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

For decades now, researchers in the social sciences and humanities have been expressing a deep dissatisfaction with the process of research-ethics review in academia. Continuing the ongoing critique of ethics review begun in Will C. van den Hoonaard's Walking the Tightrope and The Seduction of Ethics, The Ethics Rupture offers both an account of the system's failings and a series of proposals on how to ensure that social research is ethical, rather than merely compliant with institutional requirements. Containing twenty-five essays written by leading experts from around the world in various disciplines, The Ethics Rupture is a landmark study of the problems caused by our current research-ethics system and the ways in which scholars are seeking solutions.

The objective of this book is to examine how the legal order of Malta, the EU's smallest Member State, manages to cope with the obligations of the EU's acquis communautaire. As far as the legal obligations are concerned, size does not matter. Smaller Member States have the same obligations as the largest, yet they have to meet these same obligations with very fewer resources. This book examines how the Maltese legal system manages to fulfil its obligations both in terms of the supremacy of EU law, as well as how the substantive EU law is transposed and implemented. It also explores how Maltese courts look at EU law and how they manage, or not manage, to enforce it within the context of national law. It can serve as a model to demonstrate how EU law is being implemented in the smallest Member State and can serve as a basis to study the effectiveness of EU law into the domestic law of its Member States in general. Ivan Sammut is Head of Department of European and Comparative Law, and Deputy Dean within the Faculty of Laws at the University of Malta, Malta. Jelena Agranovska is Lecturer in European and Comparative Law within the Faculty of Laws, University of Malta, Malta.

The genetic era has given rise to significant legal dilemmas: who may own genetic data, when can a genetic test be performed on children, how can genetic-based discrimination be avoided, or to what extent and in what ways can genetic data be protected? The book addresses the social, ethical, and legal implications of collecting, storing, analyzing, and commercializing genetic information. Prominent biologists, medical doctors, lawyers, anthropologists, philosophers, sociologists, and theologians from different countries provide their views on the complex biological and social impacts of the imminent proliferation of genetic information. The authors explore the various uses and applications of genetic information, and discuss the current dilemmas of making laws in the field of genetics. Different models of national genome projects and biobanks, as well as the related international legal documents and national laws are also discussed. Various genome projects and biobanks are analyzed in detail.

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.

This timely book examines the interaction of health research and regulation with law through empirical analysis and the application of key anthropological concepts to reveal the inner workings of human health research. Through ground-breaking empirical inquiry, Regulatory Stewardship of Health Research explores how research ethics committees (RECs) work in practice to both protect research participants and promote ethical research. This thought-provoking book provides a new perspective on the regulation of health research by demonstrating how RECs and other regulatory actors seek to fulfil these two functions by performing a role of 'regulatory stewardship'.

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.

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.

The idea for this manual came from Pfizer in the US, which provided the Clinical Trials Centre at The University of Hong Kong, Hong Kong SAR, PR China with a nonbinding grant for its development. The general project layout protocol was accepted by Pfizer in July 2009. Pfizer has not in any way interfered with the project, except for providing nonbinding comments to the final product. The entire text of this manual was written by Johan PE Karlberg. Marjorie A Speers provided considerable and essential comments on the contents and the first and subsequent drafts. A group of international human research protection experts mostly working in non-profit institutions or organisations - see Contributors for details - reviewed and provided important comments on the contents and final draft. It was solely created with the intention to promote human research protection of participants in clinical trials. This manual will be translated into numerous languages and is provided free of charge as an electronic file over the Internet (http://www.ClinicalTrialMagnifier.com) and offered in print for a fee. The objective beyond this project is to establish educational activities, developed around the manual, and jointly organised with leading academic institutions worldwide.

This edited book promotes and facilitates cybercrime research by providing a cutting-edge collection of perspectives on the critical usage of online data across platforms, as well as the implementation of both traditional and innovative analysis methods. The accessibility, variety and wealth of data available online presents substantial opportunities for researchers from different disciplines to study cybercrimes and, more generally, human behavior in cyberspace. The unique and dynamic characteristics of cyberspace often demand cross-disciplinary and cross-national research endeavors, but disciplinary, cultural and legal differences can hinder the ability of researchers to collaborate. This work also provides a review of the ethics associated with the use of online data sources across the globe. The authors are drawn from multiple disciplines and nations, providing unique insights into the value and challenges evident in online data use for cybercrime scholarship. It is a key text for researchers at the upper undergraduate level and above.

This study is mapping the most significant challenges and obstacles for a reinforced Nordic cooperation on data resources. Focus is put on existing national databases and registers established mainly for administrative purposes but also the question of newly-generated scientific data is handled. The challenges are analysed from political, legal, ethical, organisational, technical and

financial perspectives. The broad scope targets primarily policy makers involved in eScience development on national and/or Nordic level. Involved parties in the study are Nordic Council of Ministers, NordForsk, Finnish Ministry of Education and Culture and CSC - IT Center for Science. Special focus has been put on the challenges for register-based research, since all the Nordic countries have a vast amount of population-based registers which are considered not to be used to their full potential in various research fields. One of the challenges is to find way to combine these registers with other research data and the Nordic countries have to find their own way of unique collaboration methods, since there are no equivalent pre-conditions for this kind of research in the rest of Europe. The study also gives a national overview of the current progress in the five Nordic countries, to raise awareness of important national initiatives which can contribute to a stronger collaboration on the Nordic level.

