

Herausgegeben von
Peter Axer, Gerhard Dannecker, Thomas Hillenkamp,
Lothar Kuhlen, Eibe H. Riedel, Jochen Taupitz (Geschäftsführender Direktor)

Peter Dabrock • Jochen Taupitz • Jens Ried
Editors

Trust in Biobanking

Dealing with Ethical, Legal and Social Issues
in an Emerging Field of Biotechnology

 Springer

Series Editors

Professor Dr. Peter Axer
Professor Dr. Gerhard Dannecker
Professor Dr. Dr. h.c. Thomas Hillenkamp
Professor Dr. Lothar Kuhlen
Professor Dr. Eibe Riedel
Professor Dr. Jochen Taupitz (Geschäftsführender Direktor)

Editors

Professor Dr. Peter Dabrock
Dr. Jens Ried
Friedrich-Alexander-University
Erlangen-Nuremberg
Chair for Systematic Theology / Ethics
Faculty of Philosophy
and Department of Theology
Kochstraße 6
91056 Erlangen
Germany
peter.dabrock@theologie.uni-erlangen.de
jens.ried@theologie.uni-erlangen.de

Professor Dr. Jochen Taupitz
University of Mannheim
Institute for Medical and Health Law
and Bioethics
Schloss, Westflügel
68131 Mannheim
Germany
taupitz@jura.uni-mannheim.de

Funded by the German Federal Ministry of Education and Research (grant 01GP0682)

ISSN 1617-1497

ISBN 978-3-540-78844-7

e-ISBN 978-3-540-78845-4

DOI 10.1007/978-3-540-78845-4

Springer Heidelberg Dordrecht London New York

Library of Congress Control Number: 2011940500

© Springer-Verlag Berlin Heidelberg 2012

This work is subject to copyright. All rights are reserved, whether the whole or part of the material is concerned, specifically the rights of translation, reprinting, reuse of illustrations, recitation, broadcasting, reproduction on microfilm or in any other way, and storage in data banks. Duplication of this publication or parts thereof is permitted only under the provisions of the German Copyright Law of September 9, 1965, in its current version, and permission for use must always be obtained from Springer. Violations are liable to prosecution under the German Copyright Law.

The use of general descriptive names, registered names, trademarks, etc. in this publication does not imply, even in the absence of a specific statement, that such names are exempt from the relevant protective laws and regulations and therefore free for general use.

Printed on acid-free paper

Springer is part of Springer Science+Business Media (www.springer.com)

Preface

Biobanks are promising instruments of biomedical research and are increasingly considered as essential tools for translational medicine in particular. However, there is concern that the collection of biomarkers in the course of biobanking endeavours could be misused, and thus infringe rights and almost universally accepted ethical standards. In response to these concerns, various sets of governing principles have been established in recent years or are currently discussed in order to protect individuals, families, communities and societies against involuntary use of their data, stigmatisation, discrimination or exclusion that might be caused by data misuse. All efforts addressing these concerns have been grounded on well-established standards of biomedical ethics such as informed consent procedures, protection of individual autonomy, benefit sharing etc. Nevertheless, there are issues that are underrepresented in the ethical, legal and social (ELSI) debates on the challenges posed by biobanks and biobank networks. By highlighting the often neglected aspect of *trust*, this book aims at broadening the horizon of the ELSI-debate and thus filling a gap in current ELSI-research on biobanking.

Apart from being a core issue in the field of ELSI-questions concerning the challenges of biobank research, trust is to be regarded as a focal point for any project relying on biobank infrastructures. Depending on the willingness of potential donors to provide their biospecimen (and additional information) is one of the distinctive features of (at least most non-clinical) biobanks. Therefore, trust in biobanking in general as well as in particular, i.e. in relation to a biobank one considers to contribute to, can assumed to be essential for success and effectiveness of biobank research. Following this basic insight the contributions to this book aim at elucidating meaning, prerequisites and implications of *trust in biobanking*.

