Research Ethics Committees Data Protection And Medical Research In European Countries Data Protection And Medical Research In Europe Privireal

Arthur James Wells

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.

The Data Protection Directive and Medical Research Across Europe D. Townend, J. Wright, 2017-07-05 The Data Protection and Medical Research in Europe: PRIVIREAL series focuses on the 'Privacy in Research Ethics and Law' 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 first stage of the project regarding the implementation of the Data Protection Directive, in particular in the area of medical research. It contains an introduction and overview of this topic, keynote papers addressing specific questions on the subject, and a report on both the general implementation of the Directive and the implementation in relation to medical research in 26 European countries. The book will be invaluable for those people with an interest in data protection, medical research and their implications for each other. It lays open the actual situation across Europe, including both New Member States and Newly Associated Member States.

Implementation of the Data Protection Directive in Relation to Medical Research in Europe D. Townend, S. Rouille-
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Research Ethics Committees, Data Protection, and Medical Research in Europe: key Issues

Privireal

PRIVIREAL IS A EUROPEAN COMMISSION FUNDED PROJECT EXAMINING THE IMPLEMENTATION OF DIRECTIVE 95/46/EC ON DATA PROTECTION IN RELATION TO MEDICAL RESEARCH AND THE ROLE OF ETHICS COMMITTEES. THIS VOLUME RELATES TO THE THIRD STAGE OF THIS PROJECT ON RECOMMENDATIONS AND SUGGESTIONS TO BE MADE TO THE EC ON THE IMPLEMENTATION OF THE DIRECTIVE AND THE REMIT TO BE GIVEN TO RECS TO PROTECT RESEARCH PARTICIPANTS' RIGHTS. THIS VOLUME COMBINES BOTH INTRODUCTIONS TO THE TOPIC, REPORTS FROM MANY OF THE 26 EUROPEAN COUNTRIES PARTICIPATING IN PRIVIREAL, AND THE OVERALL RECOMMENDATIONS DEVELOPED BY THE SERIES EDITORS FOR SUBMISSION TO THE EC. THESE RECOMMENDATIONS CONCERN ISSUES SURROUNDING THE IMPLEMENTATION OF THE DIRECTIVE, LAWS IN COUNTRIES WHERE THE DIRECTIVE IS NOT YET IMPLEMENTED, THE REQUIREMENTS AND PRACTICE OF RESEARCH ETHICS COMMITTEES IN RELATION TO DATA PROTECTION, AND ANY OTHER MATTERS DEEMED RELEVANT.
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.

The Data Protection Directive and Medical Research Across Europe D. Townend, J. Wright, 2017-07-05 The Data Protection and Medical Research in Europe: PRIVIREAL series focuses on the ‘Privacy in Research Ethics and Law’ 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 first stage of the project regarding the implementation of the Data Protection Directive, in particular in the area of medical research. It contains an introduction and overview of this topic, keynote papers addressing specific questions on the subject, and a report on both the general implementation of the Directive and the implementation in relation to medical research in 26 European countries. The book will be invaluable for those people with an interest in data protection, medical research and their implications for each other. It lays open the actual situation across Europe, including both New Member States and Newly Associated Member States.

Implementation of the Data Protection Directive in Relation to Medical Research in Europe D. Townend, 2022

Privacy, Confidentiality, and Health Research William W. Lowrance, 2012-06-21 The potential of the e-health revolution, increased data sharing, database linking, biobanks and new techniques such as geolocation and genomics to advance human health is immense. For the full potential to be realized, though, privacy and confidentiality will have to be dealt with carefully. Problematically, many conventional approaches to such pivotal matters as consent, identifiability, and safeguarding and security are inadequate. In many places, research is impeded by an overgrown thicket of laws, regulations, guidance and governance. The challenges are being heightened by the increasing use of biospecimens, and by the globalization of research in a world that has not globalized privacy protection. Drawing on examples from many developed countries and legal jurisdictions, the book critiques the issues, summarizes various ethics, policy, and legal positions (and revisions underway).
describes innovative solutions, provides extensive references and suggests ways forward.

