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Sigmund Simonsen

# Acceptable Risk in Biomedical Research

European Perspectives

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# Acceptable Risk In Biomedical Research European Perspectives International Library Of Ethics Law And The New Medicine

**Sigmund Simonsen,NTNU**



## **Acceptable Risk In Biomedical Research European Perspectives International Library Of Ethics Law And The New Medicine:**

*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 Choice ,1984

**Acceptable risk and the requirement of proportionality in European biomedical research law** Sigmund Simonsen, NTNU, 2010 *Human Medical Research* Jan Schildmann, Verena Sandow, Oliver Rauprich, Jochen Vollmann, 2012-03-12 Medical research involving human subjects has contributed to considerable advancements in our knowledge and to medical benefits At the same time the development of new technologies as well as further globalisation of medical research raises questions that require the attention of researchers from a range of disciplines This book gathers the contributions of researchers from nine different countries who analyse recent developments in medical research from ethical historical legal and socio cultural perspectives In addition to reflections on innovations in science such as genetic databases and the concept of targeted therapy the book also includes analyses regarding the ethico legal regulation of new technologies such as human tissue banking or the handling of genetic information potentially relevant for participants in medical research Country and culture specific aspects that are relevant to human medical research from a global perspective also play a part The value of multi and interdisciplinary analysis that includes the perspectives of scholars from normative and empirical disciplines is a shared premise of each contribution Ethics, Law and Governance of Biobanking Deborah

Mascalzoni, 2015-01-22 Biobank research and genomic information are changing the way we look at health and medicine Genomics challenges our values and has always been controversial and difficult to regulate In the future lies the promise of tailored medical treatments and pharmacogenomics but the borders between medical research and clinical practice are becoming blurred We see sequencing platforms for research that can have diagnostic value for patients Clinical applications and research have been kept separate but the blurring lines challenges existing regulations and ethical frameworks Then how do we regulate it This book contains an overview of the existing regulatory landscape for biobank research in the Western world and some critical chapters to show how regulations and ethical frameworks are developed and work How

should international sharing work How design an ethical informed consent An underlying critique the regulatory systems are becoming increasingly complex and opaque The international community is building systems that should respond to that According to the authors in fact it is time to turn the ship around Biobank researchers have a moral responsibility to look at and assess their work in relation to the bigger picture the shared norms and values of current society Research ethics shouldn't only be a matter of bioethicists writing guidelines that professionals have to follow Ethics should be practiced through discourse and regulatory frameworks need to be part of that public discourse Ethics review should be then not merely application of bureaucracy and a burden for researchers but an arena where researchers discuss their projects receive advice and practice their ethics skills

**The Ethics of Biomedical Research** Baruch A. Brody, 1998 A broad critical review of national policies on biomedical research human epidemiologic clinical trials genetic reproductive etc

**The Law and Ethics of Medical Research** Aurora Plomer, 2013-03-04 The growing globalization of medical research and the application of new biotechnologies in morally contested areas has forced a revision of international ethical guidelines This book examines the controversies surrounding biomedical research in the twenty first century from a human rights perspective analyzing the evolution and changes in form and content of international instruments regulating the conduct of biomedical research The approach adopted is comparative and includes an evaluation of human rights and UK and US law on embryonic stem cell research the HIV AIDS trials in the developing world the Alder Hey Inquiry and the human radiation and nerve gas experiments on human subjects in the US and the UK This is the first book to analyze some of the major issues in biomedical research today from an international comparative human rights perspective

*Ethics and Governance of Biomedical Research* Daniel Strech, Marcel Mertz, 2016-05-09 In this book scholars with different disciplinary and national backgrounds argue for possible answers and analyse case studies on current issues of governance in biomedical research These issues comprise among others the research care distinction risk evaluation in early human trials handling of incidental findings nocebo effects cluster randomized trials publication bias or consent in biobank research This book demonstrates how new technologies and research possibilities multiply or intensify already known governance challenges leaving room for ethical analysis and complex moral choices Clinical researchers research ethics committee members and research ethicists have all to deal with such challenges on a daily basis While general reflection on core concepts of research ethics is seldom pointless those confronted with hard moral choices do need more practical and contextualized reflection on the said issues This book particularly provides such contextualized reflections and aims to inform all those who study conduct regulate fund or participate in biomedical research