This volume contains papers which were presented during two international meetings, held at the Department of Protestant Theology, Philipps-University Marburg, Germany in 2007 and 2008, focussing on ELSI-questions arising in the field of biobank research. Junior researchers from Europe and Canada, representing a broad spectrum of disciplines including ethics, law, philosophy, medicine, social and political sciences and theology, were discussed a variety of issues related to the field of biobanking with international experts. Due to technical reasons, no scientific literature published after 2009 could be incorporated. Nevertheless, we recommend for further reading the opinion “Human biobanks for research” released by the German Ethics Council in 2010 and the Public Health Genomics Special Issue “Privacy, Data Protection, and Responsible Governance. Key Issues and Challenges for Biobanking”, edited by Peter Dabrock in 2012.

The first section, *Framing the Field of Biobanking and Trust*, contains basic considerations and, thus, serves as introductory part to the topics this book deals with. In their article “Biobanking: From Epidemiological Research to Population-based Surveillance Systems and Public Health“, A. BRAND, T. SCHULTE IN DEN

BÄUMEN and N. PROBST-HENSCH point out how relevant and promising biobank research has proven (or will be proven) to be, not only for medicine (in a more narrow sense), but especially for public health and preventive medicine.

After this introduction to the field from a public health perspective, the following two papers deal with the issue of *trust* from the ELSI-perspective. In “Trust as Basis for Responsibility”, C. RICHTER presents a thorough theological and philosophical analysis of *trust*, highlighting social and implications and ethical consequences. K. HOEYER investigates, why measures of trust-building are not only indispensable for any biobank endeavour, but are prerequisites for the effective employment of such a scientific infrastructure. As he argues in “Trading in Cold Blood? Donor Trust in Face of Commercialized Biobank Infrastructures”, the fear of commercialization as one of the often mentioned skeptical arguments – especially when private or non-public funded biobanks are discussed – is by far appropriate in any case. Nevertheless, it should not be ignored but seen as a marker pointing to the neglected issue of trust in biobanking.

In the following three sections the ethical, legal and social implications of globalized biobanking are unfolded with special regard to the issue of trust as a necessary prerequisite for successful and effective usage of biobank (infrastructures). The section on *Ethical Issues* is headed by the paper “Which Duty First? An Ethical Scheme on the Conflict between Respect for Autonomy and Common Welfare in Order to Prepare the Moral Grounds for Trust”. P. DABROCK goes further into the question, whether or not an obligation to participate in biobank research is defensible and to which extent such an obligation might influence trust-building. C. LENK addresses, based on considerations concerning different interests, the potential role of the traditional principle of justice and fairness for an ethical account of biobank research. His reflections are presented in “Donors and Users of Human Tissue for Research Purposes: Conflict of Interests and Balancing of Interests”. The third and closing article of this section is “Collection of Biospecimen Resources for Cancer Research: Ethical Framework and Acceptance from the Patients’ Point of View”. By assessing an empirical study on demands patients expressed regarding information on and assent to cancer-related biobank research, J. HUBER ET AL. develop a model for specific and need-orientated informed consent procedures.

The third section on *Legal Issues* captures the thread of informed consent which is the core theme of the following papers. Despite the fact that a considerable amount of literature has been published on problematic aspects of informed consent, it is the

S. WALLACE, S. LAZOR and B.M. KNOPPERS provide an overview on existing information and consent materials used by different biobanks, thus introducing the reader to the legal issues of this branch of research. In addition to “What is in a Clause? A Comparison of Clauses from Population Biobank and Disease Biobank Consent Materials”, M. SALVATERRA, in “Informed Consent to Collect, Store and Use Human Biological Materials for Research Purposes”, suggests a model for a standardized informed consent procedure that regards the needs of potential donors as well as of researchers. The two following articles “Once Given – Forever in a Biobank? Legal Considerations on the Handling of Human Body Materials in Biobanks from a Swiss Perspective” by B. DÖRR and “Biobanks and the Law –

Thoughts on the Protection of Self-Determination with Regards to France and Germany“ by K. NITSCHMANN compare and discuss different models of legal regulations in the field of biobanking. As data protection is of special interest for any legal approach to biomedical research in general and biobanking in particular, D. SCHNEIDER elucidates this topic in his paper “Data Protection in Germany: Historical Overview, its Legal Interest and the Brisance of Biobanking”.

