

Introduction

MUCH ADO ABOUT SOMETHING: LEGAL, ETHICAL, AND SCIENTIFIC CHALLENGES IN INTERNATIONAL BIOBANKING AND TRANSLATIONAL EXPLOITATION

The significance of large-scale, interoperable biobanks as knowledge institutions and research infrastructures in today's life science research can hardly be overestimated. Biobanks allow researchers with different scientific expertise to analyse large and diverse collections of human biological material (HBM), as well as genetic, clinical, health, and other personal data of donors.

Hence, it is no surprise that multiple types of biobanks are being established around the globe with very different financial, organizational, and legal setups. These include biobanks of various sizes that may be disease-centric, population-based, genetic or DNA/RNA, project-driven, tissue type, multiple specimen type, commercial, or virtual biobanks.¹ While their aims and ambitions may vary considerably, many are created to operate for several decennia and with the aim to provide a valuable resource and infrastructure that can be accessed by numerous research projects and by a great variety of stakeholders with different objectives. These may include private companies, university researchers, research foundations, governmental bodies, or "hybrid" consortia in the framework of private–public partnerships (PPPs).

The increasing significance and complexity of biobanking requires substantial investments in the creation, organization, and maintenance of collections of HBM and the "big data" stored in biobanks. This highlights the importance of effective governance and use of biobanks and raises the question of how to deal with a great variety of scientific, ethical, and legal challenges.

This book encompasses a broad range of chapters written by experts that address and discuss some of these challenges from an interdisciplinary perspective. These chapters have been prepared as part of the research project *Global*

¹ De Souza, Y. G., & Greenspan, J. S. (2013). Biobanking Past, Present and Future: Responsibilities and Benefits. *AIDS* (London, England), 27(3), 303–312. <http://doi.org/10.1097/QAD.0b013e32835c1244>.

Genes, Local Concerns.² Reflecting the goals of the crossfaculty research project, the project dealt with the legal, ethical, and scientific challenges in cross-national biobanking and translational exploitation. In the present book, leading international researchers discuss pressing questions, such as: How do national biobanks best contribute to translational research? What are the opportunities and challenges that current regulations present for translational use of biobanks? How does inter-biobank coordination and collaboration occur on various levels? How could academic and industrial exploitation, ownership and IPR issues be addressed and facilitated?

Special emphasis was placed on legal and ethical challenges and opportunities in addressing regulatory barriers to biobank research and the translation of research results, while at the same time securing the ethical legitimacy of the research and the societal interests in access to information and innovation.

A recurrent theme in the project which is also reflected in the chapters has been the issue of safeguarding autonomous decisionmaking. This is a classical issue in health law and medical ethics that has been revitalized in the setting of international biobanking, where samples are collected and shared across borders and therefore across different ethical and legal regimes. The legal frameworks that apply to biobanks are fragmented, vary from country to country and change over time. They are only in some countries specific to biobanks, and in most countries regulate data protection, privacy or human research generally. Yet autonomous decisionmaking is a cornerstone in most if not all Western legal systems. Equally, consent—be it blanket, broad, or informed—is of central ethical importance in the context of medical research, including biobank research. Accordingly, much attention was given to developing appropriate consent and patient involvement models that adequately protect the interests of biobank donors.

But legal, ethical, and scientific challenges also arise from rapid technological developments, in which area more and more novel uses are emerging. The complexity of these challenges is increased by the growing need to secure funding for research and for the maintenance and collection of samples at high quality facilities. Hence, additional issues have to be dealt with, ranging from obligations regarding how to properly share data and issues of ethics to commercial, legal and trust-related issues in translational medicine, and tech transfer. This also involves the discussion of principles for biobank guidelines, intellectual property policies, (open) collaboration, and governance. To prop-

² For further information see <http://globalgenes.ku.dk>. The project was funded by the UCPH Excellence Programme for Interdisciplinary Research, Principal Investigator: Timo Minssen; see <http://research.ku.dk/strengths/excellence-programmes> (both accessed 15 February 2019).

erly address this broad range of issues, the collection of contributions that were compiled for this volume have been organized into four parts and 14 chapters.

Part I of this book is devoted to issues revolving around biobanks, Big Data, and modes of collaboration.

In Chapter 1, *Klaus Hoeyer, Aaro Tupasela, and Malene Bøgehus Rasmussen* point out that cross-national collaboration in medical research has gained increased policy attention. In particular, the authors explain how various policies are developed to enhance data sharing, ensure open access, and harmonize international standards and ethics rules in order to promote access to increase scientific output and facilitate more data-intensive research, including with what is sometimes referred to as Big Data. In tandem with this promotion of data sharing, numerous ethics policies are developed to control data flows and protect privacy and confidentiality. According to the authors, both sets of policymaking however pay limited attention to the moral decisions and social ties enacted in the everyday routines of scientific work. Using the example of practices of a Danish laboratory with great experience in international collaboration regarding genetic research, the authors focus on “ethics work” and argue that it is crucial for data sharing, though it is rarely articulated in ethics policies and remains inadequately funded.

