

GOVERNING BIOBANKS: UNDERSTANDING THE INTERPLAY BETWEEN LAW AND PRACTICE

By Jane Kaye, Susan MC Gibbons, Catherine Heeney, Michael Parker and Andrew Smart,
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This insightful book provides an overview and a multidisciplinary analysis of policy-making and regulation regarding biobanks in England and Wales between 2005 and 2009. It is based on findings from the *Governing Genetic Databases Project*, conducted at the Ethox Centre at the University of Oxford. The main goal of the book is to provide fine-grained knowledge about the interplay of formal and informal governance frameworks and the actual medico-scientific practices by integrating a theoretical approach with empirical social research, focusing on the perspectives of practitioners who work with biobanks. The book consists of three main sections. Part I provides a background with regards to the research landscape, as well as the realisation of the project and motivations of the investigation. Part II contains the main findings of the socio-legal research conducted within the project. The final section of the book synthesises the key findings of Part II and provides general assessments, as well as recommendations for future governance of biobanks. This review will provide a chapter-by-chapter summary to highlight the extent of investigation undertaken, as well as the wealth of findings that were obtained.

Part 1: Chapter 1 outlines the research project and its methodology in detail and introduces the key concepts "regulation", "governance" and "biobank". The authors deploy a very broad concept of "governance", comprising all forms of influence exerted by all kinds of actors, social institutions and social mechanisms, while the term "regulation" is reserved for "the formal structure of law and legally constituted regulatory bodies" (p 14). The terms "biobank" and "genetic database" are used interchangeably and refer to collections of genetic information and associated biological data or samples in different variants. This vague characterisation tries to take into account the plasticity of the research object as well as its polymorphic nature, as displayed by the vast diversity of types of genetic databases. Moreover, it adequately reflects the deployed qualitative methods by starting with a tentative working definition that only becomes refined through empirical data. Chapter 2 summarises important developments in the field of biomedical research that lead to the

development and proliferation of biobanks and, eventually, to new uncertainties and challenges for existing governance frameworks.

Part 2: The third chapter lays the foundation for the legal analysis in the book by mapping out the regulatory space for biobanks. Through a three-stage approach, the author of Chapter 3 systematically considers relevant legal and ethical documentation, as well as the influential actors and bodies that play a part in biobanking governance, both in the formal and informal arena. Findings allude to the existence of a number of informal actors at work in an intricate and presently fragmented governance framework, such as professional associations and funding bodies. In recognising that there exists no adequate and agreed upon definition of a 'genetic database', Chapter 4 starts with the basics by seeking to establish the main features of genetic databases. Through empirical data drawn from 49 in-depth interviews with professionals involved in genetic biobanking activities, the key characteristics of biobanks are presented, namely "the age of study, size, materials held, study participants and modes of recruitment, organization setting and methodology employed" (p 99). Analysis reveals the fluidity and complexity within the structural dimensions of genetic databases, which causes challenges in establishing a fixed definition, as well as an appropriate governance framework. Chapter 5 focuses on the respondents' awareness of governance sources, both in terms of specific laws and authoritative bodies. Analysis is drawn from empirical data, which indicates overall limited knowledge and awareness on the part of practitioners with regards to both key laws and their content, as well as with regards to official governance actors in the biobanking sector, with low levels of engagement with the latter in cases of uncertainty. Findings reveal that practitioners predominantly rely on informal and internal governance mechanisms, where professional, as well as social networks, play a significant role in regulation. With regards to external oversight structures, Research Ethics Committees (RECs) and funding bodies were viewed as particularly important governance actors, as opposed to more "official bodies", such as the Human Tissue Authority and the Information Commissioner's Office. Chapter 6 goes on to present findings in relation to respondents' attitudes to biobanking governance in general, and the extent to which such attitudes and beliefs affect professional behaviour and practice. Professional background, practical experience and sensitivity towards other biobank stakeholders and actors are identified as three key influencing factors, and are duly termed as "implicit guidance". Findings reaffirm the significant influence of professional cultures and social networks in biobanking governance.

