

Kaye, J., Stranger M. (eds): December 2009, Principles and Practice in Biobank Governance. Farnham, Surrey: Ashgate. 316 pages. Hardback binding, ISBN 9780754678250. Ebook ISBN 9780754696193.

This book brings together scholars from all over the world around the topic of governing biobanks and their most significant ethical, legal and social implications (ELSI). It's mainly intended for policy makers and researchers on bioethics, sociology and law. Biobanks introduce the necessity of revising traditional governance mechanisms around the collection and long term storage and sharing of human samples together with the genotypic, phenotypic and environmental information associated with them. The potential benefits of research in this area are unquestionable. The expectations on biotechnology advances to understand and treat diseases like diabetes, Alzheimer's or Parkinson's are high. At the same time this area concentrates many bioethical problems to be solved for the interest of all stakeholders. New questions arise from this long-term engagement on the modality of consent, the implications of infants and the role of ethics committees. It demands an underlying infrastructure to de-identify samples to guarantee privacy but at the same time enable re-contacting or exercising the right to withdraw. Individual participants must understand the risks and trust the institutions.

The introduction by the editors Stranger and Kaye gives coherence to the volume, divided into four themes according to the main emphasis of the different chapters: Benefit Sharing, Consent, Privacy and Access to Data, and Governing Bodies. However, this grouping does not limit the treatment that authors give to the other disciplines.

In the **Benefit Sharing** part the main question is if the voluntary participants in biobank research studies should get any benefit or at least take part in the decision making of what to do with the results of such studies.

In Chapter 1 Nicol and Critchley report a public opinion survey relating biobanking in Australia carried out to deal with the problem of loss of public trust. Questions include if donors should receive any payment, biobank financing, arrangements that must be required to companies in order to access the repositories, the use of the results and the perceived importance of benefit sharing. The results illustrate that Australians are mainly altruistic but expect some reciprocity in terms of public benefit, such as affordable public access to healthcare benefits, and want to know before taking part in biobank research.

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Kanellopoulou studies in Chapter 2 the relationship between researchers and biobank donors in the UK. She recommends some reflection on the long-term collaborative models, going beyond the altruist unconditional gift model, to conceptualise their interaction by using reciprocity. In doing so she introduces the new ethical principle of *empowerment* as a conditional gift, in order to give research participants the role of proactive contributors.

Winickoff (US) introduces in Chapter 3 the notion of partnership governance to shift from the benefit sharing normative, a distributive value, to *power sharing* approach, a procedural one. Partnership governance would empower participants to exert a share in distributive decision-making and could be implemented by using existing architectures based on charitable trust law and corporate governance.

Informed Consent is traditionally considered as the main way to realize one of the fundamental principles of bioethics, that of patient autonomy. However, the scenario is different for biobanks as these repositories are built to stay for a long time to be used on related or unrelated research projects. In the latter case information is not available at the donation time, requiring re-consent or broad consent. The possibility to opt-out and the de-identification of samples are added conflicts in this context. Changing regulations must also deal with existing collections, some of which were not created for research purposes.

Gundermann and Stockter utilise in Chapter 4 the *Co-determination* term borrowed from the German labour law to denote the transfer of democratic decision making processes into private or public management structures, exemplified by fair trade coffee. A minimum level of broad consent seems to be inevitable. Co-determination is designed to compensate the restriction of the donor's autonomy, for example, by entailing the possibility of exerting influence on the precise use of their data and tissue in a biobank.

In Chapter 5 Otlowski (Australia) overviews some consent principles and defends the *broad consent* approach from a pragmatic point of view. She claims that obtaining specific consent for each participant on each research project in large-scale prospective biobanks is not feasible. In comparison to other alternatives, broad consent is clearly cheaper and more effective but it may be argued that the inability to give participants specific details of the use given to the data undermines the respect for their autonomy. She proposes the reconceptualisation of consent in the context of biobanks, upholding the principles that consent is intended to serve: autonomy, respect and protection.