Competence and Vulnerability in Biomedical Research Philip Bielby, 2008-09-16 Enhanced knowledge of the nature and causes of mental disorder have led increasingly to a need for the recruitment of cognitively vulnerable participants in biomedical research These individuals often fall into the grey area between obvious decisional competence and obvious decisional incompetence and as a result may not be recognised as having the legal

capacity to make such decisions themselves At the core of the ethical debate surrounding the participation of cognitively vulnerable individuals in research is when if at all we should judge them decisionally and legally competent to consent to or refuse research participation on their own behalf and when they should be judged incompetent in this respect In this book the author develops a novel justificatory framework for making judgments of decisional competence to consent to biomedical research with reference to five groups of cognitively vulnerable individuals older children and adolescents adults with intellectual disabilities adults with depression adults with schizophrenia and adults with dementia including Alzheimer s disease Using this framework the author argues that we can make morally defensible judgments about the competence or incompetence of a potential participant to give contemporaneous consent to research by having regard to whether a judgment of competence would be more harmful to the generic rights of the potential participant than a judgment of incompetence The argument is also used to justify an account of supported decision making in research and applied to evaluate the extent to which this approach is evident in existing ethical guidelines and legal provisions The book will be of interest to bioethicists as well as psychiatrists and academic medical lawyers interested in normative questions raised by the concepts of competence and capacity

International Ethical Guidelines for Biomedical Research Involving Human Subjects Council for International Organizations of Medical Sciences, World Health Organization, 1993 Annexes

**Fraud and Misconduct in Biomedical Research, 4th edition** Frank Wells, Michael Farthing, 2019-03-14 Now in its fourth edition *Fraud and Misconduct in Biomedical Research* boasts an impressive list of contributors from around the globe and introduces a new focus for the book transforming it from a series of monographs into a publication that will quickly become an essential textbook on all areas of research fraud and misconduct Key features include

*Ethical Issues in Governing Biobanks* Nikola Biller-Andorno, Alexander M. Capron, 2016-05-13 Population genomics research drawing on genetic databases has expanded rapidly with some of this information being combined in biobanks Managing this information in an appropriate way is a highly complex ethical issue in the health policy arena This book combines theoretical and empirical research to analyze the areas of conflict and consensus in the regulatory and ethical frameworks that have been developed to govern biobanks Ethicists from the Department of Ethics Trade Human Rights and Health Law ETH of the World Health Organization the Institute of Biomedical Ethics of Geneva University and the Institute of Biomedical Ethics of the University of Zurich with the support of the Geneva International Academic Network GIAN examine the conditions under which genetic databases can be established kept and made use of in an ethically acceptable way In addition to a comprehensive review of the scientific literature and a comparative analysis of existing normative frameworks they present the results of in depth interviews with experts around the world concerning the most unresolved and controversial issues The results of that study combined with their normative analysis leads to recommendations for a better international framework

**Double Standards in Medical Research in Developing Countries** Ruth Macklin, 2004-05-27 Recent international developments show that essential