Finally, S. WALLACE and B.M. KNOPPERS close this section. “The Role of P3G in Encouraging Public Trust in Biobanks” deals with the question, how ethical standards become relevant not only for the communication between science and the general public, but for trust-building, especially when large networks of biobanks are considered.

The last section on *Social Issues* is headed by H. GOTTWEIS’ considerations on “Governing Biobank Research”, focusing on the political and public challenges posed by emerging networks of biobanks. In “Sharing Orphan Genes: Governing a European-Biobank-Network for the Rare Disease Community”, G. LAUSS presents a case-study on the EuroBioBank, investigating how interests of patients might influence research protocols and the development of research infrastructures. Collection, storage and usage of human biological samples is not limited to the western world, but conducted in countries outside Europe and North America. In other cultural contexts, special ethical, legal and social problems might arise, which are not covered by European or US-American standards. The arising challenges concerning this matter are discussed by P. KUMAR PATRA AND M. SLEEBOOM-FAULKNER in their paper “Informed Consent and Benefit Sharing in Genetic Research and Biobanking in India: Some Common Impediments in Practice”. Finally, A. GANGULI-MITRA, in “Benefit-sharing, Human Genetic Biobanks and Vulnerable Populations”, connects the question on vulnerability as a possible main category for the ELSI-discourse in biobanking with the issue of benefit-sharing, stressing the (often neglected) risk that certain forms of benefit-sharing might intensify existing economic, political, social and cultural inequalities between vulnerable and less vulnerable (parts of the) populations.

The two scientific meetings, taking place in an atmosphere of intense and fruitful discussions, as well as this present book could not have been realized without the help from the whole staff of the Department of Social Ethics at the Faculty of Theology, Philipps-University Marburg, namely Dietmar Becker, Ruth Denkhaus, Elisabeth Krause-Vilmar, Jörg Niesner, Katharina Opalka and Lina Reinartz.

Our special thanks go to Carol George and Dorothee Schönau for her efforts in preparing this publication, again to Jörg Niesner, Katharina Opalka and Lina Reinartz for proof-reading and their considerable help in editing the articles. Last but not least, we owe special thanks to the German Federal Ministry of Education and Research, which funded the two conferences and the publication of this volume (grant 01GP0682). Thankfully, the *Springer Verlag* supported this publication with patience and perseverance.

Erlangen / Marburg / Mannheim 2010

*Peter Dabrock
Jochen Taupitz
Jens Ried*

Table of Contents

Preface	V
Authors and Editors.....	XI
Framing the Field of Biobanking and Trust	
<i>Angela Brand, Tobias Schulte in den Bäumen, Nicole M. Probst-Hensch</i> Biobanking for Public Health	3
<i>Klaus Hoeyer</i> Trading in Cold Blood? Trustworthiness in Face of Commercialized Biobank Infrastructures	21
<i>Cornelia Richter</i> Biobanking. Trust as Basis for Responsibility	43
Ethical Issues	
<i>Peter Dabrock</i> Which Duty First? An Ethical Scheme on the Conflict Between Respect for Autonomy and Common Welfare in Order to Prepare the Moral Grounds for Trust	69
<i>Christian Lenk</i> Donors and Users of Human Tissue for Research Purposes. Conflict of Interests and Balancing of Interests	83
<i>Johannes Huber, Esther Herpel, Frank Autschbach, Stephan Buse, Markus Hohenfellner</i> Collection of Biospecimen Resources for Cancer Research. Ethical Framework and Acceptance from the Patients' Point of View	97
Legal Issues	
<i>Susan Wallace, Stephanie Lazor, Bartha Maria Knoppers</i> What is in a Clause? A Comparison of Clauses from Population Biobank and Disease Biobank Consent Materials	113