In Chapter 6 Casado da Rocha and Etxeberria Agiriano describe the implications of the new Spanish Law on Biomedical Research which includes a specific regulation of biobanks. This legislation requires informed consent but it allows related projects, carried out by the same team or another, to access the samples, relying on research ethics committees to decide on the degree of relatedness. They have concerns that depending on the meaning given to the project relatedness it could set in place an open consent or a consent waiver model.

Hens and Dierickx (Belgium) address in Chapter 7 the ethical questions of biobanks involving minors and specific biobanks focusing solely on children's development and diseases. The problem of who should consent is unclear when both parents do not agree, and acquires a new dimension when the child reaches majority. They suggest that only minimal emotional and physical harm can be allowed for paediatric biobanks, providing benefits to the children or the group to which they belong.

Closing this part on consent, Cadigan and Davis investigate the concerns of healthy volunteers in the US in Chapter 8. They interview individuals that considered enrolment in a biobank, comparing the perspectives of those who finally enrolled (joiners) with those who did not join (decliners). Results revealed striking similarities between the perspectives of joiners and decliners in respect to payment for participation, together with ease of participation. However, joiners often seemed to frame risk and benefit in the short-term, while decliners were persuaded by the perception of long-term risk on privacy.

The following block entitled **Privacy and Access to Data** is dedicated to study how to ensure the privacy of donors, their relatives and their genetic communities (their genetically significant others), as it is known to be one of the most important issues to discourage potential donors due to their lack of trust. Risk assessment by insurance companies and employability are only two examples of discrimination potentials.

Townend, Taylor, Wright and Wickins-Drazilova (UK) report in Chapter 9 at the first stage of the PRIVILEGED project (privacy in law, ethics and genetic data). This phase consists in reviewing the literature public opinion surveys regarding privacy interests at the national and international level, e.g. the eurobarometer surveys. Their concern is that respecting the point of view of the majority could result in the alienation of significant minorities.

Chapter 10 treats the legal duties of biobanks to give feedback of significant findings when proven therapeutic or prevention is available. Skene focuses on the Australian law and questions whether participants

and their blood relatives should be re-contacted, under what circumstances and by means of what provisions.

In Chapter 11 Zarabzadeh, Watson, Bradley and Grimson overview participant confidentiality and the methods to protect the associated identity data in the context of the Irish Prostate Cancer Research Consortium (PCRC) biobank in consonance with the legal requirements. They describe four methods for concealing confidential information for use in biobanks: unidentified or *anonymous*, unlinked or *anonymized*, coded or linked or identifiable or de-identified referred as *pseudonymization*, and *identified* samples. The PCRC Biobank Information Management System (BIMS) is a middleware system storing these four categories of quality controlled data integrating sample, phenotype, genotype and medical information. It maintains a complete audit trail of all accesses to the central database, something of high importance to prevent unauthorized access. It also integrates the Standard Operating Procedures (SOPs) adhering to legislation and ethical considerations.

The need to exchange human biological material enforces researches to deal with procedural issues across countries with different legislations. Rial-Sebbag, Mahalatchimy, Platzer and Cambon-Thomsen describe in Chapter 12 the Human Sample Exchange Regulation Navigator (hSERN), a Web-based tool developed within the Global Allergy and Asthma European Project, Ga²len, to import-export human biological samples, together with Material Transfer Agreements (MTA) beyond the legal requirements. The existing solution between France and the UK is expected to be extended to other countries to reduce the obstacles for cooperation within biobank networks.

Chapter 13 by Kaye deals with informed consent, protection of privacy and governance concepts in the context of biobanking networks, aimed at developing common standards and procedures to improve quality. The challenge is to be able to compare samples within existing networks of networks, especially applied to the related data rather than the physical tissues, accessing from a single portal. The purpose of the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) is to build a Pan-European Biobanking Infrastructure following these results.

