



# GOVERNING BIOBANKS

UNDERSTANDING THE INTERPLAY BETWEEN LAW AND PRACTICE

Jane Kaye, Susan MC Gibbons,  
Catherine Heeney, Michael Parker  
and Andrew Smart

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## GOVERNING BIOBANKS

Biobanks are proliferating rapidly worldwide because they are powerful tools and organisational structures for undertaking medical research. By linking samples to data on the health of individuals, it is anticipated that biobanks will be used to explore the relationship between genes, environment and lifestyle for many diseases, as well as the potential of individually tailored drug treatments based on genetic predisposition. However, they also raise considerable challenges for existing legal frameworks and research governance structures. This book critically examines the current governance structures in place for biobanks in England and Wales. It shows that the technologies, techniques and practices involved in biobanking do not always conform neatly to existing legal principles and frameworks that apply to other areas of medical research. Using a socio-legal approach, including interview data gathered from the scientific community, this book provides unique insights and makes recommendations about appropriate governance mechanisms for biobanking in the future. It also explores the issues around the secondary use of information, such as consent and how to protect privacy, when biobanks are accessed by a number of different third parties. These issues have relevance both within England and Wales and to a wide international audience, as well as for other areas where large datasets are used.

In memory of my mother, Margaret Kaye,  
6 March 1931–22 February 2011  
*Jane Kaye*

For Jeremy and Mummie  
*Susan MC Gibbons*

## *Preface*

The idea for the Governing Genetic Databases project originated because of a discussion with a scientist talking about his research. In early 2004, Jane Kaye and Michael Parker went to see Professor Kwiatkowski from the Wellcome Trust Centre for Human Genetics in Oxford (WTCHG) about a funding application for a project to be called the Malaria Genomic Epidemiology Network (MalariaGEN) that he was proposing to submit to the Bill and Melinda Gates Foundation and the Wellcome Trust. MalariaGEN was going to bring together more than 30 partner institutions in 21 countries (in both developing and developed countries) and to involve the collection of very large numbers of DNA samples combined with clinical data from malaria-endemic countries in Africa and South East Asia. At around the same time, Mike Parker, Andrew Smart and Jane Kaye were also involved in the Oxford Genetics Knowledge Park where the ethical, legal and social implications of the collection of DNA samples, with the possibility of the information being used for a number of secondary research projects was also being identified as an important area requiring further research. The legal research that Sue Gibbons had carried out as part of the ELSAGEN project had highlighted the complexity of the law that applied to biobanks in the UK. Together, these projects reflected developments that were happening not just in the UK, but across the world, and the important and difficult questions they raised provided the background motivation for the Governing Genetic Databases Project which has resulted in this book.

The work carried out for the Governing Genetic Database project was funded by Wellcome Trust grant number WT 076070/Z/04/Z. In carrying out this research Michael Parker, Jane Kaye and Andrew Smart were also funded through the Oxford Genetics Knowledge Park by the UK Departments of Health and of Trade and Industry. Jane Kaye was funded by a Wellcome Trust Fellowship (grant number WT 081407/Z/06/Z). During the period of the project, Michael Parker's contribution was also supported by grants from the Wellcome Trust (number 087285/Z/08/Z) and the European Commission (LSHM-CT-2007-037273). During the writing of the book Catherine Heeney has been supported by Governing Genetic Databases Project Grant Wellcome Trust Code WT 076070/Z/04/Z, European Commission LSHB-CT-2006-037319 and by a CSIC JAE. doc Fellowship. Jane Kaye would like to thank Patrick Ky and Patrick Woolley for their assistance with Chapters One and Two. We would also like to thank the team at Hart Publishing and Sarah Newton for her copy editing.

