

Governing Biobanks: Understanding the Interplay Between law and Practice

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Governing Biobanks provides an extensive look into the world of biobanking and the role of law in this context. More specifically, the text critically examines the adequacy of existing legal frameworks and research governance structures that have been put in place following the rapid proliferation of biobanks worldwide. Although the text primarily revolves around biobank governance in England and Wales, the issues and insights outlined are equally relevant to a wider international audience.

The early chapters begin by highlighting the methodology employed in the sociological, ethical and legal research for the purposes of the text, as well as clarifying key parameters and definitions, such as ‘governance’ and ‘biobanks’. The authors’ then set the scene for the rest of the book by introducing new technologies that have emerged, with notable emphasis on the Human Genome Project (‘the HGP’) acting as the catalyst for the growth of biobanks. This helps the reader appreciate the sudden emergence of biobanks and their importance, and why governance structures have failed to keep up. Indeed, it almost pre-emptively foreshadows inadequate governance mechanisms in regulating cross-jurisdictional medical research.

The body of the text is split into three discrete sections; mapping the regulatory space, governance of biobanks, and reflection and recommendations. This structure allows navigation through the field of biobanking and governance in a logical fashion by first providing the reader with an understanding of how various bodies interrelate and how that interrelationship influences the governance of biobanks in England and Wales. By initially providing this knowledge, the authors’ assume the reader has no prior knowledge before proceeding to the practical aspect of biobank governance.

The research methodology and socio-legal perspectives taken by the authors are impressive. In Chapter Three, Gibbons does an immaculate job of drawing on legal research work to create a clear, coherent map of the key actors involved in the regulation of biobanks. This is complemented in the following chapter, where Heeney applies a sociological approach in identifying what a ‘typology of practice’ might include. These two chapters effectively form the foundation from which

the book builds, painting a picture of a complex and unsystematic legal framework governing biobanks today.

The next quadrilogy of chapters builds on earlier findings and analyses the complex array of stakeholders' awareness, engagement and attitudes towards governance and their implications. Conclusions drawn from the authors' research are delayed until the final instalment for the purposes of accurately portraying the complete picture. By compiling and analysing data on attitudes, the authors are able to identify and reveal where existing laws and instruments – or the lack thereof – have caused the greatest concern.

Particularly intriguing is the issue of potential 'mismatches' between current governance and practitioners, especially with respect to how the law should distinguish between 'biological material' and 'data'. It is undoubtedly a grey area, with many conflicting viewpoints taken, both on a practical and ethical basis. It is no surprise that the biggest criticism of current governance is the artificially 'bright-line' approach taken in distinguishing between the two. For example, 'biological materials' include tissue, data, samples, DNA, genetic materials and so forth. The legalistic 'bright-line' approach seeks to artificially place these components into neat boxes for the purposes of regulation. However in reality, they are all nested in the same continuum incapable of clear delineation. It is demonstrated that such an approach is archetypal of legalistic reasoning and does not accord with scientific realities, serving to hinder rather than promote medical research. This raises several crucial problems such as practitioners inadvertently violating governance requirements and laws due to the difference in their understanding of biological materials as compared to policy and lawmakers, rendering existing forms of governance unfit for purpose.

The final chapters of the text contain the authors' reflections and recommendations for biobanking governance. It becomes apparent that the inherent problem surrounding biobank practices is in their complexity and fluidity, unlike traditional legal frameworks which tend to be uniform or static. As put forward by the text, this necessarily entails the development of coherent overarching mechanisms capable of governing biobanking. These mechanisms not only have to be responsive, but transparent and accountable as well. For example, the authors' push for a single authoritative body capable of laying down universal requirements for biobanking practice. This would harmonise the system as a whole by reducing the number of regulatory actors who clog up the regulatory space with inconsistent governance regimes. The authors' are tremendously persuasive in this aspect, pushing for (*inter alia*) one authoritative body, improving the role of law and developing a professional culture among researchers.

Governing Biobanks provides a snapshot of the rise of biobanks globally and the regulatory failings accompanying it. The authors are under no illusion that much confusion and uncertainty exists in biobank governance, and set about identifying the underlying problems in an empirical, logical manner. The socio-legal perspective provides unique insights into the world of biobanking, recognising issues that a purely legalistic point-of-view would not have picked up on. Overall, there is no doubt that the timely release of this book will serve to address the gaps in biobank governance, as well as inject some much needed coherence into regulatory frameworks around the world.

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