

## BOOK REVIEW

### HUMAN GENETIC BIOBANKS IN ASIA: POLITICS OF TRUST AND SCIENTIFIC ADVANCEMENT

*Margaret Sleeboom-Faulkner (Editor)*

Oxford: Routledge, 2009, 211pp (incl index), £100, ISBN-0-7103-1341-1 (hbk)

Biobanks are essential tools for genetic research, particularly genome-wide association studies (GWAS) and for the pharmaceutical industry for the translation of research findings into new products. Biobanks will also serve in the development of personalised medicine (The Royal Society, *Personalised Medicine: Hopes and Realities* (2005)). Jeroboams of printing ink have been devoted to the ethical, regulatory and social challenges associated with biobanks, particularly in relation to consent and privacy. Some scholars argue that the traditional consent model is simply too outdated for the genome era of high throughput genetic profiling and analysis, where entire populations can be genotyped in a matter of days and, future undefined research may be undertaken. There has been a focus shift to “governance” approaches to the administration, management, custodianship and security of biobanks. The establishment of increasing numbers of biobanks around the world has led to a rush of policy statements (NCI, *First-Generation Guidelines for NCI-Supported BioRepositories* (Washington DCL National Cancer Institute, National Institutes of Health, US Department of Health and Human Services, 2006) and academic commentary debating the nature, form and content of the instruments needed to regulate this activity. In addition, some large-scale biobanks have developed their own governance frameworks (for example, UK Biobank. *Ethics and Governance Framework*, Version 2).

Biobanking issues have been canvassed extensively, but predominantly from European and North American perspectives. European and North American models of regulation are based on some unique, individualistic cultural and legal traditions. In this respect, European and North American biobanks cannot, and should not, provide a single one-size-fits-all model for the establishment, recruitment, collection of samples and operation of biobanks around the world. Biobanks have been set up in Japan and Taiwan and biobanking is underway in China, India and Indonesia. These countries have different cultural, welfare, healthcare and regulatory practices and traditions that should inform biobanking in these countries. Margaret Sleeboom-Faulkner’s volume of edited essays entitled *Human Genetic Biobanks in Asia: Politics of Trust and Scientific Advancement* is a valuable contribution to an understanding of these differences. The essays in this volume discuss many of the common themes in biobanking around the world, including consent, privacy, benefit-sharing, data-sharing and public trust, but contextualised to the rapidly expanding catalogue of Asian biobanks.

The genome era has seen the establishment of large-scale population biobanks in many western countries for the purpose of facilitating research into major diseases including cancer, cardiovascular disease, mental health and diabetes through genome wide association studies. But there is no single biobank model and Sleeboom-

Faulkner's introductory chapter provides a fine overview of the different categories of tissue samples, serum and genetic information collections that are used for medical research or population based studies. Tohru Masui also gives a similarly useful and concise account (at pp 69-73).

Chapters 2 to 5 are grouped as Part I under the heading "Biobanking in Welfare Societies". Chapter 2 discusses the Taiwan Biobank and public trust, which is widely seen as a fundamental cornerstone in genetic research. Data linkage has become a major concern and a challenge to building public trust in Taiwan. This will, no doubt become a similar concern around the world as different publics become more aware of the extent of data linkage. The essay discusses unique problems with attitudes of the indigenous Taiwanese populations to recruitment and sampling but returns to common ground with concerns about commercial involvement and benefit sharing. Collaborations between biobanks and drug companies are becoming more common and there are increasing linkages between existing private and public collections and Taiwan Biobank is similarly considering these collaborations.

