfranchisement of prisoners

Stephens' Detection of New Adverse Drug Reactions John Talbot,Patrick Waller,2004-11-19 A key text for all those involved in pharmacovigilance Detection of new adverse drug reactions is fundamental to the protection of patients from harm that may occur as a result of medication This book explores the methods used to investigate new adverse drug reactions discussing all elements from the scientific background and animal toxicology through to worldwide regulatory and ethical issues Stephens Detection of New Adverse Drug Reactions provides comprehensive and up to date coverage of material fundamentally

important to all those active in the field whether they work in the pharmaceutical industry drug regulatory authorities or in academia The fifth edition of this classic reference work includes new chapters on vaccine safety surveillance managing drug safety issues with marketed products operational aspects of drug safety function safety of biotechnology products future of pharmacovigilance Reviews of previous editions This book surpasses all its educational aims Not only is the subject matter covered comprehensively but the material is presented in a very user friendly manner The editors have succeeded in producing a highly specific definitive reference book which doubles as a most enjoyable read Commended by the 1999 BMA Medical Book Competition For anyone entering the field of adverse reaction monitoring one could not wish for a better primer International Journal of Risk and Safety in Medicine

Engaging with Ethics in International Criminological Research Michael Adorjan, Rose Ricciardelli, 2016-06-10 Despite a voluminous literature detailing the procedures of research ethics boards and institutional ethical review processes there are few texts that explore the realpolitik of conducting criminal research in practice This book explores the unique lived experiences of scholars engaging with ethics during their criminological research and focuses on the ethical dilemmas that researchers encounter both in the field and while writing up results for publication Who benefits from criminological research What are the roles and impacts of ethics review boards How do methodological and theoretical decisions factor in to questions of ethical conduct and research ethics governance This book is divided into four parts Part I Institutional arrangements and positionality explores the ongoing and expanding process of ethics protocol and procedures principles of confidentiality and the positionality of the researcher Part II Trust and research with vulnerable populations examines the complexity of work involving prisoners indigenous peoples and victims of extreme violence power dynamics between researchers and participants and the challenges of informed consent Part III Research on and with police reflects on the importance of transparent relations with police best practices and the consequences of undertaking research in authoritarian contexts Part IV Emerging areas scrutinizes the ethics of carceral tours and suggests possible alternatives and offers one of the first sociological and criminological examinations of dark net cryptomarkets Drawing upon the experiences of international experts this book aims to provoke further reflection on and discussion of ethics in practice This book is ideal for students undertaking courses on research methods in criminology as well as a key resource for criminology researchers around the world

Case Studies in Nursing Ethics Sara T. Fry, Robert M. Veatch, Carol R. Taylor, 2010-08-06 Medical Device Epidemiology and Surveillance S. Lori Brown, Rosalie A. Bright, Dale R. Tavris, 2007-03-13 Medical devices are crucial in medical care today and device technology advances at a dizzying pace Medical Device Epidemiology and Surveillance is the first book to provide an overview of medical device epidemiology and surveillance as well as perspectives from regulatory agencies the medical device industry the health insurance industry and academia The book is edited by experts from the US Food and Drug Administration with contributions from experienced specialists working in this field in the US and around the world It features chapters describing broad

themes in medical device epidemiology and surveillance as well as chapters that describe specific medical devices Medical Device Epidemiology and Surveillance is an essential reference for epidemiologists pharmacoepidemiologists academics graduate students and everybody working in the medical device industry **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 **Exploring Challenges, Progress, and New Models for Engaging the Public in the Clinical Research Enterprise** Institute of Medicine,Board on Health Sciences Policy,Clinical Research

Roundtable,2003-07-25 This report is a summary of a workshop focused on exploring the role of the public in the Clinical Research Enterprise The Clinical Research Enterprise depends upon practitioners policy makers and others for participation in trials ethical review of research and continued support of research funding However the role of the public has expanded beyond this traditional model as consumers have begun to demand a role in the formulation of the research agenda and in the design review and pursuit of research This report identifies four major challenges to the Clinical Research Enterprise enhancing public participation in clinical research which includes making the system safer and faster developing the necessary information systems that are needed to make the clinical research enterprise a coordinated and seamless whole fostering an adequately trained workforce and ensuring adequate funding for clinical research In addition the report identifies two translational blocks from basic science into clinical practice and from the clinical identification of things that work into broader application to improve medical care and the public s health This workshop summary addresses the contribution of the public to overcoming these obstacles **Clinical Trials in Latin America: Where Ethics and Business Clash** Nuria Homedes,Antonio Ugalde,2013-11-29 The outsourcing of clinical trials to Latin America by the transnational innovative pharmaceutical industry began about twenty years ago Using archival information and field work in Argentina Brazil Costa Rica Mexico and Peru the authors discuss the regulatory contexts and the ethical dimensions of human experimentation in the region More than 80% of all clinical trials in the region take place in these countries and the European Medicines Agency has defined them as priority countries in Latin America The authors raise questions about the quality of data obtained from the trials and the violation of human rights during their implementation Their findings are presented in this volume the first in depth analysis of clinical trials in the region

The Top Books of the Year Responsible Research A Systems Approach To Protecting Research Participants The year 2023 has witnessed a remarkable surge in literary brilliance, with numerous engrossing novels captivating the hearts of readers worldwide. Lets delve into the realm of top-selling books, exploring the engaging narratives that have captivated audiences this year. Responsible Research A Systems Approach To Protecting Research Participants : Colleen Hoover "It Ends with Us" This heartfelt tale of love, loss, and resilience has gripped readers with its raw and emotional exploration of domestic abuse. Hoover skillfully weaves a story of hope and healing, reminding us that even in the darkest of times, the human spirit can triumph. Responsible Research A Systems Approach To Protecting Research Participants : Taylor Jenkins Reids "The Seven Husbands of Evelyn Hugo" This spellbinding historical fiction novel unravels the life of Evelyn Hugo, a Hollywood icon who defies expectations and societal norms to pursue her dreams. Reids compelling storytelling and compelling characters transport readers to a bygone era, immersing them in a world of glamour, ambition, and self-discovery. Responsible Research A Systems Approach To Protecting Research Participants : Delia Owens "Where the Crawdads Sing" This mesmerizing coming-of-age story follows Kya Clark, a young woman who grows up alone in the marshes of North Carolina. Owens spins a tale of resilience, survival, and the transformative power of nature, entrancing readers with its evocative prose and mesmerizing setting. These popular novels represent just a fraction of the literary treasures that have emerged in 2023. Whether you seek tales of romance, adventure, or personal growth, the world of literature offers an abundance of captivating stories waiting to be discovered. The novel begins with Richard Papen, a bright but troubled young man, arriving at Hampden College. Richard is immediately drawn to the group of students who call themselves the Classics Club. The club is led by Henry Winter, a brilliant and charismatic young man. Henry is obsessed with Greek mythology and philosophy, and he quickly draws Richard into his world. The other members of the Classics Club are equally as fascinating. Bunny Corcoran is a wealthy and spoiled young man who is always looking for a good time. Charles Tavis is a quiet and reserved young man who is deeply in love with Henry. Camilla Macaulay is a beautiful and intelligent young woman who is drawn to the power and danger of the Classics Club. The students are all deeply in love with Morrow, and they are willing to do anything to please him. Morrow is a complex and mysterious figure, and he seems to be manipulating the students for his own purposes. As the students become more involved with Morrow, they begin to commit increasingly dangerous acts. The Secret History is a exceptional and suspenseful novel that will keep you speculating until the very end. The novel is a cautionary tale about the dangers of obsession and the power of evil.

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