

Ethics and Regulation of Clinical Research

Robert J. Levine

Second Edition

Ethics And Regulation Of Clinical Research Second Edition

Evan DeRenzo, Eric A. Singer, Joel Moss



Ethics And Regulation Of Clinical Research Second Edition:

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 *Ethics and Regulation of Clinical Research. Second Edition* Robert J. Levine, 1988 The book is organized around the federal regulations their application frequently requires interpretation and judgment New in this edition are sections on academic misconduct research on diseases with anticipated permanent incompetence eg Alzheimer s research on the fetus and in vitro fertilization The first edition made extensive use of the reports of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research This edition adds frequent references to the report of the President s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research Randomized controlled trials present some of the most difficult ethical and regulatory issues Their locus is the conflict between the obligation of physicians to select treatments believed to be in the best interest of patients and the obligation of researchers to design a trial that will advance the interests of future patients

An Insider's Guide to Clinical Trials Curtis L Meinert, 2011-05-18 This book serves as an invaluable guide on how clinical trials are designed and run how to interpret the results and what to make of them in general The book includes shopping guides for trials a list of common abbreviations used by trialists and tools for patients for deciding if or when to enroll in a clinical trial

Children and Health Care L.M. Kopelman, J.C. Moskop, 2007-08-26 Before a separate Department of Medical Humanities was formed the editors of this volume were faculty members of the Department of Pediatrics at our medical school Colleagues daily spoke of the moral and social problems of children s health care Our offices

were near the examining rooms where children had their bone marrow procedures done Since this is a painful test we often heard them cry The hospital floor where the sickest children stayed was also nearby The physicians nurses and social workers believed that children s health care needs were not being met and that more could and should be done Fewer resources are available for a child than for an adult with a comparable illness they said These experiences prompted us to prepare this volume and to ask whether children do get their fair share of the health care dollar Since the question What kind of health care do we owe to our children is complex responses should be rooted in many disciplines These include philosophy law public policy and of course the health professions Representing all of these disciplines contributors to this volume reflect on moral and social issues in children s health care The last hundred years have brought great changes in health care for children The specialty of pediatrics developed during this period and with it a new group of advocates for children s health care Women s suffrage gave a political boost to the recognition of children s special health needs

A Comprehensive and Practical Guide to Clinical Trials Delva Shamley,Brenda Wright,2017-06-07 A Comprehensive and Practical Guide to Clinical Trials provides an overview of the entire process of clinical research in one thorough and easy to read handbook that offers those involved in clinical research a clear understanding of how the components of a study are related It focuses on the practical aspects of the preparation and execution of a clinical trial and offers tools and resources to help the entire team understand how their responsibilities tie together with the tasks and duties of other members This allows for better planning and prioritization and can lead to more effective and successful clinical trials With practical examples checklists and forms this book is a useful guide for planning and conducting clinical trials from beginning to end Describes the entire clinical trial management process from start to finish in a step by step guide Provides best practice elements including case studies practical examples activities and checklists

Ethical Considerations When Preparing a Clinical Research Protocol Evan DeRenzo,Eric A. Singer,Joel Moss,2020-06-12 Ethical Considerations When Preparing a Clinical Research Protocol Second Edition provides a foundation for improving skills in the understanding of ethical requirements in the design and conduct of clinical research It includes practical information on ethical principles in clinical research how to design appropriate research studies how to consent and assent documents how to get protocols approved special populations confidentiality issues and the reporting of adverse events The book s valuable appendix includes a listing of web resources about research ethics along with a glossary making it an invaluable resource for scientists collaborating in clinical trials physician investigators clinical research fellows and more Walks investigators and trainees through the identification of the ethical aspects of each section of a clinical research protocol Includes case histories that illustrate key points Contains information on conducting clinical research within the pharmaceutical industry Includes internet resources and worldwide web addresses for important research ethics documents and regulations Contains a chapter on Study Design and Methodology that is purposely expanded to explicitly address biostatistical considerations

Clinical Bioethics James F. Drane,1994-03 Medical

practice is an inherently ethical enterprise More than ever before medical practice requires that medical professionals develop and exercise high ethical standards Health care practitioners who ignore basic concepts of medical ethics risk exposing their patients to serious harm and open themselves and their institutions to charges of malpractice Clinical Bioethics provides for the busy clinical professional a concise comprehensive treatment of the basics in this complex new field

Clinical Trials Steven Piantadosi,1997 This book gives the reader important accounts of basic statistical procedures used in clinical trials It covers several areas of study including biostatistics biomathematics biometry and epidemiology There is emphasis for trialists to learn good methodology while giving quality clinical treatment Discusses and explores controversial issues such as ethics and offers pragmatic information regarding allegations of fraud or misconduct

Ethical and Regulatory Aspects of Clinical Research Ezekiel J. Emanuel,2003 Professionals in need of such training and bioethicists will be interested

Textbook of Clinical Trials in Oncology Susan Halabi,Stefan Michiels,2019-04-24 There is an increasing need for educational resources for statisticians and investigators Reflecting this the goal of this book is to provide readers with a sound foundation in the statistical design conduct and analysis of clinical trials Furthermore it is intended as a guide for statisticians and investigators with minimal clinical trial experience who are interested in pursuing a career in this area The advancement in genetic and molecular technologies have revolutionized drug development In recent years clinical trials have become increasingly sophisticated as they incorporate genomic studies and efficient designs such as basket and umbrella trials have permeated the field This book offers the requisite background and expert guidance for the innovative statistical design and analysis of clinical trials in oncology Key Features Cutting edge topics with appropriate technical background Built around case studies which give the work a hands on approach Real examples of flaws in previously reported clinical trials and how to avoid them Access to statistical code on the book s website Chapters written by internationally recognized statisticians from academia and pharmaceutical companies Carefully edited to ensure consistency in style level and approach Topics covered include innovating phase I and II designs trials in immune oncology and rare diseases among many others

Nursing Research Louise De Raeve,1996 A multi contributed book that uniquely addresses important ethical issues in nursing research Features the work of expert authors and an appendix on the Helsinki Declaration of the World Medical Association

The Milbank Quarterly ,1923

Clinical Research Coordinator Handbook Deborah Norris,2009 In this fully revised and expanded fourth edition of the essential reference for clinical research coordinators Deborah Norris provides expanded coverage of CRC duties and regulatory requirements including new sections on investigator responsibilities data clarification and adverse event reporting The book s five appendices include a directory of CRC resources updated forms and checklists state regulatory requirements and contact information conversion charts and tables and a glossary

Ethics Applied ,2000

Human Experimentation and Research George F. Tomossy,David N. Weisstub,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 Yale Law Journal** ,1988 *Psychopharmacology Bulletin* ,1996 **Journal of the American Medical Association** American Medical Association,1892 *Bibliography of Bioethics* LeRoy Walters,1975 *Legal-ethical Considerations, Restrictions, and Obligations for Clinicians who Treat Communicative Disorders* Franklin H. Silverman,1992

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