



# New Challenges for Biobanks: Ethics, Law and Governance

Edited by Kris Dierckx and Pascal Barry



Interpretatio

# New Challenges For Biobanks Ethics Law And Governance

**Kris Dierickx**



## **New Challenges For Biobanks Ethics Law And Governance:**

New Challenges for Biobanks Kris Dierickx, 2009 The book is a collection of papers presented during an international conference held in Leuven May 18 20 2009 organized by the Centre for Biomedical Ethics and Law of the Catholic University of Leuven and the GeneBanC project      *Ethics, Law and Governance of Biobanking* Deborah Mascalcioni, 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      Comparative Issues in the Governance of Research Biobanks Giovanni Pascuzzi, Umberto Izzo, Matteo Macilotti, 2013-01-30 In the last few years the boom in biobanking has prompted a lively debate on a host of interrelated legal issues such as the Gordian knot of the ownership of biological materials as well as privacy concerns The latter are due to the difficulty of accepting that biological samples must be completely anonymous without making it practically impossible to exploit their information potential The issues also include the delicate role and the changing content of the donor's informed consent as the main legal tool that may serve to link the privacy and property interests of donors with the research interests and the set of principles that should be at the core of the biobanking practice Lastly the IP issues and the patentability of biological samples as well as the protection of databases storing genetic information obtained from the samples are covered Collecting eighteen essays written by eminent scholars from Italy the US the UK and Canada this book provides new solutions to these problems From a comparative viewpoint it explores the extent to which digital technology may assist in tackling the numerous regulatory issues raised by the practice of biobanking for research purposes These issues may be considered and analyzed under the traditional paradigms of Property Privacy Informed Consent and Intellectual Property      Governing Biobanks Jane

Kaye, Susan Gibbons, Catherine Heeney, Andrew Smart, 2012-02-03 Biobanks are proliferating rapidly worldwide because they are powerful tools and organisational structures for undertaking medical research By linking samples to data on the health of individuals it is anticipated that biobanks will be used to explore the relationship between genes environment and lifestyle for many diseases as well as the potential of individually tailored drug treatments based on genetic predisposition However they also raise considerable challenges for existing legal frameworks and research governance structures This book critically examines the current governance structures in place for biobanks in England and Wales It shows that the technologies techniques and practices involved in biobanking do not always conform neatly to existing legal principles and frameworks that apply to other areas of medical research Using a socio legal approach including interview data gathered from the scientific community this book provides unique insights and makes recommendations about appropriate governance mechanisms for biobanking in the future It also explores the issues around the secondary use of information such as consent and how to protect privacy when biobanks are accessed by a number of different third parties These issues have relevance both within England and Wales and to a wide international audience as well as for other areas where large datasets are used

Biobanks and Tissue Research Christian Lenk, Judit Sándor, Bert Gordijn, 2011-07-30 The research field of biobanks and tissue research is highly promising Many projects around the globe are involved in the collection of human tissue and health data for research purposes These initiatives are driven by the perspective of decisive breakthroughs in the knowledge of the genetic pathways involved in widespread diseases However there are considerable ethical and legal challenges to be considered as well These challenges encompass the use of body material for research purposes the misuse of genetic and other health data by third parties trust in science and medicine concerns regarding privacy use of genetic data for forensic applications by the state and the police and regulatory issues This volume is divided into three parts the inclusion of the public the rights of donors and patients examples and recommendations for the future of tissue research It presents a comprehensive overview of the most important topics in the field by renowned scholars in medical ethics and biolaw

*Public Regulation of Tumor Banks* Xavier Bioy, 2018-06-30 The multidisciplinary book assesses the legal and economic uncertainties surrounding the collection storage provision and economic development of biological samples tumors tissues cells and associated personal data related to oncology Public partly public and private sector actors in the field of cancer care and research hold collections supported by significant public and social funding Under certain conditions particularly in the context of networking sometimes promoted by public authorities these collections can also represent major economic assets and scientific resources However this involves a number of issues and institutional constraints legal the will of the source person non pecuniary damage freedom to establish collections competence in deciding on their use legal frameworks for their distribution desire for return on investment for public institutions notably in terms of industrial and intellectual property economic cost of establishing and running biological resource centres destroying resources emerging markets profit

sharing public health policy choices prioritisation of therapeutic measures over research fundamental or clinical trials conservation of resources promotion of scientific and not commercial value of collections The establishment heritage recognition patrimonialisation development and sharing of these resources thus merit our calling into question present practices and their evolution as well as the leverage available to public authorities incentives legislation regulation in a context where norms emerge from professional practice to become widely used in collaborative networks Filling a gap in the current literature on law and economics which pays little heed to these specific considerations this book explores these considerations to bring to light the economic implications of ethical choices and governance issues in the health sector structural organisation of local national and European actors in oncology It is intended for researchers in fields such as law economics and biomedical sciences as well as for public policymakers