Research Ethics Committees, Data Protection and Medical Research in European CountriesRoutledge

La réglementation des données médicales est aujourd'hui un thème majeur du droit médical et du droit des nouvelles technologies. L'importance du sujet provient de l'exploitation croissante des technologies de l'information et de la communication dans le secteur des soins de santé et des risques nouveaux que cela entraîne pour les droits et libertés des citoyens. Les contributeurs au présent ouvrage ont été sélectionnés en vue de fournir une approche multidisciplinaire de haut niveau de la matière. Réunies, leurs contributions donnent une vision globale des défis à résoudre dans les années futures afin d'assurer la protection des citoyens au regard des traitements de données médicales. La publication de cet ouvrage a été rendue possible grâce au soutien de la Fondation Brocher (http.//www.brocher.ch). L'étude de Philippe Laurent et Loura Vilches Armesto a reçu le prix décerné par la Fondation Bullukian lors du 160 Congrès Mondial de Droit Médical tenu à Toulouse en 2006.

Part I Setting the scene -- Introduction: Individual rights, the public interest and biobank research 4000 (8) -- Genetic data and privacy protection -- Part II GDPR and European responses -- Biobank governance and the impact of the GDPR on the regulation of biobank research -- Controller' and processor's responsibilities in biobank research under GDPR -- Individual rights in biobank research under GDPR -- Safeguards and derogations relating to processing for archiving purposes in the scientific purposes: Article 89 analysis for biobank research -- A Pan-European analysis of Article 89 implementation and national biobank research regulations -- EEA, Switzerland analysis of GDPR requirements and national biobank research regulations -- Part III National insights in biobank regulatory frameworks -- Selected 10-15 countries for reports: Germany -- Greece -- France -- Finland -- Sweden -- United Kingdom -- Part IV Conclusions -- Reflections on individual rights, the public interest and biobank research, ramifications and ways forward. .

This book analyses the features and functionality of the relationship between the law, individual or collective values and medical-scientific evidence when they have to be interpreted by judges, courts and para-jurisdictional bodies. The various degrees to which scientific data and moral values have been integrated into the legal discourse reveal the need for a systematic review of the options and solutions that judges have elaborated on. In turn, the book presents a systematic approach, based on a proposed pattern for classifying these various degrees, together with an in-depth analysis of the multi-layered role of jurisdictions and the

means available to them for properly handling new legal demands arising in plural societies. The book outlines a model that makes it possible to focus on and address these issues in a sustainable manner, that is, to respond to individual requests and technological advances in the field of biolaw by consistently and effectively applying suitable legal instruments and jurisdictional interpretation.

This unique compilation of legal and ethical guidance was first published in 2003, and incorporates key guidelines.

The rapid development of information technology has exacerbated the need for robust personal data protection, the right to which is safeguarded by both European Union (EU) and Council of Europe (CoE) instruments. Safeguarding this important right entails new and significant challenges as technological advances expand the frontiers of areas such as surveillance, communication interception and data storage. This handbook is designed to familiarise legal practitioners not specialised in data protection with this emerging area of the law. It provides an overview of the EU's and the CoE's applicable legal frameworks. It also explains key case law, summarising major rulings of both the Court of Justice of the European Union and the European Court of Human Rights. In addition, it presents hypothetical scenarios that serve as practical illustrations of the diverse issues encountered in this ever-evolving field.

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.

Hallinan argues that the substantive framework presented by the GDPR offers an admirable base-line level of protection for the range of genetic privacy rights engaged by biobanking.

Principles of Medical Law provides a comprehensive analysis of the common law and statutory provisions pertaining to healthcare provision in England and Wales. Now in its third edition, this classic text has been fully updated to cover major statutory changes as well as significant developments in case law.

This book departs from the usual principles-based approach and instead takes a predominantly consequentialist (harms and benefits) approach. It aims to be free of abstract philosophy, but will use the analysis of cases and a reasoned approach to examine alternative arguments.

"Conducting research to high ethical standards is of great importance to the student and the university. Having an Ethics Protocol

is the way of ensuring such standards can be met. Researching with the use of an approved Ethics Protocol also affords protection to the student. Many research degree candidates need advice to help complete an application for the approval of their Ethics Protocol. This book shows how to do this in a practical and effective way. The book provides background on the issue of research ethics to help students and faculty have a greater understanding of the motivations behind the requirements to write an application to the Ethics Committee for the approval of an Ethics Protocol. The process of ethics approval and the function of the Ethics Committee are addressed along with how to cope with amendments to an Ethics Protocol. The book draws on the work of the authors who have had direct experience with Ethics Committees and helping students comply with the requirements."--Back cover.

