HUMAN GENETIC DATA BANKS: FROM CONSENT TO COMMERCIALIZATION – AN OVERVIEW OF CURRENT CONCERNS AND CONUNDRUMS

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Contents

Summary

Biobanks are not a new phenomenon but they have changed in line with scientific developments particularly in the area of genomics. They have moved from small-scale clinical and academic tools to large-scale population and specific disease collections. Since DNA banks are optimistically regarded as essential resources to finding connections between genes and many common diseases and to developing more individualist predictive medicine, significant financial investment has been poured into the upkeep and continued development of these banks, even though the current expectations of their immediate benefit may be overstated. DNA databanks, like human genetic research, is the subject of much legal, ethical and social debate. Issues

raised by the establishment and use of these databanks are related to consent, confidentiality, privacy, access and genetic discrimination. Each issue raises debate over the balancing act between individual autonomy and notions of community, common heritage and solidarity. Interestingly, the controversy that surrounds commercialization tends to ignore both the individual and common heritage notions. Concerns arise particularly where banks and related research give rise to 'spin off' companies, commercial development and the establishment of property rights. Considerable debate exists as to whether the development of biomedical products will translate into significant public benefit or whether greater support, particularly in the context of publicly funded health care programs, is needed. In order to sustain ongoing support for DNA databanks and deal with public concerns it may be worthwhile to consider public involvement with DNA database and research stakeholders. If partnership is not feasible, then some imaginative way of collaboration may, rather than being onerous, facilitate research, protect individual rights and advance commercial interests.

1. Introduction

Building on remarkable developments in genomics and information technology, several human genetic data bases (also referred to as databanks or biobanks) have been set up around the world. The questions and concerns raised by the development and management of such databanks range from specific legal/ethical issues such as informed consent, privacy, confidentiality, and discrimination, to broader social justice concerns associated with the commercial operation of these databanks or the commercialization of research findings resulting from the use of these banks. Debates about benefit sharing, ownership and access to genetic data are associated with the commercialization of the databanks. This chapter aims at giving an overview of the legal, ethical, and social issues raised by the development of these databanks.

Biobanks are not new, although they have changed in line with significant scientific developments, particularly in genomics. They clearly have become the subject of much more social debate. No longer simply small-scale clinical and academic research tools, they now often consist of large-scale collections of significant disease, ethnic, or geographically located populations. Biobanks have become increasingly prevalent due to the growth of biomedical research, the rising size of collections, the technical and computational advances of procedures such as high-throughput genomics techniques and large scale SNP genotyping to characterize genetic variation, and the evolving exchange practices of biological material and information amongst researchers.

DNA biobank projects are expected to contribute to relieving human suffering, improving health, and rendering health care more efficient. They are likely to lead to an increased understanding of the genetic components of health and disease. The applications of this improved understanding may have a huge impact, through better disease prevention and improved health care interventions. From this perspective, there is a strong case to be made for the development of genomic and population genomic research.

Indeed, DNA biobanks are being touted as an essential resource to finding connections

between genes and many (common) diseases as they permit medical, genetic and sometimes genealogical data to be compiled, housed, analyzed, compared, merged or cross-matched for associations. They are also being supported as a step forward in ushering in more individualistic predictive medicine, associated with developments in pharmacogenomics, which offers the possibility of tailoring drugs to individual genetic profiles and the potential of minimizing adverse drug reactions.

However, in spite of the significant investments in these databanks and the advances in technology, it should be noted that all these goals will not easily be achieved. The benefits and expectations of databanks may often be overstated. The actual science of finding links between the location and sequence of genetic variations and human disease and determining the causes of and treatments for disease is still in its infancy. Research linking genetic variation to disease focused in the past on rare diseases caused by mutations of highly penetrant single gene diseases such as Huntington's disease. With the search for both genetic and non-genetic causes to common multifactorial diseases such as cancer and diabetes now on the agenda, research has shifted and expanded enormously – at great financial - and at times seemingly great individual and community, cost.