*Global Genes, Local Concerns* Timo Minssen, Janne Rothmar Herrmann, Jens Schovsbo, 2019 With interdisciplinary chapters written by lawyers sociologists doctors and biobank practitioners *Global Genes Local Concerns* identifies and discusses the most pressing issues in contemporary biobanking Addressing pressing questions such as how do national biobanks best contribute to translational research and how could academic and industrial exploitation ownership and IPR issues be addressed and facilitated this book contributes to the continued development of international biobanking by highlighting and analysing the complexities in this important area of research

Anti-doping: Policy and Governance Barrie Houlihan, Mike McNamee, 2014-10-20 The book addresses a series of key aspects of contemporary anti doping policy At the broader philosophical level questions are asked about whether the scale of anti doping activity and the intrusiveness of anti doping policy in the lives of athletes is proportionate to the problem of doping Aspects of existing anti doping practice are also explored at the level of transnational organisations such as the EU and WADA and also at the level of the personal choices that need to be made by athletes and doctors in relation to doping control Other contributions examine the complex issue of assessing the extent of doping and also understanding the factors that motivate athletes to use performance enhancing drugs The analyses provided by academic contributors are complemented by three contributions from the World Anti Doping Agency UK Anti Doping and the International Tennis Federation which provide insights into the strategies designed to reduce the prevalence of doping in sport and the management of anti doping processes This book was published as a special issue of the International Journal of Sport Policy and Politics

**Innovation in Scientific Research and Emerging Technologies** Laura Palazzani, 2019-08-31 This book discusses the ethical and legal challenges related to innovations with reference to both scientific research and emerging technologies It analyzes scientific research with specific reference to experimentation with a focus on vulnerable people minors women people in developing countries compassionate care biobanks and ethical committees In the context of emerging technologies it examines the ethical and legal aspects of neuroscience genomics ICT big data biometrics converging technologies enhancement and robotics The book provides conceptual tools and categories to help readers

understand and acquire a critical awareness of the current debates in the field      **The Ethical and Legal Regulation of Human Tissue and Biobank Research in Europe** Katharina Beier,Nils Hoppe,Silvia Schnorrer,Christian Lenk,2011

Human tissue and biobank research is of increasing importance for understanding the causes of widespread diseases and developing effective therapies However while the success of biobank research depends on the availability of a large number of samples and the consolidation of collections across country borders is very desirable from the perspective of researchers the legal and ethical requirements for the procurement storage and use of human tissue samples are rather heterogeneous across different countries Moreover the lack of comprehensive supranational regulation on human tissue and biobanking can be seen as posing a serious threat to transnational biomedical research Against this background it was one of the aims of the EU funded Tiss EU project Evaluation of Legislation and Related Guidelines on the Procurement Storage and Transfer of Human Tissues and Cells in the European Union an Evidence Based Impact Analysis to analyse the ethical and legal regulation of human tissue and biobank research across the 27 European Member States plus Switzerland The results of nine international workshops and three conferences are gathered in this volume While the country reports evaluate the implementation of ethical and legal guidelines at a national level point out their strengths and deficits and where required create an evidence base for the revision of said legislation the conference reports address more general ethical and legal issues in this field The volume is completed by a final presentation of project s results Publisher s description      Bioethics

Marcus Düwell,2013 This book is a philosophically oriented introduction to bioethics It offers the reader an overview of key current debates in bioethics in the areas including organ retrieval stem cell research justice in healthcare and issues in environmental ethics including issues surrounding food and agriculture The book also seeks to go beyond describing the issues in order to provide the reader with the methodological and theoretical tools for a more comprehensive understanding of bioethical debates The book investigates the theoretical foundations and normative implications of bioethical debates and situates the areas of ethics into their philosophical context      *Explorations in Baltic Medical History, 1850-2015* Nils