In Chapter 2, *Michael Madison* takes a more general perspective. He considers biobanks as a case of knowledge commons, or collaborative institutions designed for the preservation and generation of knowledge. He explains how analyses of knowledge commons often focus on legal and contractual dimensions of openness and access to shared commons resources. It is important, however, to put those analyses in a broader context. Given the number and diversity of biobank institutions worldwide, and the critical role sometimes played by public policy and state support in ensuring their continued existence and service, it is pointed out in this chapter that it is important for researchers to consider, empirically and in a systematic manner, all relevant aspects of biobank governance, including their shared sources of strength and weakness and particular sources of opportunity and concern.

Part II of this book focuses on biobanks, translational medicine, and tech transfer.

In Chapter 3, *Nicholson Price* explains and discusses the importance and relevance of the Big Data dimension of biobanking for the promotion of translational medicine. The chapter is divided into two parts. The first briefly describes the sources of medical data, the promises of medical big data, and the key challenge of data fragmentation. The second discusses the role of biobanks in medical big data, focusing on their role in infrastructure for innovation and their potential for facilitating translational research. The author argues that viewing biobank-related data as infrastructure would place them at a distinctly earlier point in the commercialization pipeline, serving more to facilitate later

steps in translational medicine rather than being viewed as potentially commercializable products themselves.

In Chapter 4, *Brian J. Clark* and *Tina Bossow* explain and discuss the need of the bioscience industries to gain access to biosamples in order to boost their research and development (R&D) capabilities and hence to enhance the chances of translational innovation. But the authors also highlight that it is important that both sourcing and use are responsible and well governed. In their view, a pivotal question for access is whether the bioscience industries can demonstrate that they use human biological samples (HBS) and data in ways that are socially responsible, ethical, compliant with applicable laws or regulations, and safe. Moreover, the authors stress that this same question should equally apply to any user of HBS, whether a for-profit industrial user or a nonprofit or public institutional user.

This leads us to Part III, which addresses central issues relating to the interface of biobanks, human rights, and patient involvement.

In Chapter 5, *Peter Yu* starts by providing a brief survey of three distinct sets of human rights issues that are all related to biobanks. The first set concerns the human rights involved in the collection, processing, use, or storage of the biological materials collected by biobanks. The second set pertains to the human rights issues implicated by the development of scientific productions utilizing the collected materials. The third set relates to the human rights obligations of three types of biobanks: public biobanks, private biobanks, and biobanks formed out of public–private partnerships (PPPs). The author stresses that the goal of this chapter is not to provide detailed analyses of these three sets of human rights issues; instead, the chapter aims to offer preliminary sketches of the various human rights issues that can be implicated by biobanks.

Åsa Hellstadius and *Jens Schovsbo* argue in Chapter 6 that patent law should be understood in light of health law and human rights, thus highlighting free and informed consent as a vital issue that falls under the morality exclusion enshrined in European patent law. The authors argue that consequently compliance with requirements of free and informed consent should be monitored *ex officio* by patent authorities, and could in rare circumstances lead to nonpatentability. In their view, there is no doubt that this avenue, where protection of donor rights is tied directly to the commercial potential, would give added gravitas to free, informed consent.

In Chapter 7, *Jane Kaye* and *Megan Pricor* demonstrate how a technological platform can support individual decisionmaking in making consent dynamic. It allows for the ongoing engagement of donors in a way that reflects their personal preferences. In the context of biobanking, the authors explain how a Dynamic Consent tool may enable potential participants to give broad consent or to specify in advance that their permission must be sought for each new use of their samples or data. They can revisit and change these specifi-

cations over time, including withdrawing their consent and being assured that this has taken effect.

In Chapter 8, *Esther Van Zimmeren* explores whether “Dynamic Consent” could be an effective tool to increase transparency and trust in general, and more specifically regarding commercialization issues. She starts with a short description of the trust literature and tailors some important concepts from that literature to the discussion on biobanks before delving in more detail into the literature on biobanks and trust and the potential role of Dynamic Consent for generating trust. The author acknowledges the link between interpersonal and organizational trust, which seems to be quite critical within the context of biobanks. Moreover, she highlights the intricate dynamics and potential roles of particular persons and third parties in influencing the level of organizational trust in biobanks when they use Dynamic Consent interfaces.

