

## Trust in Biobanking

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

Bearbeitet von  
Peter Dabrock, Jochen Taupitz, Jens Ried

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# 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 and 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.

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 defendable 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 Brisanse 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 Denkhäus, Elisabeth Krause-Vilmar, Jörg Niesner, Katharina Opalka and Lina Reinartz.

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Peter Dabrock  
Jochen Taupitz  
Jens Ried