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Sigmund Simonsen

# Acceptable Risk in Biomedical Research

**European Perspectives** 



**Jessica J Manson** 

Acceptable Risk in Biomedical Research Sigmund Simonsen, 2012-01-04 This book is the first major work that addresses a core question in biomedical research the question of acceptable risk The acceptable level of risks is regulated by the requirement of proportionality in biomedical research law which state that the risk and burden to the participant must be in proportion to potential benefits to the participant society or science This investigation addresses research on healthy volunteers children vulnerable subjects and includes placebo controlled clinical trials It represents a major contribution towards clarifying the most central but also the most controversial and complex issue in biomedical research law and bioethics The EU Clinical Trial Directive the Council of Europe's Oviedo Convention and its Additional Protocol and national regulation in member states are covered It is a relevant work for lawyers and ethicists and the practical approach makes a valuable tool for researchers and members of research ethics committees supervising biomedical research of Human Genetic Databases Bernice Elger, 2016-05-13 Following the boom in population databases in recent years there has been sustained and intense international debate about political processes and legal and ethical issues surrounding the protection and use of genetic data As a result several national and international organizations and committees have published widely differing guidelines and statements concerning genetic databases and biobanks Ethical Issues of Human Genetic Databases compares the new area of biobanking with the tradition of ethically accepted classical research and highlights the distinctive features of existing databases and guidelines The volume identifies areas of consensus and controversy while investigating the challenges posed to classical health research ethics by the existence of genetic databases analyzing the reasons for such varying guidelines The book will be essential to academics biobankers policy makers and researchers in the field of medical ethics 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

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