This paper first describes various types of biobanks before turning to a series of common ethical and legal issues raised by the development of biobanks and by research involving banked tissue. These issues include consent, privacy, discrimination, commercialization, benefit sharing and ownership. As will become clear, regardless of the nature of the biobank, involvement of participants and related communities in some capacity is likely essential to the initiation, ratification and implementation of any database project. Values embedded in the often used term "common heritage of humanity," and values of solidarity and public benefit need to be balanced against individual autonomy and the right to self-determination, as well as against efforts to advance and promote research. Despite the fact that scientific advances are expected with regard to identifying disease associated genes and predictive personalized medicine, the concerns and conundrums raised over the general issues are cause for further thought and debate that may be useful beyond the context of DNA biobanks.

2. Types of Biobanks: Population Banks vs. Disease Specific Banks

2.1 Types of Banks

The development of population databanks depends in part on the socio-economic, political, and current health context of the country in which these banks are developed. Some countries, like for example Estonia, may be eager to promote a genetic research sector through the establishment of a population databank, as part of an overall strategy to further develop their economy. Other countries, such as the UK, may already be a leader in genetics research, and use a population databank both as a tool of industrial development and to improve their existing health care system. Other disease-specific data banks may have been developed as a result of historical initiatives of local researchers, or because of the high prevalence of specific rare diseases in the region. The historical development and the socio-economic context in which the databases

have been developed may affect all aspects of the database, from consent to concerns about discrimination.

2.1.1 Population Biobanks

Population biobanks are a testament to the shift that has taken place from local to national and international projects. They are designed as research infrastructures rather than as projects aimed at the study of a particular illness or genetic characteristic. They constitute strategic resources, allowing for the conduct of research involving data originating from populations or communities that may be separated by distance or in time. The resulting research may lead to the production of new data, which may in turn enrich the initial database. As platforms for research they are established over a prolonged period often spanning several generations; thus the anticipated results and benefits need also be considered over the long term. The hope is that large-scale DNA collections will open up the possibility of prediction and prevention of disease from a public health perspective. Databanks in Iceland, Estonia, the province of Quebec, Sweden, Norway, and the United Kingdom provide some of the best-known models of this form of biobank.

A population–based genetic study is defined in *UNESCO*'s Declaration on Human Genetic Data as "[a] study which is aimed at understanding the nature and extent of genetic variation among a population or individuals within a group or between individuals across different groups." To understand the complexity of common multifactorial diseases and the contribution of gene-environment interactions to disease, recourse to large collections of samples derived from individuals from one or more communities or populations is required. Since comparisons are statistical in nature, to be meaningful, they need to be performed on a large scale and involve samples from both patients and healthy controls. They are also most powerful when carried out on cohorts of patients and healthy controls having a common ethnic origin so as to minimize unrelated variations.

Since population genetic databases are a structured collection of material, discoveries and inventions, they could ordinarily be covered by regulations on data collection and intellectual property. But, what makes population genetic databases unique is that it involves the altruistic participation of many people, sharing a common heritage, with the potential for research results to benefit society in a number of ways. There are few examples of such mass contribution to a project conducted by a comparatively small number of researchers where benefits are typically concentrated in the hands of a small number of stakeholders (unless contractually agreed otherwise). In the context of genetic databases, the old adage of "strength in numbers" does not seem to apply.

2.1.2 Specific Disease Banks

Other banks respond to a specific scientific need, that is, samples from individuals with a rare disease or from families with multiple cases of the same disease. Although sometimes difficult to achieve, an appropriate sample size is needed for adequate statistical research analysis. There are a variety of single disease repositories ranging from the study of cystic fibrosis to cancers including breast and colon cancer. For

example, in the case of colon cancer, The Ontario Familial Colon Rectal Cancer Registry (OFCRC), created in 1997 as part of an initiative of the U.S. National Cancer Institute and the first of its kind in Canada, collects detailed health and genealogical data, as well as blood samples and tumour tissue, from colorectal cancer patients and their families in Ontario.