**G3P - Good Privacy Protection Practice in Clinical Research** Karl-Heinz Schriever, Markus Schröder, 2014-10-02

Establishing ethical and privacy protection aspects in scientific research, especially in medical research, has a long history. Medical data are usually more sensible than other personal data and require therefore an even higher degree of protection than other personal data. In recent research projects genetic evaluations become more and more important and trigger thereby new and continuing activities in the context of data protection. Genetic data as a subset of medical data are the most sensible category of personal data and require therefore the highest degree of data protection. The book provides a systematic and itemized approach to data protection in clinical research including the handling of genetic material, genetic samples as well as derived genetic data and the subsequent secure storage of them. The set up of different kinds of clinical trials having in addition a genetic part, the concept of a genetic informed consent as well as collection schemes of samples are described in detail. Technical requirements and aspects of data protection including pseudonymization and anonymization procedures taking into account ethics committees requirements as well as the underlying legal framework are also presented. Without any exception, all principles and methods presented are best practices, repeatedly applied in different clinical environments and by no means theoretical considerations.

**GDPR Requirements for Biobanking Activities Across Europe** Valentina Colcelli, Roberto Cippitani, Christoph Brochhausen-Delius, Rainer Arnold, 2024-01-27

The book deals with the effective operation of the rules related to biomedical research and pays attention to the activities of the national legislatures of the 27 Member States in the field of scientific research. This multilevel system has an impact on biobanking activity. The book answers questions realized by operators on the main biobanks around the EU in the field of GDPR. The authors and editors used the questions born from brainstorming among members of the Association European, Middle East & Africa for Biopreservation and Biobanking (ESBB) to offer to the operators in biobanking activity and researchers quickly answer to their daily questions, but with authors highest quality. Further the book provides a comprehensive review of the rapidly expanding field of biobanking. It provides researchers and scholars working on biobanking and bio-sharing and more in general in the university hospitals and clinical trial consortiums, and companies, biomedical researchers, but also jurists and the professionals (in particular judges, lawyers, officers) an instrument rigorous but easy to use of the GDPR in the case of biobanking activities. The book identifies a methodological path to tackle the legal or ethical problem on a specific scientific-technological to verify existing solutions and give ideas for future applications. The importance of the legal solution influences the implementation of the development of the biobanking activity service itself.

**La protection des données médicales** Deryck Beyleveld, 2008

**Identity, Security and Democracy** Emilio Mordini, Manfred Green, 2009

Many people think of personal identification as
only part of the security/surveillance apparatus. This is likely to be an oversimplification, which largely misrepresents the reality. 'Personal identity' means two separate concepts, namely that an individual belongs to specific categories and also that this individual is distinguished by other persons and understood as one. In other words, there are two different aspects involved in personal recognition: distinguishing between individuals and distinguishing between sets of people. The latter is likely to be the real issue. Dictatorships of any kind and totalitarian regimes have always ruled by categorizing people and by creating different classes of subjects. When rules want their subjects to humiliate themselves or their fellows, they create categories of people or exploit existing categories. From social and political points of view this allows a process known as 'pseudospeciation' to be produced. Pseudospeciation is a process which turns social and cultural differences into biological diversities. It promotes cooperation within social groups, overpowering the selfish interests of individuals in favor of collective interests, yet it also inhibits cooperation between groups, and it fosters conflict and mistrust. This work is dedicated to the thorny and multifaceted relations between identity, security and democracy. Identity, Security and Democracy shows how full of nuances the process of human identification is.

Encyclopedia of Environmental Health, 2019-08-22 Encyclopedia of Environmental Health, Second Edition, Six Volume Set presents the newest release in this fundamental reference that updates and broadens the umbrella of environmental health, especially social and environmental health for its readers. There is ongoing revolution in governance, policies and intervention strategies aimed at evolving changes in health disparities, disease burden, trans-boundary transport and health hazards. This new edition reflects these realities, mapping new directions in the field that include how to minimize threats and develop new scientific paradigms that address emerging local, national and global environmental concerns. Represents a one-stop resource for scientifically reliable information on environmental health Fills a critical gap, with information on one of the most rapidly growing scientific fields of our time Provides comparative approaches to environmental health practice and research in different countries and regions of the world Covers issues behind specific questions and describes the best available scientific methods for environmental risk assessment