Chapters 3 and 4 both deal with the Japan Biobank, which aims to study some forty seven specific diseases by providing DNA but not data to researchers. Chapter 3 is a scholarly comparison between the population-based UK Biobank and the disease-study Japan Biobank. This essay compares the Japan Ministry guidelines, including their enforceability and interpretation by individual Ethics Review Committees, with the different regulatory framework of the UK Biobank. Again, similar themes arise with public trust but with unique variations in the forms of passive Japanese patients, mistrust of the medical establishment and a fear of genetic discrimination. The essay is particularly illuminating on the operation of informed consent in the recruitment of biobank participants. This essay foreshadowed much of the criticism made about one of the world's biggest biorepositories for disease study by Gottweiss in 2008 (H Gottweiss and A Petersen, *Biobanks –Governance in Comparative Perspective* (London: Routledge, 2008)).

Chapter 4 continues the comparison between Japan Biobank and UK Biobank by examining differences in establishment, research focus (DNA in Japan and epidemiology in the UK), regulation and recruitment based on different professional, research, and historical and governmental traditions in each country. This essay has a strong scientific focus and recognises the increasingly closer translational link between biobank research and clinical application, including clinical trials. The other major Japanese biobank, Pharma SNP Consortium consists of some forty-three pharmaceutical companies that have collected anonymised and unlinked samples and data for use as normal controls in drug trials. Biobanks may obviate the need for some drug trials when data on the interaction between drugs and DNA become available. The issue of the use of biobank data to facilitate patient recruitment into, or identify potential non-responders for exclusion from, clinical trials raises new privacy and governance concerns that await debate.

Chapter 5 sets out the results of a survey of the attitudes of 301 participants to biobanking to inform decision-makers on whether to invest in biobanking in Hong Kong. The survey was on biobanking in general with specific questions on dyslexia sufferers in Hong Kong. This report identifies trust and privacy issues in biobanking of genetic and health data on dyslexia but within the unique learning, social (particularly the Chinese collectivist cultural emphasis on "face" and the possibility of genetic disability bringing "disgrace" to a family) and medical environment of Hong

Kong. The joint authors of this chapter noted the “uneasiness” of some participants to donate DNA or to share it with overseas collaborators but still had some “optimism” for such a biobank provided there was a “clear understanding of the limitations and advantages of biobanking”. This essay is an endorsement of the OECD *Guidelines for Human Biobanks*, which include requirements for proper public engagement in the creation and operation of a public biobank.

Part II has five chapters under the heading of “Biobanking and Problems of Equality”. Chapter 6 by the editor of the volume is a disturbing case study of unchecked hubris by a prominent Dutch scientist, working for the largest Indonesian pharmaceutical company to create the largest biorepository in Indonesia. This crafted account follows the scientist’s steps against the backdrop of Cavalli-Sforza’s controversial Human Genome Diversity Program and Indonesia’s traditional and close medical research ties with its former colonial ruler. This account also draws upon his correspondence to fellow scientists, academics and politicians and places Dr X on a roundabout of viewpoints as progressive scientist, businessman or enlightened visionary and then as exploitative genetic reductionist, imperialist or Orientalist.

The author concludes that the “attraction to genetic samplers of Indonesian people as biological resources does not just lie in the unique and valuable nature of their DNA, but in the relative ease with which research permits are received, bureaucratic procedures can be avoided, the low price of schooled labour, and the relative lack of resistance that vulnerable (illiterate, uneducated, or poor) people display to becoming targets of research”. The reader is left in no doubt about the institutional biolaw and bioethical deficit and with a sense of cultural scientific imperialism that demands international and national responses in the form of massively improved research regulation and governance before any further steps are taken in Indonesia’s biobanking journey. This is a confronting comparator to the Taiwan and Japan biobank stories of trust; this is a story of public protection.

Chapter 7 also highlights the necessary OECD precondition for proper regulatory and governance issues to be addressed before, rather than during, the creation of a biobank. This chapter raises the spectre of biopiracy of Indian human bioresources, particularly after the infamous neem tree patent issue. The chapter notes that official guidelines not only require Indian DNA samples to be analysed by national scientists in national laboratories but also prevent the transfer of DNA samples out of the country. These regulatory efforts are underwritten by the Department of Biotechnology and the Indian Council of Medical Research, which has, since the time of this essay undertaken steps towards a national biorepository. The essay notes the guidelines for sample consent - access to and ownership of DNA, quality control and data collection are not mandatory - and questions the operational integrity of these guidelines amongst the “4635 castes, 3000 communities and 28,000 endogamous groups” in India. The author emphasises the need for government to protect against the threat of foreign biopiracy.

