The Ethics of Research Biobanking
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Preface

This study is the result of an interdisciplinary research collaboration and co-production between scholars from eight different countries (Denmark, Iceland, France, Norway, Portugal, Sweden, the UK and USA). This collaboration, which has lasted since 2004, has been made possible through generous funding from the Norwegian Research Council and the Norwegian Institute of Public Health. Besides, several of the contributors have received additional forms of funding and support from other agencies, institutions and individuals. All these are duly acknowledged in the relevant chapters.

The aim of this study has been to investigate some of the ethical, legal and social challenges raised by research biobanking in its different modern forms and formats. The ambition has been to communicate the results of this endeavour in such a form that it may reach relevant academic and professional audiences (e.g. biobank curators, biobank researchers, ethicists, gene-epidemiologists, health law experts, philosophers, social scientists and advanced and graduate students in the relevant disciplines) as well as health and research regulators, ministries, politicians and the general public.

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Introduction

Jan Helge Solbakk, Søren Holm, and Bjørn Hofmann

Why is it that we talk about collections of biological materials or samples as “biobanks”? What is the rationale behind using the word bank to name these institutions? And to what extent is it justifiable to frame these institutions within a vocabulary of hard currency, i.e., of economical values? These were some of the queries that started off this project. The etymology behind the word “bank” may give us some initial clues to address these questions: The word originates from the ancient Greek word trapeza, which, literally speaking, means a “four-footed table,” from tra (akin to tettares four) + peza foot. In modern Greek, this is still the word used for bank. Similarly, the Italian word “banco” or “banca” and the French word “banque” refer to the money-changers and lender’s exchange table or counter. In Renaissance Italy, these were benches and/or counters located in public places, from which the money-changers and lenders used to operate and on which they would display their material in terms of different currencies (Rochet 2002, Liddell et al. 1940).

We will probably never get to know exactly why the analogy of table came into use in relation to the activity of money-changers and lenders. What made this analogy attractive may, however, be somewhat easier to grasp. Our suggestion is that it functioned as a simple analogy to characterize the dynamics of change and exchange – over a table – that took place between different stakeholders, i.e., the money-changers and lenders and their different customers.

We believe that this suggestion may also be of help in explaining why the analogy of bank has come into such abundant use in relation to collections of biological material or samples. It captures in a succinct way the ethical core activities of these institutions, i.e., the different activities of exchange and change that take place between donors of biological samples and guardians or curators of such samples (Editorial 2007) as well as between bio-guardians/curators and users of biological samples, i.e., health professionals and researchers. Because of the last decades’ advances within genetic and gene-epidemiological as well as genomic research, stem cell research and regenerative medicine, the amount of such activities of exchange and change have increased enormously. Besides, a whole range of
new forms of exchange and change of biological samples have seen the day, while at the same time old collections of diagnostic samples stored for decades in dusty hospital cellars have gained new life and attention due to the interest from different research communities, in particular genetics, gene-epidemiology and genomics research communities. At the same time in many countries, new and huge – public as well as private – collections of biological samples and health information have been – or are in the process of being – established to advance and encourage further research within these areas. Such forms of research may not only be important to develop new diagnostic tests and tools for gene-related diseases or unveil the possible causes and origins of gene-related forms of disease in a sample population; allegedly such forms of research may also give rise to better and more efficient methods of treatment, including drugs aimed at prevention as well as therapy. Interesting to observe is also that stakeholders outside the research communities, i.e., private and public investors, have become heavily involved in this enterprise. The reason for this is evident: the great expectations raised by the economic potential of research biobanking and biobank research. This observation gives perhaps some further insight into the question why the bank analogy has gained so much conceptual and persuasive power and space within this field of research and development.

All these different activities and initiatives in relation to setting up new research biobanks, converting dusty collections of pathological samples into biobanks for research, developing new research programs and investing into the set up of such enterprises and programs have also generated a lot of attention and interest among ethicists, policymakers, and health law experts, in particular in relation to questions about the best and safest way of regulating such enterprises and activities. This book is the result of a research collaboration between ethicists, health law experts, social scientists, and gene-epidemiologists from eight different countries (Denmark, Iceland, France, Norway, Portugal, Sweden, UK, and USA). The aim of this collaboration has been to investigate some of the ethical, legal, and social challenges raised by research biobanking in its different modern forms and formats.

The ethical, legal, and social issues raised by research biobanking can be divided into four main clusters of issues:

- Issues concerning how biological materials are entered into the bank
- Issues concerning research biobanks as institutions
- Issues concerning under what conditions researchers can access materials in the bank, problems concerning ownership of biological materials and of intellectual property arising from such materials
- Issues related to the information collected and stored, e.g., access-rights, disclosure, confidentiality, data security, and data protection

The first cluster of issues has been much discussed. Relevant problems are, for instance what kind of consent should be given by persons who give material to a research biobank, under what conditions can material in diagnostic or therapeutic biobanks be “converted” into research materials, and under what conditions can materials obtained without consent or against the will of the “donor” be “converted” into research materials? Other problems in this cluster of issues concern exactly
what rights the donor gives to the bank and what rights the donor retains, questions about incentives for giving to, grounds for withdrawal from the bank as well as renewed consent from children with stored tissues when they reach the age of legal maturity.