Building on the two previous chapters, Chapter 7 elaborates on the attitudes of respondents in relation to particular laws, with focus on the Human Tissue Act 2004 and intellectual property rights, as well as towards certain regulatory actors, namely towards RECs, funding bodies and the NHS. A cross-sectional analysis of the data reveals eight primary areas of concern in relation to governance. These include ambiguity in relation to legal frameworks, which causes confusion in practice; the law's differential treatment of biological material and data, which results in potential blurring when attempting to categorise DNA samples, genetic material and genotype data; and excessive bureaucracy. Although findings in this chapter highlight the criticisms and general hostility on the part of respondents towards biobanking governance, with views that there is a 'complicating' or 'hampering' of research, the following chapter goes on to paint the rest of the picture. The findings in Chapter 8 show that many respondents actually express a *desire for governance* and an interest in the improvement of the current governance framework. This apparent paradox, in view of the highlighted general *hostility* towards governance, is dissolved by considering the (more or less) latent functions of governance and regulation. More specifically, the analyses of the interviews revealed that many of the practitioners thought of biobanking governance primarily as having the purpose of (a) confirming the (often taken for granted) appropriateness and legitimacy of *existing* biobanking projects and related activities; and (b) demonstrating the legitimacy of these activities to other stakeholders and 'the general public'.

Chapter 9 concentrates on the enactment of governance arrangements (p 233) in the context of access to biobank data or data sharing. The authors deploy a range of ideas from science and technology studies and stress the influence of social context factors and different social locations of those involved in decision-making concerning access, as well as non-access, to biodata and samples. A key insight here is that data sharing in the context of biobanking is not only determined by official regulatory frameworks but, once again, also by informal social factors and practices of negotiation between different agents. In our view, these findings in Chapter 8 and 9 offer useful insights for policymaking, as they appear to be relevant for the efficient introduction and likelihood of acceptance of new governance mechanisms in the future.

Part III: Chapter 10 provides an overview of the current state of affairs in the governance landscape and simultaneously draws upon the legal and sociological findings presented in Part II to identify the many deficiencies in the present framework. Analysis indicates the ad hoc emergence of a poly-centred, informal and self-regulated system, which may lack legitimacy. Chapter 11 goes on to examine the ethical issues raised in biobanks in view of the findings presented in Chapter 4, which highlighted the complexity in structural organisation. Principal areas in relation to ethical governance are additionally explored. Chapter 12 concludes the book by discussing and assessing the project findings in light of the 'better regulation principles' (as articulated by the UK *Better Regulation Task Force*), namely consistency, transparency, accountability, targeting and proportionality, and duly explores the way forward with regards to the establishment of an appropriate governance framework for biobanks and biobanking activities. This chapter highlights, amongst other things, the need for an overarching governance structure that takes into account the heterogeneous and complex nature of biobanks, and which is able to respond adequately to the specific functioning and needs of different types of biobanks.

The approach taken in this book is a multi-faceted one, where research and analysis are conducted vertically and horizontally to present a broad range of findings. Furthermore, given that research is not limited to the formal sector, the authors prudently identify the significant function of informal mechanisms that are currently in place, emphasising the intricacy of biobank functioning and governance. The findings aptly identify a number of informal bodies at work within the governance structure. However, discussion does at times fall short of exploring normative questions about the role and power held by informal actors, such as RECs, as well as offering guidance with regards to their potential prospective roles in any future framework. Nevertheless, this book successfully fulfils its objective by capturing and discussing the governance framework at work in the biobanking sector, highlighting the tension between practice and existing governance structures. The findings and analysis presented provide for the much-needed knowledge base for the development of more appropriate governance structures. Given the multidisciplinary nature, as well as the practical application of the book, it is a worthwhile read not only for academics but also law and policy makers involved in the biobanking sector.

Before concluding, there are some general remarks concerning the sociological research methodology. First of all, the deployment of qualitative research methods, above all semi-

structured interviews, to gather in-depth information about the field seems highly sensible to us. We particularly like the way in which difficulties in the initial phase of the investigation (e.g. *how* to give a working definition of 'biobank' without in-depth knowledge of the field) are made explicit and the clear exposition of epistemic limitations of the analysis due to the applied sampling strategy. However, despite the fact that chain referral sampling might have been unavoidable as a starting point for the empirical investigation, given lack of information about the field, it would have been prudent to say something more concrete about possible distorting effects on the intended generalizability of the findings. Although the authors do not claim that the empirical findings are statistically representative, they do argue for theoretical generalizability. The elucidation of this notoriously difficult concept and the discussion of potential influences of the sampling strategy on the scope of the findings seem somewhat unclear though, especially bearing in mind that the authors give general policy recommendations *based* on the empirical findings.

The book is extremely clearly written and well structured. It offers helpful contextualisation and concise chapter summaries, making it easy to read and to find what you are looking for. Each chapter is self-contained, and so can be read individually as well as in conjunction with other sections. Furthermore, references to other chapters within the book additionally facilitate navigation. Above all, this book is an excellent example for a sensible multidisciplinary approach that is not 'prescribed from above' but actually springs from current issues in the governance of biomedical research, thereby leading to a fruitful integration of socio-legal research and normative assessments.

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