Hansson,Jonatan Wistrand,2019 This book explores the history of medicine in the Baltic Sea region and provides different answers to one central question How has the circulation of knowledge in the Baltic Sea region influenced medicine as a discipline and illness as an experience during the nineteenth and twentieth centuries From synopsis      Governing

Intellectual Property Rights Within Publicly Funded Biobanks Rajam Neethu,2019-06-21 Governing Intellectual Property Rights Within Publicly Funded Biobanks R Neethu The boom in biobanks and health databases as research infrastructures have evoked various legal and ethical debates Since then numerous new developments have emerged such as digitalization big data research and artificial intelligence which has important implications for biobank based research and collaborations This new paradigm offers new legal challenges for commercial involvement particularly within a publicly funded setting In this innovative book the author shows that securing maximum social benefit out of the knowledge emanating from the use of

biobank resources lies in managing intellectual property inputs and outputs effectively in keeping with the values core to such research Focusing on the challenges of involving intellectual property rights IPRs particularly in the precompetitive phase of biobank based research the book offers an extensive understanding of the role of different IPRs and identifies the gaps in the law and its implications for biobanks The analysis covers important aspects in relation to biobanks such as Digital integration and biomedical data storage Ownership of biological samples Commercialization and benefit sharing Partnership models Public sector research Disposition of samples Consent Cross border exchange Trade secrecy Privacy Regulatory stewardship Business strategies Ethical considerations over biological resources Patenting of inventions relating to personalized medicine Ethical parameters within patent law and Rights regarding genetic data and databases The book includes observations case studies and interviews conducted by the author In conclusion the author offers cogent recommendations for legal interoperability of IP rules and research practices designed to enhance the ability of biobanks to share access and reuse data This book is the first of its kind to explore the organizational and legislative choices for biobanks particularly while engaging in the protection of research results and technology transfer within a publicly funded setting It will be of substantial interest to all stakeholders in biobanking especially policymakers biobankers and researchers working in the field of health law as well as for legal practitioners academics and patient interest groups

Law and Legacy in Medical Jurisprudence Edward S. Dove, Niamh Nic Shuibhne, 2022-03-10 Graeme Laurie stepped down from the Chair in Medical Jurisprudence at the University of Edinburgh in 2019 This edited collection pays tribute to his extraordinary contributions to the field Graeme often spoke about the importance of legacy in academic work and forged a remarkable intellectual legacy of his own notably through his work on genetic privacy human tissue and information governance and the regulatory salience of the concept of liminality The essays in this volume animate the concept of legacy to analyse the study and practice of medical jurisprudence In this light legacy reveals characteristics of both benefit and burden as both an encumbrance to and facilitator of the development of law policy and regulation The contributions reconcile the ideas of legacy and responsiveness and show that both dimensions are critical to achieve and sustain the health of medical jurisprudence itself as a dynamic interdisciplinary and policy engaged field of thinking

**Human Tissue Research** Christian Lenk, 2011-01-27 The use of human tissue for medical research and scientific progress raises many ethical and legal challenges This multi authored interdisciplinary text provides a fascinating insight into interlinking research perspectives and serves as a comprehensive reference to the state of play ethically and legally in Europe

Histories of State Surveillance in Europe and Beyond Kees Boersma, Rosamunde van Brakel, Chiara Fonio, Pieter Wagenaar, 2014-05-09 Does the development of new technology cause an increase in the level of surveillance used by central government Is the growth in surveillance merely a reaction to terrorism or a solution to crime control Are there more structural roots for the increase in surveillance This book attempts to find some answers to these questions by examining how governments have increased their

use of surveillance technology Focusing on a range of countries in Europe and beyond this book demonstrates how government penetration into private citizens lives was developing years before the war on terrorism It also aims to answer the question of whether central government actually has penetrated ever deeper into the lives of private citizens in various countries inside and outside of Europe and whether citizens are protected against it or have fought back The main focus of the volume is on how surveillance has shaped the relationship between the citizen and the State The contributors and editors of the volume look into the question of how central government came to intrude on citizens private lives from two perspectives identification card systems and surveillance in post authoritarian societies Their aim is to present the heterogeneity of the European historical surveillance past in the hope that this might shed light on current trends Essential reading for criminologists sociologists and political scientists alike this book provides some much needed historical context on a highly topical issue