Next, *Nana Kongsholm* argues in Chapter 9 that efforts to harmonize informed consent requirements in international biobanking risk overlooking local factors that may compromise free and informed consent, particularly when research is conducted in developing countries. Drawing on findings from an interview study with donors in rural Pakistan, the author demonstrates how psychological, cultural, and structural factors in this particular context may pose serious ethical challenges that are far from adequately accommodated by (and may in fact thrive under) any standard consent scheme. She argues that vulnerabilities to exploitation in research are highly dependent on social conventions. Hence, customs and harmonization efforts should be supplemented with appropriate efforts to highlight and accommodate such vulnerabilities.

Chapter 10, by *Tim Caulfield* and *Blake Murdoch*, also points to the fact that there are numerous social forces and cultural trends that may be intensifying unresolved consent issues, while acknowledging the practical needs that drove the adoption of the modified consent strategies. They argue that researchers, participants, and institutions would all benefit from a defensible, sustainable, and conceptually coherent consent policy. Given the rise in privacy concerns, the increased interest in rights of control, the rapid pace of technological development, and the lack of consensus on preferred consent type, the authors urge policymakers and politicians to clear up the confusion.

Finally, Part IV of the book is devoted to biobanks, guidelines, and good governance.

In Chapter 11, *Helen Yu* points out how one of the core objectives of responsible research and innovation (RRI) is to maximize the value of publicly funded research so that it may be returned to benefit society. In the case of biobanking, however, the personal nature of human biological materials and potential altruistic intentions of participants to donate samples intensifies the need to adhere to RRI principles with respect to the research, development, and commercialization of innovations derived from biobanks. To bridge the

seemingly contradictory and competing objectives of open science and commercialization, the author proposes a holistic innovation framework directed at improving RRI practice to obtain the optimal social and economic values from research.

Next, *Franziska Vogl* and *Karine Sargsyan* explain in Chapter 12 how access to long-term funding for biobanks is still an issue and strategies to recover biobanking costs are emerging. The usage of all collected samples, or use of the well-functioning and expensive infrastructure only for one project collection, is unusual. Instead, a considerable number of biobanks are opting for diversity and running additional population-based collections almost without any time limitations for retrospective and epidemiological studies. That means that research usage of biospecimens is unspecified in terms of time and matter. This, however, is often untenable and the authors point out that those involved in biobanks need to ask themselves how much it will cost to terminate themselves, should it become necessary.

In Chapter 13, *Eva Ortega-Paino* and *Aaro Tupasela* refer to the BBMRI-ERIC's experiences and structures to ask in what ways biobank networks can facilitate sharing, not only of samples but also of information for improving and tackling diseases. The authors further stress that biobank networks give rise to new governance structures in which new ethical and legal (soft law) norms are established and exercised. These norms have considerable implications in relation to how we perceive the acceptability of new practices regarding the collection, distribution, and use of biobanking samples. The authors finally point out how biobanks and biobank networks play a crucial role in maintaining the social and technical norms that allow for tissue economies to emerge and function.

Finally, Chapter 14, authored by *Kathleen Liddell*, *Johnathan Liddicoat*, and *Matthew Jordan*, brings “the issue of IP policies for large bioresources out of the long shadows of rhetoric about openness.” In doing the so, the authors highlight two fictions: *first*, that the idea of openness is clearly defined; *second*, that organizations are committed to openness. At the same time the chapter emphasizes that the “harmonization of bioresources’ access policies” is a feasible and desirable goal. The authors conclude by outlining future research to improve openness and IP policies for large bioresources.

Having reached the end of the *Global Genes, Local Concerns* project, it is our hope that our publications and the chapters we compiled for this volume contribute to the continued development of international biobanking by highlighting and analyzing the complexities in this important area of research. We also hope that this volume and the challenges that it highlights help to raise greater interest and attention from the medical community biobank operators and funders, policymakers, regulators, commentators, and the mass media.

The complexity of the issues touched upon indicates that many questions remain unsolved. Hence, we are very grateful for all the great presentations and inspiring interactive panel debates seen during the project, which provided more than enough fodder for future research projects. The constructive comments and questions we received from the multistakeholder participants in the project also demonstrated how important further research is in this area.

This again reminds us of the fact that biobanks are providing an increasingly important research infrastructure not only for biomedical researchers that are working *with* them, but also for the social, economic, and legal scientists conducting research *on and about* biobanks. It remains a vital task for we scientists to help clear up the sometimes opaque and elusive legal and economic challenges of international biobanking, in order to provide the basis for better access to high-quality research material and better use and sharing of these essential resources.

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