The second cluster of issues is concerned with the biobank as an institution. What kind of institution is it? Under what conditions can it be sold, merged with other biobanks, exported, divided, or destroyed? These issues are much less discussed in the literature, but may be of importance for the two other clusters of issues (is the distinction between public and private biobanks for instance important when regulating consent procedures?)

The third cluster of issues raises questions concerning research ethics governance of the use of stored biological materials as well as questions concerning how a biobank should set priorities among a number of competing research projects. This cluster is also concerned with ownership and intellectual property issues, including various modes and levels of profit sharing, if any. Thereby it also touches upon the basic question what biological material is.

The fourth cluster of issues concerns the long-term relations between researchers and users of the biobanks on one side and the sampled population on the other. It includes access to results on individual or global level, ways of dissemination of information about biobank use and data protection and confidentiality issues. There is a considerable interplay between the ethical and legal issues in each of the described clusters. If, for instance, relatively liberal rules are implemented concerning the entry of materials into biobanks, stricter rules concerning the use of these materials are likely to be needed and vice versa.

The book is organized in two separate parts. The first part represents an attempt to gain new knowledge about the different regulative issues implicated in the establishment of biobanks for research, conversion of old collections of pathological samples or more recent collections of therapeutic samples (blood, bone marrow, umbilical cord blood, sperm, oocytes, fertilized eggs, embryos, aborted fetuses, etc.) into such enterprises, and the development and conduct of research based on samples and health information stored in such banks. In this part of the book, we undertake an investigation along traditional pathways, i.e., we pursue the different regulatory options possible to envisage within a normative terrain dictated by different conceptions and interpretations of the informed consent doctrine.

As already alluded to, the traditional approach to the ethical and legal issues raised by research biobanking has been to extend the informed consent and other research ethics procedures that are already in place and to supplement them by measures directly transferred from the area of data protection. Informed consent was originally developed in the context of the doctor–patient relationship, and later extended to the researcher–research participant relationship but still mainly in the clinical setting. In this setting, it is normally possible to inform the potential research participant about the exact nature and purpose of the research project in considerable detail. However, in the context of research biobanking, this level of specification is hardly achievable, because the research performed on banked materials is, by nature, open ended. We cannot know how the materials stored today will be used
in 20 years’ time, because we have no idea what will be possible in 20 years’ time. Furthermore, it is practically impossible to obtain actual informed consent for each new use of the stored materials. This problem of specification might be an indication that current consent procedures are insufficient to provide the donors of biomaterials with adequate protection of their rights. In the biobank setting, consent is required not only for a specific research procedure, but also for a transfer of some or all of the rights of control over the actual material and its use. If this is conceptualized as a “transfer of ownership,” informed consent suddenly looks like a very odd procedure for such a transfer, since ownership is usually transferred by means of contracts, and based on the advice of lawyers, not on information given by medical doctors. If, on the contrary, one considers this not as ownership, but as “right of control” over its use without proprietary rights, then the direct consent or the consent to transfer this right over use to a body or another person looks more appropriate. In any case, the clarification of this issue seems to be crucial, so even if the traditional approach is problematic, it is, nevertheless, important to continue analyses along these lines, since they are the currently acknowledged legitimate basis for biobanking. In the book ten different chapters are dedicated to researching these questions within the different possible normative options offered by the traditional approach.

Although the primary objective of this book is to critically assess the traditional regulatory approach to research biobanking and develop alternative ways of conceiving of and regulating research biobanks, our main hypothesis is that besides attempting to directly extend the analysis of the traditional approach described above, it will be equally fruitful to investigate the conceptual potential of analogies from a range of areas outside medical research, i.e., analogies other than that of a table or counter where people change and exchange valuables between themselves and a common institution. The second part of this book represents an attempt to pursue this goal. The analogies we propose are not intended as templates or models to be followed, but as tools for analysis. Examples of such analogies are ordinary commercial banking, voluntary associations, clubs (e.g., book clubs) or unions, libraries, conscription, taxation, and management of art pieces. By developing these analogies, analysing their implications, and identifying their limitations we believe that it will be possible to:

- Achieve a deeper understanding of the structural arrangement of research biobanking
- Critically assess the vocabulary prevailing in the field of biobanking, in particular the labels employed and the roles, rights and duties ascribed to the different parties affected by or involved in biobanking (donor, “biobanker,” researcher, research ethics committees, the sampled population)
- Make recommendations regarding different ways in which a biobank could be structured as a social institution

This part of the book, which consists of 11 chapters, aims more specifically at pursuing the following objectives: To explore a range of analogous social contexts where people transfer something to a common institution and to draw out