Chapter 8 also focuses on India and the then proposed, but only recently started, National Repository (NR), which aims to capture the unique genetic diversity of the Indian population for drug companies planning to conduct clinical trials in the country. There is a discussion of the ethical, legal and social aspects of the NR points of view and the proposed collection processes through screening programs and from patients in hospitals. The authors questioned the operation of the NR in light of the social, economic and healthcare disparities across the country. The conventional

bioethical issues, such as informed consent, confidentiality, benefit sharing and public trust, are discussed. Interestingly, the authors note that the promissory and “explorative nature” of genomic research makes the idea of benefit sharing challenging to predict by referring to the views and practices of researchers and community leaders themselves. A main concern for the authors is to minimise “the gap between the bioethical guidelines and protocols and the practice at ground level”.

Chapters 9 and 10 focus on China. Chapter 9 notes a number of the common themes in European and North American discussions on biobanking and, effectively, “contextualises the development of large-scale population-based biobanks in China”. China, like India, sees biobanking in the context of national bio-resources, including unique flora and fauna species. The author notes that one of the dominant discourses in China has been centred on the risk of “losing genetic resources”. Similarly, China’s diverse population of some fifty-six ethnic groups are seen as valuable genetic resources not only for studying and treating human diseases but also for studying human hereditary evolution. The author highlights the differences between debates on trust in biobanking in China and in North America and Europe. While debates in the latter areas focus on trust in confidentiality and protection of *individual* donors, debates in China stress the need to retain national governance of biobanks to prevent biopiracy by foreign companies and academics. The national Interim Measures for the Administration of Human Genetic Resources 1998 are included as an appendix to this essay and these have been discussed by Zhu Xuezhong et al, “The Progress of Chinese Legal Protection in Genetic Resources” (2008) 5 *Journal of International Biotechnology Law* 59–63.

Chapter 10 is another useful and informative empirical survey of attitudes of Chinese scientists and regulators on two key ethical issues in creating genetic databases. Noting the national plans to develop collections of human genetic samples, the author examines attitudes to consent and benefit sharing. Again, the work provides valuable insights into differences in attitudes between debates on consent and benefit sharing in biobanking in China and in North America and Europe. The findings of the survey showed a “clear disagreement on issues such as family consent and benefit-sharing mechanisms”. In the case of the former, the author notes “individual autonomy is easily dismissed” in preference to community and family views, posing problems for researchers seeking consent. Secondly, the author notes the absence of clear guidelines to regulate benefit-sharing. The regulatory vacuum extends to an “urgently needed” introduction of appropriate ethical guidelines for review of research involving human genetic samples/data collections and usage. This survey provides useful insights into the unique aspects of informed consent and research review procedures in China.

Sleeboom-Faulkner’s volume of case studies had its origins in an international collaboration culminating in the presentation of papers at a meeting in Shanghai in 2004. The chapters do not, therefore, deal with significant developments in the last five years, such as the 2005 Report of the OECD, *The Creation and Governance of Human Genetic Research Databases*, which resulted at the end of 2009 in *Guidelines for Human Biobanks and Genetic Research Databases*. Similarly, the new phase of harmonisation of biobank collections to facilitate coordination of research efforts internationally is not discussed in the essays. This in no way detracts from the valuable insights of this fine volume of essays into biobanking in Asia.

Prof Don Chalmers  
Distinguished Professor, University of Tasmania

**DOI:** 10.2966/scrip.070110.216



© Don Chalmers 2010. This work is licensed under a [Creative Commons Licence](#). Please click on the link to read the terms and conditions.