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## **Part I**

# **Setting the Scene**



# From an Idea to a Project

Jane Kaye, Susan MC Gibbons, Catherine Heeney,  
Michael Parker and Andrew Smart

## HISTORY OF PROJECT

THIS BOOK PROVIDES a snapshot of a period of time from 2005–2009 when a large number of biobanks were being established in the UK and elsewhere. When this project commenced, advances in computer technology and high-throughput DNA sequencing had led to an increase in the amount of genetic research being conducted in the UK and the possibility of being able to establish resource collections.<sup>1</sup> Such advances had also led to a rapid increase in the number of collections of DNA samples that were being amassed, either for individual projects or specifically as resources for multiple other researchers to use.<sup>2</sup> These advances signalled the change in research focus from genetics to the study of the complexity of the whole genome, and also a change in practice to the investment in infrastructure projects or platforms. The results of the Human Genome Project, which involved the sequencing of the whole genome, had recently been completed in 2001. Large population biobanks—such as the Icelandic Health Sector Database (1999), the Estonian Genome Project (2000), and UK Biobank (2001)—had gained considerable attention because of their ambitious plans that tested many of the existing principles of medical research practice and data protection law. In addition, funders were supportive of proposals to establish disease-specific biobanks, as well

<sup>1</sup> FP Perera and IB Weinstein, 'Molecular Epidemiology: Recent Advances and Future Directions' (2000) 21(3) *Carcinogenesis* 517 (and references cited therein); R Tutton and O Corrigan, 'Introduction: Public Participation in Genetic Databases' in R Tutton and O Corrigan (eds), *Genetic Databases: Socio-ethical Issues in the Collection and Use of DNA* (London, Routledge, 2004).

<sup>2</sup> JV McHale, 'Regulating Genetic Databases: Some Legal and Ethical Issues' (2004) 12 *Medical Law Review* 70; I Hirtzlin, C Dubreuil, N Préaubert, J Duchier, B Jansen, J Simon, PL de Faria, A Perez-Lezaun, B Visser, GD Williams and A Cambon-Thomsen, 'An Empirical Survey on Biobanking of Human Genetic Material and Data in Six EU Countries' (2003) 11 *European Journal of Human Genetics* 475.

as encouraging the collection of DNA samples as ‘add-ons’ to existing longitudinal studies.

Despite this growth in the number of collections being established, there were no clear or accepted models for the organisational, procedural or security mechanisms of biobanks within the UK. Also, there was a lack of clarity in terminology with a number of different terms being applied to these kinds of research repositories, both within the UK and elsewhere. In the UK, ‘genetic database’ was the most commonly used term. This was a situation in which practice, terminology and standards were in a state of development and still emerging, and there was considerable uncertainty within the research community. Researchers and clinicians had to ‘re-invent the wheel’ in many cases when creating biobanks. They drew on the shared cultural practices of their professions and past experience in areas such as pathology, clinical trials and epidemiology, as a basis to develop structures and procedures for managing these collections. However, none of those areas had dealt with some of the specific issues raised by genetics. This lack of precedent created uncertainty and led to different procedures being established in different institutions or in different disease areas of medicine. This also led to regional and national differences which are now having an effect on the ability of researchers to share samples and data, particularly within global collaborations.

The legal framework in the UK also provided no answers to the questions and difficulties that researchers were experiencing and with which they were having to struggle. We had concerns that researchers could be at risk of operating unlawfully, as practices appeared to be emerging in a different direction to the law, but also without any close or well-informed consideration of the legal requirements. The law that applied to medical research and genetics in the UK was, and still is, a complex, inconsistent, fragmented, confusing and incomplete regulatory framework.<sup>3</sup> The legal research that Sue Gibbons had done as part of the ELSAGEN project had demonstrated this.<sup>4</sup> Unlike many other jurisdictions in Europe, in the UK