medications can be made affordable and accessible to developing countries and that double standards need not prevail This is the first book to examine these issues drawing the bold conclusion that double standards in medical research are ethically unacceptable BOOK JACKET **Ethics and Law for Chemical, Biological, Radiological, Nuclear & Explosive Crises** Dónal P. O'Mathúna,Iñigo de Miguel Beriain,2019-04-25 This book provides a current analysis of the legal and ethical challenges in preparing for and responding to chemical biological radiological nuclear and explosive CBRNE crises From past events like the Chernobyl nuclear incident in Russia or the Bhopal chemical calamity in India to the more recent tsunami and nuclear accident in Japan or the Ebola crisis in Africa and with the on going threat of bioterrorism the need to be ready to respond to CBRNE crises is uncontroversial What is controversial is whether we are on a path that adequately prepares us for the next event The ethical and legal scholars in this volume hold that much work remains to be done and offer this book to stimulate further reflection and dialogue around CBRNE crises This is an indispensable book for both students and scholars of bioethics international law public health as well as for regulators and administrators developing policy and legislation related to public health planning and emergency responses *Beyond Consent* Jeffrey P. Kahn,Anna C. Mastroianni,Jeremy Sugarman,2018 Since the publication of the first edition of *Beyond Consent* issues of justice remain critical in discussions debates and policy making in biomedical research in involving human subjects The second edition adds new content in two different ways first by asking authors to examine the issues identified in the first edition by asking what has changed and what new issues arise in the contemporary environment and second by adding chapters to take on issues that are salient today and looking forward The result is a new treatment of the issues of justice in research through fresh perspectives and by examining the latest issues The editors have assembled a group of leading scholars and researchers as contributors and author the final chapter themselves This collection is a vital resource for students and scholars of bioethics medicine and public health policy as well as for members of institutional review boards IRBs research administrators and policy makers

**Biomedical Research** Council of Europe,2004-01-01 This publication the fifth in the Ethical Eye series contains contributions from a multidisciplinary group of authors from different countries in Europe which examine a range of ethical issues arising from the use of biomedical research Topics discussed include the problems of obtaining consent standards for the selection and recruitment of participants for research the use of placebos clinical trials of new medicines or experimental treatments for cancer sufferers industry sponsored clinical trials the internationalisation of medical research and gender aspects The publication looks at various international and European standards governing this field including the Helsinki Declaration of the World Medical Association EU Directive 2001/20 on pharmaceutical research and the Council of Europe s Convention on Human Rights and Biomedicine Research Ethics Committees, Data Protection and Medical Research in European Countries D. Townend,2017-05-15 The Data Protection and Medical Research in Europe PRIVIREAL series represents the results of this EC funded project examining the implementation of Directive 95/46/EC on data protection in

relation to medical research and the role of ethics committees in European countries The series consists of five separate volumes following the complete development of the PRIVIREAL project This volume relates to the second stage of this project and is concerned with the setting up and role of research ethics committees It assesses their legal responsibilities especially with regard to data protection matters and contains reports from more than 20 European countries on these issues Focusing on the theoretical role and practical operation of research ethics committees and the impact of relevant international and national instruments this volume will be an essential resource for all those concerned with data protection issues in medical research

*Ethics in Biomedical Research* Matti Häyry, Tuija Takala, Peter Herissone-Kelly, 2007 This book deals with the international assessment and regulation of biomedical research In its chapters some of the leading figures in today's bioethics address questions centred on global development scientific advances and vulnerability The series Values In Bioethics makes available original philosophical books in all areas of bioethics including medical and nursing ethics health care ethics research ethics environmental ethics and global bioethics

*Liability for and Insurability of Biomedical Research with Human Subjects in a Comparative Perspective* Jos Dute, Michael G. Faure, Helmut Koziol, 2004-02-27 Recent Dutch legislation has been introduced stating that biomedical research on humans can only be undertaken when an insurance contract covering the damage as a result of death or personal injury of the patients has been concluded The aim of this legislation is to ease the acquiring of compensation for test subjects in case damage arises in the course of biomedical research As such victims are able to claim compensation directly from the insurer irrespective of any liability This volume presents a critical evaluation of the functioning of this legislative arrangement and the situation in various European countries is examined Country reporters from Belgium England France Germany the Netherlands Spain Sweden and Switzerland describe the insurance and liability arrangements relating to biomedical research in their country The concluding three reports of this volume examine the situation from both a comparative and international perspective

*The Belmont Report* United States. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978

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