**Bioeconomies** Vincenzo Pavone, Joanna Goven, 2017-09-18 This book explores the promissory discourses and practices associated with the bioeconomy focusing especially on the transformation of institutions the creation appropriation and distribution of value the struggle over resources power and meaning and the role of altruism kinship and care practices Governments and science enthusiasts worldwide are embracing the bioeconomy championing it as the key to health wealth and sustainability while citing it as justification to transform research and regulatory institutions health and agricultural practices ethics of privacy and ownership and conceptions of self and kin Drawing together studies from Asia Australia the Americas and Europe this volume encompasses subjects as diverse as regenerative medicine population health research agricultural finance biobanking assisted reproduction immigration breastfeeding self help groups GM fish and mining sewage

*Principles and Practice in Biobank Governance* Mark Stranger, 2016-04-15 Rapid technological advances the establishment of large scale biobanks and the exchange of data across international boundaries raise a variety of questions for regulators struggling with the problem of how to govern such stores of information and the processes connected with them Engaging with the pressing issues of privacy consent access to data and benefit sharing *Principles and Practice in Biobank Governance* draws together the latest empirical research from the UK Europe America Australia and Asia to focus on these challenges Current models of governance are critiqued principles and policies are debated and new models and theoretical frameworks are presented through this intellectually stimulating informative volume This truly international volume offers new insights from a range of disciplinary perspectives and will be essential reading for policy makers and scholars across a range of social sciences including sociology bioethics law and social policy

**Transparency, Power, and Influence in the Pharmaceutical Industry** Katherine Fierlbeck, Janice Graham, Matthew Herder, 2021-06-14 There is plenty of controversy surrounding pharmaceuticals but it cannot be denied that the pharmaceutical industry is both socially beneficial and profitable Regulators are expected to ensure that the economic success of the industry does not come at the expense of public safety yet they have also assumed a cooperative role by

providing advice on regulation and by targeting unmet medical needs Concerns over regulatory standards conflicts of interest and the manipulation of information on drug safety and effectiveness have led to public mistrust and a greater need for transparency between the pharmaceutical industry and government regulators Transparency Power and Influence in the Pharmaceutical Industry evaluates the progress made in holding the pharmaceutical industry responsible for creating transparency in the industry from development to market The contributors to this volume examine the various mechanisms introduced to make the regulatory process more informative and situate these efforts within the larger project of enhancing the safety of drugs vaccines and other products *Environmental Epigenomics in Health and Disease* Randy L.

Jirtle, Frederick L. Tyson, 2013-05-13 There are now compelling human epidemiological and animal experimental data that indicate the risk of developing adult onset complex diseases and neurological disorders are influenced by persistent epigenetic adaptations in response to prenatal and early postnatal exposures to environmental factors Epigenetics refers to heritable changes in gene function that occur without a change in the sequence of the DNA The main components of the epigenetic code are DNA methylation histone modifications and non coding RNAs The epigenetic programs are established as stem cell differentiate during embryogenesis and they are normally faithfully reproduced during mitosis Moreover they can also be maintained during meiosis resulting in epigenetic transgenerational disease inheritance and also potentially introducing phenotypic variation that is selected for in the evolution of new species The objective of this two volume book is to provide evidence that environmental exposures during early development can alter the risk of developing medical conditions such as asthma autism cancer cardiovascular disease diabetes obesity and schizophrenia later in life by modifying the epigenome Consequently epigenetic research promises to markedly improve our ability to diagnosis prevent and treat the pathological conditions of humans however it also introduces unique legal and ethical issues This volume highlights the correlation between environmental factors and complex diseases such as autism addiction neurological diseases diabetes obesity and cancer It concludes with a chapter on legal and ethical implications of epigenetics

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In a world defined by information and interconnectivity, the enchanting power of words has acquired unparalleled significance. Their power to kindle emotions, provoke contemplation, and ignite transformative change is truly awe-inspiring. Enter the realm of "**New Challenges For Biobanks Ethics Law And Governance**," a mesmerizing literary masterpiece penned by a distinguished author, guiding readers on a profound journey to unravel the secrets and potential hidden within every word. In this critique, we shall delve into the book's central themes, examine its distinctive writing style, and assess its profound affect on the souls of its readers.

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