In the last decade, there is a clear move towards greater participant involvement. Some high profile controversies may have contributed to this development. One controversy involving Canavan disease led to significant debate within the scientific community and resulted in the legal case of *Greenberg v. Miami's Children's Hospital and Reuben Matalon*. The case arose as a complaint by members of families affected by Canavan disease, who had actively been involved in the promotion and development of research on the disease. With Greenberg at the helm, they helped with the recruitment of participants, the collection of samples, the establishment of a registry, financial support, and access to other established registries all in an effort to develop relevant genetic testing and potential treatment for the disease. The members of these families were upset when they realized that the researchers and institutions involved had concluded restrictive licensing agreements and charged money for the carrier and prenatal genetic tests that had been developed with their help. The families argued that the payment charged for the tests impeded access to testing that they had greatly assisted in.

In reaction to the perceived loss of control over biological samples, some disease groups may now organize themselves by creating their own databanks and playing an essential role in access to samples and facilitation of research. PXE International, a Washington, DC based foundation of sufferers of the connective tissue disorder condition pseudoxanthoma elasticum (PXE), stands as a prime example of a patient advocated, disease specific database. The development of the PXE International Blood and Tissue Bank, initially founded and privately funded by the Terry's, parents of two children affected by the disease, now finances itself through both private and public funds. The bank is the only centralized repository in the world of blood and tissue samples from people affected by PXE. It has been one of the most significant contributors to advances in PXE research. The disease-specific biobank accelerated the discovery of the PXE gene, assisted in the development of a diagnostic test that may become the first for a rare condition, and negotiated joint possession of intellectual property rights to ensure broad and affordable availability of testing and to retain influence over downstream development.

Unlike the 'big' diseases of cancer or diabetes, specific disease banks often lack the funding and collective power to effectively bargain with researchers. What is unique about PXE and other groups like the Alpha –1 Foundation (a Florida non-profit group representing α-1 antitrypsin deficiency) is that these banks are rooted in the concept of autonomy. Informed consent provides the participant with a trump card to steer researchers toward working on finding the gene associated with their disease and to negotiate acceptable benefit terms on which researchers may use the tissue concerned. Disease like PXE and Alpha –1 are not 'blockbuster' diseases like diabetes or cancer with researchers lining up to work on the condition. But, if the gene PXE or Alpha-1 plays a role in the development of hypertension or cardiovascular disease, then PXE

may use their collection as a negotiating tool: access to samples in exchange for finding a test or cure for PXE. Many ethical and legal concerns can be addressed by improving communication and open debate between researchers and participants control over the purpose, use and exploitation of biobanks and related research projects.

3. Legal and Ethical Issues in the Establishment and Use of Biobanks: How to Reconcile Autonomy with the Existence of Common Interests?

3.1. Consent

Informed consent is defined as 'autonomous authorization' - protecting both the autonomy of the individual and the fundamental right to decide. True informed consent is strictly defined as specific consent given for well-defined uses. It requires intentional non-coerced decision making based on sufficient information, substantial understanding, the possibility of dialogue, and time to think about the implications before a decision is taken. In some jurisdictions, the term 'informed choice' is preferred, to highlight the fact that it is more than simply accepting a proposal, i.e. that it involves the ability to make a meaningful choice. It is not easy to apply this concept in the context of large-scale biobanks, related research projects, long-term use of samples or data, and numerous exchanges. The main stumbling block is the difficulty in adequately informing participants of the nature and purpose of the research as well as possible risks or benefits, since it is difficult to foresee how pharmacogenetic, genetic or biomedical research will develop in years to come. Consent in this light only amounts to broad open consent, which for some authors is equivalent to no consent at all.

Principles of informed consent are certainly applicable to research on human beings in general. Yet the core ideas behind the concept, namely autonomy and self-determination, need to be considered in the specific context of biobanks. Autonomy and self determination imply that people can decide what is done to their body and body parts and what measures might be taken that affect their personal (informational) sphere. This notion extends to the handling of bodily substances intended for biobanks and the right to decide on the use to which one's personal data may be put.