<sup>3</sup> D Price, ‘From Cosmos and Damien to Van Veltzen: the Human Tissue Saga Continues’ (2003) 11 *Medical Law Review* 1; C Mannhalter, ‘Collection, Storage and Use of Genetic Data: Issues of Gene Banks’, paper presented at conference on UNESCO Universal Declaration on the Human Genome and Human Rights: present status—future perspectives (June 2003); J Bohannon, ‘UK Researchers Hope for Clarity in Tissue Use’ (2002) 298 *Science* 1867; J Black, ‘Regulation as Facilitation: Negotiating the Genetic Revolution’ in R Brownsword, W Cornish and M Llewellyn (eds), *Law and Human Genetics: Regulating a Revolution* (Oxford, Hart Publishing, 1998); R Brownsword, ‘Regulating Human Genetics: New Dilemmas for a New Millennium’ (2004) 12 *Medical Law Review* 14.

<sup>4</sup> European Commission Framework 5, Quality of Life grant, ‘Ethical, Legal and Social Aspects of Genetic Databases: A European Comparison (ELSAGEN)’ with partners in Iceland, Sweden, Estonia and the UK, Contract number QLG6-CT-2001-00062, 2002–2005.

there was no specific legal instrument dedicated to biobanks.<sup>5</sup> Thus, it was very difficult to ascertain precisely what laws did govern biobanks within the UK at that time,<sup>6</sup> and also what was required of researchers and biobank operators, as practice itself was still evolving. At the same time, there were—and still remain—no universally accepted definitions of ‘genetic databases’ or ‘biobanks’ to be found in the law, guidelines or codes of practice within the UK.<sup>7</sup> There was also uncertainty whether these new emerging practices, procedures and standards were being developed in compliance with legal requirements.<sup>8</sup> This was largely to do with the fact that the legal requirements were insufficiently clear, too diffusely spread, excessive, and did not apply specifically to this new area of DNA collections.

Compounding the confusing state of existing UK law, and uncertainty over how it should be applied to biobanks, genetic information also has characteristics<sup>9</sup> that test traditional legal principles. For example, the law made, and still does, a distinction between ‘information’ and ‘biological samples’. Different rules and governance regimes apply to each. Often, these regimes impose differing standards—for example, in relation to participant consent. Yet, DNA/genetic material is *both* information *and* bodily sample. It can be difficult to determine, for legal purposes, when it should be treated as one or the other. The familial nature of genetic information also has implications for determining privacy interests and who should have a right to access the results of genetic tests or research.<sup>10</sup> There is also a need to understand how the complex notion of ‘public interest’ should be

<sup>5</sup> J Kaye and P Martin, ‘Safeguards for Research Using Large Scale Dna Collections’ (2000) 321 *British Medical Journal* 1146; P Martin and J Kaye, ‘The Use of Large Biological Sample Collections in Genetics Research: Issues for Public Policy’ in P Glasner (ed), *Reconfiguring Nature: Issues and Debates in the New Genetics* (Aldershot, Ashgate, 2004).

<sup>6</sup> H Newiss, ‘Genetic Databanks: How Secure Is Your Information?’ (2001) 1(6) *Genetics Law Monitor* 1; J Strobl, E Cave and T Walley, ‘Data Protection Legislation: Interpretation and Barriers to Research’ (2000) 321 *British Medical Journal* 890.

<sup>7</sup> McHale, ‘Regulating Genetic Databases’, above n 2; Black, ‘Regulation as Facilitation’, above n 3; Brownword, ‘Regulating Human Genetics’, above n 3; P Martin, ‘Genetic Governance: The Risks, Oversight and Regulation of Genetic Databases in the UK’ (2001) 20 *New Genetics and Society* 157.

<sup>8</sup> PR Ferguson, ‘Legal and Ethical Aspects of Clinical Trials: the Views of Researchers’ (2003) 11 *Medical Law Review* 48.