The final part of this work is dedicated to **Governing Bodies**. Emerging biobanks can profit from the experience of those before them, adopting and adapting principles and practice to their legal, social, cultural and political environments through policies and guidelines, with the big picture of networks of networks in mind.

Bédard, Wallace, Lazor and Knoppers outline the research conducted at the request of the Québec Ministère de la Santé et des Services Sociaux (MSS). The main issue is to understand the elements required to set up a governance structure for the CARTaGENE biobank, a founding member of the P³G Consortium. They surveyed 18 biobanks to compare six sets of governance procedures: (1) scientific evaluation; (2) ethics evaluation; (3) data protection and public health laws, and laws on statistics; (4) bio-security standards for laboratories; (5) guidelines for research with human participants; and (6) professional guidelines. Information on governing bodies was also collected and compared in four areas: mandate, membership, operation and financing. They document and justify the decision to disband the Institute for Populations, Ethics and Governance (IPEG) created to oversee the aforementioned biobank.

During the planning of the UK Biobank, expected to contain health and lifestyle data and biological samples from around 500,000 people from the UK, an Interim Advisory Group (IAG) was created. Two recommendations emerged from the deliberations. Firstly, the adoption of the Ethics and Governance Framework (EGF); secondly, the creation of the Ethics and Governance Council (EGC) to oversee the project and to monitor and advise on its operation. In Chapter 15 Richards, Hunt and Laurie describe the UK biobank and discuss the reasons that conducted the creation of this EGC body in order to build and maintain public trust through its advisory and monitoring role, which makes it different from Research Ethics Committees.

Lemmens and Austin point out in Chapter 16 that a growing awareness of privacy concerns results from advances in genetic research shifting the potential risks from the physical to the informational dimension. They discuss how some Canadian provinces have promoted the integration of the concept of Fair Information Practices (FIP) into the existing system of research ethics review. Eight major principles form the core of FIP: Collection Limitation, Data Quality, Purpose Specification, Use Limitation, Security Safeguards, Openness, Individual Participation and Accountability. The core good governance principles of the Canadian Research Ethic Boards (REB) governance system are: effectiveness and efficacy, accountability, respect for the rule of law, transparency, participation, and responsiveness. They contrast this new model with the one relying on non-specialized REB existing on other provinces which, they argue, do not fulfil established minimum criteria for good governance. They conclude describing the Personal Health Information Access and Protection of Privacy in the province of British Columbia which sets up Data Stewardship Committees responsible to

manage the disclosure, research planning, and sharing of information in these banks.

Closing this book, in Chapter 17 Wesbrot reports the results of two major inquiries carried out by the Australian Law Reform Commission (ALRC) dealing with the ELSI of human genetic research and the governance of biobanks. The first inquiry, in 2003, was concerned with the use of genetic information. It resulted in a report called "*Essentially Yours: The Protection of Human Genetic Information in Australia*". The second, carried out in 2008, was concerned with the adequacy of Australian privacy laws and practices grouped in four broad categories: ethical oversight; biobank governance; commercialization, access and equity, and benefit sharing; and protection from collateral damage: genetic discrimination. It resulted in a report called "*For Your Information: Australian Privacy Law and Practice*". The author discusses the situation of biobanks in Australia and the ALRC policy recommendations derived from these inquiries.

Having read this work it is clear that sooner or later we are all candidates to participate in bigger or smaller long-term biobanks, local, national or international. It is clear that many of us will profit from advances resulting research on this area, being diagnoses and/or treatments. It may become usual that clinical samples and check-up information feed regularly biobanks, especially under public schemas. Research carried out with our samples must be safe, but not at the expense of our autonomy. The risk of using clinical tissues and records is mostly informational. If we consider blood relatives we are not risk-free even without taking part directly. What is done with the outcome of the research is also important as it may discourage or encourage potential participants. What is nowadays technically possible must be ethically feasible as this will be the key aspect for the public trust. Governing bodies must take seriously these challenges to obtain the best out of this potential of welfare.

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