It seems important to pay attention to the need to respect people's autonomy, and thus to promote informed consent in the context of genetic data base research. However, an over-emphasis of the need for informed consent may sometimes obscure the fact that there are important broader issues at stake, which relate to the collective nature of biobanks. Biobanks raise issues related to science and health policy, to solidarity in research participation and distribution of benefits, and so on. Some authors have therefore suggested that while informed consent is a necessary condition for the establishment and use of biobanks, it is not a sufficient one. In this sense further discussion may be needed to determine how an individual perspective can be reconciled with a more collective perspective to more fully promote health and societal well-being. This seems to be in line with the notion that genetic information exists at both the personal (individually unique) and collective (shared by all of us) levels. An informed consent process that honours both the individual and the collective may more

adequately respond to special context of human genetic databases.

It should also be noted that informed consent is an ideal that is rarely if ever fully achieved. An over-emphasis on consent, without sufficient attention to societal, economic, structural and other challenges to individual decision-making, may undermine rather than protect the interest of individuals. It is worth reiterating in this context that informed consent does not itself protect individuals, rather it allows individuals to exercise their right to decide whether and how their body, its parts and the associated data will be used in research. Reasons for limitation on this right relate to the need to protect people in vulnerable positions, to promote solidarity, or to recognize that people sometimes have to relinquish some control over the use of their own samples and data for the common good. In addition, it can be argued that some limits on individual freedom actually may promote a more valuable concept of autonomy, i.e. autonomy that is associated with a the ability to make meaningful decisions with the notion of human flourishing. There are several different types of consent, with varying degrees of limitations on the right to decide.

3.1.1. Types of Consent

Consent may be specific, general, presumed, and on an individual or group basis. The conundrum is that while it is impossible to consent to research that is not yet foreseen, it is also true that at the time of the giving of samples, future research is almost a given, even if the ambit of future research is not yet clear. Does it make sense to speak of consent when future uses are neither known nor understood?

3.1.1.1. General and Specific Consent

The trend seems to be toward general consent as opposed to specific consent despite difficulties in obtaining informed consent.

The Estonian *Human Genome Research Act* requires a donor's consent to be explicit without exception. In Sweden, the *Biobank [Medical Care] Act* also requires explicit consent for the collection of biological samples. However the Swedish Act only regulates samples collected in connection with health care and does not have a special category for research biobanks. The *Swedish Personal Data Act* provides an exception from the requirement of explicit consent in the case of sensitive personal data to be processed for health care, treatment, hospital care services, and so on. Some authors have suggested that this exception allows for too broad an exception since it permits the processing of a great deal of personal data into biobanks without consent. In Norway, *the Act Relating to Biobanks* provides for explicit consent in the case of research biobanks, which are specifically set out in the legislation. It also requires that previously collected material and data put to a different, wider, or new use other than that provided for in the original consent, obtain new, voluntary, express, and informed consent except in circumstances where new consent is too difficult to achieve. Anonymized material does not require consent, but must be assessed by a regional ethics committee. Other statues take a similar approach.

Generally speaking, with specific consent, biological samples can only be used for a very clearly defined purpose. It requires re-contacting for each new purpose not

foreseen in the initial consent although it is not entirely clear whether new research with similar ends requires re-contacting. At its extreme, participants may need to consent to each and every use of their DNA sample. When specific consent is strictly imposed, consent has to be given for each physical taking, each research purpose, and each commercial application. Each time, information has to be provided as to the nature of the procedures, the risks and benefits, and so on. Although specific consent seems to be most in line with the idea of protecting individual autonomous choice, and in keeping with the notion that consent is an ongoing rather than static process, it comes at a high cost in terms of research resources, time and manpower. It is also likely to involve considerable intrusion into participants' personal lives.