The Law and Ethics of Data Sharing in Health Sciences Marcelo Corrales Compagnucci, Timo Minssen, Mark Fenwick, Mateo Aboy, Kathleen Liddell, 2024-01-02 Data sharing – broadly defined as the exchange of health-related data among multiple controllers and processors – has gained increased relevance in the health sciences over recent years as the need and demand for collaboration has increased. This includes data obtained through healthcare provisions, clinical trials, observational studies, public health surveillance programs, and other data collection methods. The practice of data sharing presents several notable challenges, however. Compliance with a complex and dynamic regulatory framework is essential, with the General Data Protection Regulation being a prominent example in a European context. Recent regulatory
developments related to clinical trial transparency, trade secrecy, data access, AI training data, and health data spaces further contribute to the difficulties. Simultaneously, government initiatives often encourage scientists to embrace principles of “open data” and “open innovation.” The variety of regulations in this domain has the potential to impede widespread data sharing and hinder innovation. This edited volume, therefore, compiles comparative case studies authored by leading scholars from diverse disciplines and jurisdictions. The book aims to outline the legal complexities of data sharing. By examining real-world scenarios from diverse disciplines and a global perspective, it explores the normative, policy, and ethical dilemmas that surround data sharing in the health sciences today. Chapter Patient Perspectives on Data Sharing, Chapter Supplementary Measures and Appropriate Safeguards for International Transfers of Health Data after Schrems II are available open access under a Creative Commons Attribution 4.0 International License via link.springer.com.

Consent in European Data Protection Law Eleni Kosta, 2013-03-21 Today, consent is a fundamental concept in the European legal framework on data protection. The analysis of the historical and theoretical context carried out in this book reveals that consent was not an intrinsic notion in the birth of data protection. The concept of consent was included in data protection legislation in order to enhance the role of the data subject in the data protection arena, and to allow the data subject to have more control over the collection and processing of his/her personal information. This book examines the concept of consent and its requirements in the Data Protection Directive, taking into account contemporary considerations on bioethics and medical ethics, as well as recent developments in the framework of the review of the Directive. It further studies issues of consent in electronic communications, carrying out an analysis of the consent-related provisions of the ePrivacy Directive.

Big Data Ethics in Research Nicolae Sfetcu, The main problems faced by scientists in working with Big Data sets, highlighting the main ethical issues, taking into account the legislation of the European Union. After a brief Introduction to Big Data, the Technology section presents specific research applications. There is an approach to the main philosophical issues in Philosophical Aspects, and Legal Aspects with specific ethical issues in the EU Regulation on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (Data Protection Directive - General Data Protection Regulation, GDPR). The Ethics Issues section details the specific aspects of Big Data. After a brief section of Big Data Research, I finalize my work with the presentation of Conclusions on research ethics in working with Big Data. CONTENTS: Abstract 1. Introduction - 1.1 Definitions - 1.2 Big Data dimensions 2. Technology - 2.1 Applications - 2.1.1 In research 3. Philosophical aspects 4. Legal aspects - 4.1 GDPR - Stages of processing of personal data - Principles of data processing - Privacy policy and transparency - Purposes of data processing - Design and implicit confidentiality - The (legal) paradox of Big Data 5. Ethical issues - Ethics in research - Awareness - Consent - Control - Transparency - Trust - Ownership - Surveillance and security - Digital identity - Tailored
Health Data Pools Under European Data Protection and Competition Law

Giulia Schneider, 2022-04-13

This book explores the emerging economic reality of health data pools from the perspective of European Union policy and law. The contractual sharing of health data for research purposes is giving rise to a free movement of research data, which is strongly encouraged at European policy level within the Digital Single Market Strategy. However, it has also a strong impact on data subjects' fundamental right to data protection and smaller businesses and research entities ability to carry out research and compete in innovation markets. Accordingly the work questions under which conditions health data sharing is lawful under European data protection and competition law. For these purposes, the work addresses the following sub-questions: i) which is the emerging innovation paradigm in digital health research?; ii) how are health data pools addressed at European policy level?; iii) do European data protection and competition law promote health data-driven innovation objectives, and how?; iv) which are the limits posed by the two frameworks to the free pooling of health data? The underlying assumption of the work is that both branches of European Union law are key regulatory tools for the creation of a common European health data space as envisaged in the Commissions 2020 European strategy for data. It thus demonstrates that both European data protection law, as defined under the General Data Protection Regulation, and European competition law and policy set research enabling regimes regarding health data, provided specific normative conditions are met. From a further perspective, both regulatory frameworks place external limits to the freedom to share (or not share) research valuable data.

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Introduction

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