<i>Mariaelena Salvaterra</i> Informed Consent to Collect, Store and Use Human Biological Materials for Research Purposes. An International Framework	127
<i>Bianka Sofie Dörr</i> Once Given – Forever in a Biobank? Legal Considerations Concerning the Protection of Donors and the Handling of Human Body Materials in Biobanks from a Swiss Perspective	139
<i>Kathrin Nitschmann</i> Biobanks and the Law. Thoughts on the Protection of Self-Determination with Regards to France and Germany	153
<i>Daniel Schneider</i> Data Protection in Germany. Historical Overview, its Legal Interest and the Brisance of Biobanking	169
<i>Susan Wallace, Bartha Maria Knoppers</i> The Role of P3G in Encouraging Public Trust in Biobanks	189
Social Issues	
<i>Herbert Gottweis</i> Biobanks: Success or Failure? Towards a Comparative Model	199
<i>Georg Lauss</i> Sharing Orphan Genes. Governing a European-Biobank-Network for the Rare Disease Community	219
<i>Prasanna Kumar Patra, Margaret Sleeboom-Faulkner</i> Informed Consent and Benefit Sharing in Genetic Research and Biobanking in India. Some Common Impediments in Practice	237
<i>Agomoni Ganguli-Mitra</i> Benefit-sharing, Biobanks and Vulnerable Populations	257

Authors and Editors

Frank Autschbach, MD is Professor of Medicine at Ruprecht-Karls-University Heidelberg (Germany)

Angela Brand, MD, PhD is Professor of Social Medicine and Director of the European Centre for Public Health Genomics at the University of Maastricht (The Netherlands)

Stephan Buse, MD is researcher at the Department of Urology at Ruprecht-Karls-University Heidelberg (Germany)

Peter Dabrock, PhD is Professor of Systematic Theology and Ethics at Friedrich-Alexander-University Erlangen-Nuremberg (Germany)

Bianca Dörr, PhD is Assistant Professor of Law at University of Zurich (Switzerland)

Agomoni Ganguli-Mitra, MSc is Research Fellow at the Institute of Biomedical Ethics at the University of Zurich (Switzerland)

Herbert Gottweis, PhD, is Professor of Political Sciences and member of the Life Science Governance Research Platform at the University of Vienna (Austria)

Esther Herpel, MD is Leader of the Tissue Bank of the National Centre for Tumor Diseases, Heidelberg (Germany)

Klaus Hoeyer, PhD is Associate Professor of Public Health at the University of Copenhagen (Denmark)

Markus Hohenfellner, MD is Professor of Medicine at Ruprecht-Karls-University Heidelberg and Director of the University Hospital for Urology, Heidelberg (Germany)

Johannes Huber, MD, PhD is physician at the University Hospital for Urology, Heidelberg (Germany)

Bartha Maria Knoppers, PhD is Professor of Law and Director of the Centre of Genomics and Policy at McGill University Montreal (Canada)

Georg Lauss, M.A. is researcher at the Department of Political Sciences and member of the Life Science Governance Research Platform at the University of Vienna (Austria)

Stephanie Lazor is Research Assistant at the Centre of Genomics and Policy at McGill University Montreal (Canada)

Christian Lenk, PhD is Assistant Professor of Medical Ethics at Georg-August-University Göttingen (Germany)

Kathrin Nitschmann, PhD is lawyer with specialisation in biomedical law and comparative law

Prasanna Kumar Patra, PhD is Research Fellow at the Department of Anthropology at the University of Sussex (UK)

Nicole Probst-Hensch, PhD is Leader of the Molecular Epidemiology Group at the Centre for Clinical Research at the University of Zurich (Switzerland)

Cornelia Richter, PhD is Assistant Professor of Systematic Theology at Philipps-University Marburg (Germany)

Jens Ried, PhD is Assistant Professor of Systematic Theology and Ethics at Friedrich-Alexander-University Erlangen-Nuremberg (Germany)

Daniel Schneider is lawyer with specialization in health and food law

Tobias Schulte in den Bäumen is Assistant Professor of Law at the University of Maastricht (The Netherlands)

Margaret Sleeboom-Faulkner, PhD is Lecturer at the Department of Anthropology at the University of Sussex (UK)

Jochen Taupitz, PhD is Professor of Law and Director of the Institute for Medical and Health Law and Bioethics at the University of Mannheim (Germany)

Susan Wallace, PhD is Assistant Professor of Law and Head of the Policymaking Core of the International Working Group on Ethics, Governance and Public Participation of the P3G Consortium at McGill University Montreal (Canada)