<sup>9</sup> R Mackenzie, ‘Paradigms of Author/Creator Property Rights in Intellectual Property Law: Ethical Implications for the Acquisition, Access, and Control of Genetic Information’ in AK Thompson and RF Chadwick (eds), *Genetic Information: Acquisition, Access, and Control* (New York, Kluwer Academic/Plenum Publishers, 1999); M Richards, ‘How Distinctive is Genetic Information?’ (2001) 32 *Studies in History and Philosophy of Biological and Biomedical Science* 663.

<sup>10</sup> BM Knoppers, ‘Genetic Information and the Family: Are We Our Brother’s Keeper?’ (2002) 20(2) *Trends in Biotechnology* 85; D Bell and B Bennett, ‘Genetic Secrets and the Family’ (2001) 9 *Medical Law Review* 130; GT Laurie, ‘Obligations Arising from Genetic Information: Negligence and the Protection of Familial Interests’ (1999) 11(2) *Child and Family Law Quarterly* 109.

construed and protected<sup>11</sup> if the human genome is to be regarded as the common heritage of humankind. By the early 2000s, these characteristics had triggered a heated debate as to whether genetic information should be treated as 'special' or 'exceptional' and whether its use should be the subject of separate regulation and governance structures; a debate which remained hotly contested and largely unresolved in 2004.<sup>12</sup>

In addition, population biobank proposals, such as the Icelandic Health Sector Database, had led to an extensive international debate over the principles that should be applied to biobanks.<sup>13</sup> This debate had highlighted in particular the need to consider the familial nature of genetic information and the perceived risk to privacy that biobanks may present.<sup>14</sup> In short, the principal issues raised by the debate were: consent, especially for secondary research purposes;<sup>15</sup> feedback to participants;<sup>16</sup> benefit-sharing;<sup>17</sup> participation

<sup>11</sup> L Beecham, 'BMA Annual Representative Meeting: Debate Needed on Balance Between Patient Confidentiality and Needs of Research' (2004) 329 *British Medical Journal* 7457; K Korts, S Weldon and ML Guðmundsdóttir, 'Genetic Databases and Public Attitudes: A Comparison of Iceland, Estonia and the UK' (2004) 8(1/2) *TRAMES* 131; V Árnason and G Árnason, 'Informed Democratic Consent? The Case of the Icelandic Database' (2004) 8(1/2) *TRAMES* 164; Kaye and Martin, 'Safeguards for Research', above n 5; G Laurie, *Genetic Privacy: A Challenge to Medico-legal Norms* (Cambridge, Cambridge University Press, 2002).

<sup>12</sup> S Holm, 'There is Nothing Special About Genetic Information' in AK Thompson and RF Chadwick (eds), *Genetic Information: Acquisition, Access, and Control* (London, Kluwer Academic/Plenum Publishers, 1999); LO Gostin and JG Hodge, 'Genetic Privacy and the Law: An End to Genetics Exceptionalism' (1999) 40 *Jurimetrics* 21; TH Murray, 'Genetic Exceptionalism and "Future Diaries": Is Genetic Information Different from Other Medical Information?' in MA Rothstein (ed), *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (New Haven, CT, Yale University Press, 1997).

<sup>13</sup> BM Knoppers, 'Of Populations, Genetics and Banks' (2001) 1 *Genetics Law Monitor*; Árnason and Árnason, 'Informed Democratic Consent' above n 11.

<sup>14</sup> HDC Roscam Abbing, 'Central health Database in Iceland and Patient's Rights' (1999) 6 *European Journal of Health Law* 363; JR Gulcher, K Kristjánsson, H Guðbjartsson and K Stefánsson, 'Protection of Privacy by Third-Party Encryption in Genetic Research in Iceland' (2000) 8 *European Journal of Human Genetics* 739.