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There has been an increasing interest in research ethics over the last decade given the increasing ethical regulation of social research. 'Ethical literacy' encourages researchers to understand and engage with the ethical issues that emerge in the process of research. This book provides a short, succinct and accessible overview of the field, highlighting the key issues and everyday ethical dilemmas that researchers are likely to face in different contexts. Covering a range of methods, the book provides clear guidance for researchers on how to identify an approach that fits with their moral and intellectual framework. It explores ethical issues relating to 'traditional' research methods as well as to new and emerging methods and approaches - particularly visual and online methods. Illustrated throughout with real-world examples, this book also includes an annotated bibliography of key texts and other helpful resources. What are Qualitative Research Ethics? will be a vital resource for social science researchers across a range of disciplines.

With concerns rising over the ethical dimensions of behavioral research and the developments in ethical codification and the research review process, Ethical Issues in Behavioral Research looks at the research community’s response to the ethical challenges that arise in the application of research approaches. Focuses on ethical and legal aspects of participant research on the internet Presents a practical framework for ethical decision making Discusses the revised ethical principles and code of conduct of the American Psychological Association A new chapter detailing ethical issues in marketing and opinion research, including a contrast of market and academic research and a summary of the author’s research comparing ethical trends in

psychology and marketing fields Offers in-depth coverage of recent ethical developments outside of the United States including an update of the survey of the international codes of ethics and recommendations for avoiding ethical pitfalls encountered in cross-national research Includes a list of useful internet links devoted to ethical issues in research Includes a Foreword by Herbert C. Kelman

Compared to the US, European data and privacy protection rules seem Draconian. The European rules apply to any enterprise doing business in the EU. The new rules are far more stringent than the last set. This book is a quick guide to the directives for companies, particularly US, that have to comply with them. Where US organizations and businesses who collect or receive EU personal data fail to comply with the rule, the bottom line can suffer from very significant official fines and penalties, as well as from users, customers or representative bodies to pursuing litigation. This guide is essential for all US enterprises who directly or indirectly deal with EU personal data.

This book of edited chapters helps researchers from clinical and nonclinical disciplines plan, carry out, and analyze research, and evaluate the quality of research studies. The focus of the book is a multidisciplinary approach to research methods that are relevant to researchers from different disciplines working side by side in the investigation of population health, the evaluation of health care, and health care delivery.

The Data Protection and Medical Research in Europe: PRIVIREAL series represents the results of the 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 role of research ethics committees across Europe in ensuring that participants in medical research gain the protection of the Directive. The work examines the specific provision of each Member State. It provides an overview of the European position through a comparative analysis of the domestic positions, and through a series of papers addressing key issues in the area. This book presents a valuable guide to the role and operation of research ethics committees and will be essential reading for all those involved with data protection issues in medical research.

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. Represents the results of PRIVIREAL, an 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.

This report identifies eight key data governance mechanisms to maximise benefits to patients and to societies from the collection, linkage and analysis of health data, and to minimise risks to both patient privacy and the security of health data.

Comprehensive guide for researchers to the ethical issues raised by different kinds of biomedical research.

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.

There has been a rapid increase in the pace and scope of international collaborative research in developing countries in recent years. This study argues that whilst ethical regulation of biomedical research in Africa and other developing countries has attracted global attention, legal liability issues, such as the application of common law rules and the development of legally enforceable regulations, have been neglected. It examines some of the major research scandals in Africa and suggests a new ethical framework against which clinical trials could be conducted. The development of research guidelines in Uganda, Tanzania, Malawi and Nigeria are also examined as well as the role of ethics committees. Providing a detailed analysis of the law of negligence and its application to research ethics committees and their members, common law and constitutional forms of action and potential negligence claims, the book concludes by suggesting new protocols and frameworks, improved regulation and litigation. This book will be a valuable guide for students, researchers, and policy-makers with an interest in medical law and ethics, bioethics, customary law in Africa and regulation in developing countries.

This book constitutes the refereed proceedings of the 9th International Conference on Games and Learning Alliance, GALA 2020, held in Laval, France, in December 2020. The 35 full papers and 10 short papers were carefully reviewed and selected from 77 submissions. The papers cover a broad spectrum of topics: Serious Game Design; Serious Game Analytics; Virtual and Mixed Reality Applications; Gamification Theory; Gamification Applications; Serious Games for Instruction; and Serious Game Applications and Studies.

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.

The need for quality improvement and for cost saving are driving both individual choices and health system dynamics. The health services research that we need to support informed choices depends on access to data, but at the same time, individual privacy and patient-health care provider confidentiality must be protected.

The EU's General Data Protection Regulation created the position of corporate Data Protection Officer (DPO), who is empowered to ensure the organization is compliant with all aspects of the new data protection regime. Organizations must now appoint and designate a DPO. The

specific definitions and building blocks of the data protection regime are enhanced by the new General Data Protection Regulation and therefore the DPO will be very active in passing the message and requirements of the new data protection regime throughout the organization. This book explains the roles and responsiblies of the DPO, as well as highlights the potential cost of getting data protection wrong.