<sup>15</sup> J Kaye, 'Abandoning Informed Consent: The Case of Genetic Research in Population Collections' in R Tutton and O Corrigan (eds), *Genetic Databases: Socio-ethical Issues in the Collection and Use of DNA* (London, Routledge, 2004); T Caulfield, REG Upshur and A Daar, 'DNA Databanks and Consent: A Suggested Policy Option Involving an Authorization Model' (2003) 4(1) *BMC Medical Ethics* 1; E Wright Clayton, KK Steinberg, MJ Khoury, E Thomson, L Andrews, MJ Ellis Kahn, LM Kopelman and JO Weiss, 'Informed Consent for Genetic Research on Stored Tissue Samples' (1995) 274(22) *Journal of the American Medical Association* 1786; G Williams and D Schroeder, 'Human Genetic Banking and the Limits of Informed Consent' in P Glasner (ed), *Reconfiguring Nature: Issues and Debates in the New Genetics* (Aldershot, Ashgate, 2004).

<sup>16</sup> S Eriksson, 'Should Results from Genetic Research be Returned to Research Subjects and Their Biological Relatives?' (2004) 8(1/2) *TRAMES* 46.

<sup>17</sup> Korts, Weldon and Guðmundsdóttir, 'Genetic Databases and Public Attitudes', above n 11; AC da Rocha, 'Ethical Aspects of Human Genetic Databases: Distinctions on the Nature, Provision, and Ownership of Genetic Information' (2004) 8(1/2) *TRAMES* 34.

in decision-making;<sup>18</sup> protecting privacy;<sup>19</sup> access;<sup>20</sup> ownership;<sup>21</sup> and intellectual property<sup>22</sup> (especially patents and copyright).<sup>23</sup>

However, it was unclear whether the principles that were being proposed for the population biobanks that were being developed as research resources would or should also be applicable to smaller collections established for specific research projects focusing on particular diseases. In addition, it was not appropriate simply to transplant such principles into the UK context without considering carefully their potential implications and fit.<sup>24</sup> For instance, a blanket requirement that all research collections should have an independent oversight body, such as that proposed at the time for UK Biobank, clearly would have been unduly burdensome if applied to a collection of several hundred samples, maintained by one research group, for a single research project. Accordingly, the principles being developed within the context of the population biobanks debate needed to be assessed carefully before being applied to other types of collections, and sound reasons needed to be identified and articulated before such principles were accepted, modified or rejected.

In 2005, the Human Tissue Act 2004 was still to be fully implemented. The Human Tissue Authority, which had the authority to issue codes of practice and licences to regulate tissue collections, had just been established. At that time, it remained uncertain whether (or how far) the scope of its authority would extend to genetics and biobanks. Now that the Act is fully operational, it is evident that extracted DNA falls largely outside its scope. While the regulation of biobanks by such a body as the Human Tissue Authority was seen by many as a means to bring some much needed

<sup>18</sup> RR Sharp and MW Foster, 'Involving Study Populations in the Review of Genetic Research' (2000) 28(1) *Journal of Law, Medicine and Ethics* 41.

<sup>19</sup> S Alpert, 'Privacy and the Analysis of Stored Tissues', commissioned paper, National Bioethics Advisory Commission *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance* (Rockville MD, The Commission, January 2000) vol II, A-1; Laurie, *Genetic Privacy*, above n 11; MA Rothstein, 'Genetic Secrets: A Policy Framework' in MA Rothstein (ed), *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (New Haven, CT, Yale University Press, 1997).

<sup>20</sup> BM Knoppers, M Hirtle, S Lormeau, CM Laberge and M Laflamme, 'Control of DNA Samples and Information' (1998) 50 *Genomics* 385.

<sup>21</sup> Rocha, 'Ethical Aspects of Human Genetic Databases', above n 17.

<sup>22</sup> T Caulfield, 'Regulating the Commercialization of Human Genetics: Can We Address the Big Concerns?' in AK Thompson and RF Chadwick (eds), *Genetic Information: Acquisition, Access, and Control* (New York, Kluwer Academic/Plenum Publishers, 1999).

<sup>23</sup> HT Greely, 'Informed Consent and Other Ethical Issues in Human Population Genetics' (2001) 35 *Annual Review of Genetics* 785; HT Greely, 'Human Genomics Research: New Challenges for Research Ethics' (2001) 44(2) *Perspectives in Biology and Medicine* 221; S Wilson, 'Population Biobanks and Social Justice: Commercial Or Communitarian Models? a Comparative Analysis of Benefit Sharing, Ownership and Access Arrangements' (2004) 8(1/2) *TRAMES* 80.

<sup>24</sup> JE Wylie and G Mineau, 'Biomedical Databases: Protecting Privacy and Promoting Research' (2003) 21 (3) *TRENDS in Biotechnology* 113.

clarity and certainty to the situation, this would not be an easy task—not least, as no typology had ever been developed of the various kinds of human biobanks used for research purposes in this jurisdiction. (The EUROGENEBANK Project did carry out a survey of ‘biobanks’, but this was based only on information from 12 respondents from across the UK.<sup>25</sup>) Also, no research had been conducted either into the question of what a biobank would look like if it were to be constructed and run in conformity with the legal requirements, or, beyond the appropriate limits of law, the ethical principles that should apply to different types of biobanks. Without such research, we felt that the regulatory bodies would be left in a quandary, having to attempt to regulate the unknown. An anticipated output of our project, then, was to provide an evidence base for such authorities to develop guidelines for governing biobanks within England and Wales, which would be based on a clear understanding of both the theoretical and practical issues that practitioners were facing.

#### OTHER PROJECTS

Prior to the research reported in this book, there had been no research projects of this size focused specifically on the governance of biobanks within the UK. Some studies had been conducted on biobanks within Europe. The ELSAGEN<sup>26</sup> project (2002–2005), for example, compared four population biobanks that had been or were in the process of being established: namely, the Icelandic Health Sector Database (1999), the Estonian Genome Project (2000), the Swedish UmanGENE and UK Biobank (2001). The approach of the ELSAGEN project was to carry out empirical research into public attitudes to these biobanks and to compare the legal frameworks and regulatory bodies in each jurisdiction, whilst also focusing on the ethical concerns around population biobanks in these countries.<sup>27</sup> As a member of this consortium, we could draw upon the legal research. The European Commission also had funded a number of projects that focused on the ethical, legal and social issues of biobanking. The EUROGENEBANK Project<sup>28</sup> involved a quantitative survey to determine the numbers and types of biobanks that were in existence and what they were being used for in six European countries, as a first step towards a comprehensive audit of biobanks. More recent projects on biobanking concerns are GeneBanC

<sup>25</sup> Hirtzlin et al, ‘An Empirical Survey on Biobanking’, above n 2.

<sup>26</sup> European Commission Framework 5, Quality of Life grant, ‘Ethical, Legal and Social Aspects of Genetic Databases’, above n 4.

<sup>27</sup> V Árnason et al (eds), *Your Genes in a National Bank? Ethical, Legal and Social Concerns* (Cambridge, Cambridge University Press, 2008).

<sup>28</sup> Hirtzlin et al, ‘An Empirical Survey on Biobanking’, above n 2.



(2006–2009)<sup>29</sup> and PRIVILEGED (2007–2009)<sup>30</sup> which focus on privacy and data protection issues, and Tiss.EU (2008–2011) that is concerned with the legal frameworks for samples and tissue across the European Union.<sup>31</sup>

Governance in genomics was a little explored area in the literature at this time with only a Wellcome Trust report<sup>32</sup> and a paper<sup>33</sup> by Paul Martin on the specific topic of governance and biobanks in the UK. Since then, governance of biobanks has become a topic of greater interest and concern.<sup>34</sup> There have been a number of papers using legal analysis that have concentrated on how current legal requirements might apply to biobanks within the UK and Europe.<sup>35</sup> There have also been a number of empirical studies that have sought the opinions of research participants and the general

<sup>29</sup> <http://www.genebank.eu/> (accessed 30 January 2011).

<sup>30</sup> <http://www.privileged.group.shef.ac.uk/> (accessed 30 January 2011).

<sup>31</sup> <http://www.tisseu.uni-hannover.de/index.php> (accessed 30 January 2011).

<sup>32</sup> P Martin and J Kaye, *The Use of Biological Sample Collections and Personal Medical Information in Human Genetics Research* (London, Wellcome Trust, 1999).

<sup>33</sup> Martin, 'Genetic Governance', above n 7.

<sup>34</sup> See, eg, J Gerards and H Janssen, 'Regulation of Genetic and Other Health Information in a Comparative Perspective' (2006) 13 *European Journal of Health Law* 339 [esp s 4]; M Majumder, 'Cyberbanks and Other Virtual Research Repositories' (2005) 33 *Journal of Law Medicine and Ethics* 31; M Deschenes and C Salle, 'Accountability in Population Biobanking: Comparative Approaches' (2005) 33 *Journal of Law Medicine and Ethics* 40 [esp s 3]; M Rothstein, 'Expanding Ethical Analysis of Biobanks' (2005) 33 *Journal of Law Medicine and Ethics* 89 [esp p 97]; D Winickoff, 'Partnership in UK Biobank: A Third Way for Genomic Property' (2005) 33 *Journal of Law Medicine and Ethics* 440 [esp 445–50]; H Gottweis and K Zatloukal, 'Biobank Governance: Trends and Perspectives' (2007) 74 *Pathobiology* 206; S Wallace et al, 'Governance Mechanisms and Population Biobanks: Building a Framework For Trust' (2008) 6(2) *GenEdit* 11; B Salter and M Jones, 'Biobanks and Bioethics: The Politics of Legitimation' (2005) 12 *European Public Policy* 710; SMC Gibbons, 'Regulating Biobanks: A Twelve-Point Typological Tool' (2009) 17 *Medical Law Review* 313; J Kaye and M Stranger (ed), *Principles and Practice in Biobank Governance* (Aldershot, Ashgate, 2009).

<sup>35</sup> BM Knoppers, 'Biobanking: International Norms' (2005) 33 *Journal of Law Medicine and Ethics* 7; A Cambon-Thomsen, E Rial-Sebbag and BM Knoppers, 'Trends in Ethical and Legal Frameworks for the Use of Human Biobanks' (2007) 30 *European Respiratory Journal* 373; LB Andrews, 'Assessing Values to Set Policies for Consent, Storage, and Use of Tissue and Information in Biobanks' in K Dierickx and P Borry (eds), *New Challenges for Biobanks: Ethics, Law and Governance* (Antwerp and Oxford, Intersentia, 2009); DE Winickoff, 'Biosamples, Genomics, and Human Rights: Context and Content of Iceland's Biobanks Act' (2001) 4 *Journal of Biolaw and Business* 11–17; M Anderlik, 'Commercial Biobanks and Genetic Research: Ethical and Legal Issues' (2003) 3 *American Journal of Pharmacogenomics* 203–15; T Caulfield, 'Tissue Banking, Patient Rights, and Confidentiality: Tensions in Law and Policy' (2004) 23 *Medical Law International* 39–49; G Richardson, 'The Banking of Embryonic Stem Cells: The Legal and Ethical Framework in the UK' (2004) 20 *Law Human Genome Review* 147–60; J Kaye, 'Do we Need a Uniform Regulatory System for Biobanks Across Europe?' (2006) 14 *European Journal of Human Genetics* 245–46; SMC Gibbons et al, 'Lessons from European Population Genetic Databases: Comparing the Law in Estonia, Iceland, Sweden and the United Kingdom' (2005) 12(2) *European Journal of Health Law* 103; J Kaye, HH Helgason, A Nömper et al, 'Population Genetic Databases: A Comparative Analysis of the Law in Iceland, Sweden, Estonia and the UK' (2004) 8 *TRAMES* 15–34.