General or broad consent on the other hand, allows samples to be used for purposes unforeseen and not specifically delineated at the time of the initial collection without the need for participant re-contact. This type of consent restricts any undue emphasis on autonomy that may impede on collections or research for the pubic good.

There is much support for broad consent for population genetic databases: The World Health Organization, in its *Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetics Services*, considers it to be the most efficient and economical approach. Various other consultative bodies, such as the German Nationaler Ethikrat, the European Commission, the French Comite Consultatif National d'Ethique and the HUGO Ethics Committee have also endorsed or recognized the approach in recent recommendations or reports. Its use is justified by two main arguments: (i) it is impossible to obtain informed consent for practical reasons and (ii) there is minimal risk to participants as information will be anonymous. Some authors, such as Kaye, argue that broad consent should only be permissible where combined with opt out consent for secondary uses and accountable, transparent, oversight mechanisms are in place.

Other authors have pointed out that while the occurrence of further possible uses has not always been predictable, it is now at least a foreseeable event even if future uses cannot be defined in detail. At the start of all new collections it may be wise to set a policy for future uses in the protocol, with appropriate information and consent to provide as much transparency as possible. The goal is to protect the possibility of long term broader uses within a framework that protects participant rights and collective interests.

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Bibliography

Act on Health Sector Database no.139/1998 [Iceland's Act is a pioneer in the field but remains infamous

for its presumed consent provisions. Despite ongoing questions about encryption, the Act still provides a strong regulatory framework. Questions about its encryption process remain].

Act Relating to Biobanks [Norway's Act No. 12 of 21 February 2003 on Biobanks. Entered into force July 1, 2003, pursuant to Royal Decree May 23, 2003. Ensures material in biobanks used for health related purposes, including diagnosis, treatment, research & teaching in a way that meets satisfactory ethical standards]

Allen A. L. (1997). Genetic Privacy: Emerging Concepts and Values. *Genetic Secrets; Protecting Privacy and Confidentiality in the Genetic Era* (ed. M. A. Rothstein), 31. New Haven: Yale University Press. [Sets out the cluster of privacy].

Annas G. J. (2000). Rules for Research on Human Genetic Variation - Lessons From Iceland. *New England Journal of Medicine* 324(24), 1830.

Árnason V. (2004). Coding and Consent: Moral Challenges of the Database Project in Iceland *Bioethics* 18, 27.

Atkinson Grosjean J. (2006). *Public Science, Private Interests: Culture and Commerce in Canada's Networks for Centres for Excellence*. Toronto: University of Toronto Press.

Biobanks in Medical Care Act No. 297 of May 23, 2003. [Sweden's Act in force as of Jan. 1, 2003. Ensures regulation as part of medical care].

Bovenberg J. (2005). Whose Tissue is it Anyway? *Nature Biotechnology* 23:8, 929. [New tax system may provide and alternate and equitable balance between the rights of researchers and donors of biological material].

Bovenberg J. (s.d.) (2006). *Property Rights in Blood, Genes and Data*. Nijhoff Law Specials Vol. 66. Leiden: Martinus Nijhoff Publishers.

Cambon –Thomsen A. (2004). The Social and Ethical Issues of Post-Genomic Human Biobanks *Nature Reviews Genetics* 5, 866. [Genomics research which thrives on sharing samples and information is affected by ethical questions: do ethical principles prevent of promote sharing if stored sources? How does large scale biobanking alter the way in which ethical issues are addresses].

Cambon-Thomsen A., Sallée C. et al. (2005) Populational Genetic Databases: Is a Specific Ethical and Legal Framework Necessary? *GenEdit* 3:1, 1 [Despite the lack of harmonization of rules, international texts have become increasingly more specific].

CARTaGENE, A Genetic Map of Quebec.

[See onlinehttp://www.cartagene.qc.ca/index2.cfm?lang=1. CARTaGENE is a longitudinal project on population genomics for the study of health and disease in aging that will collect and analyze DNA, social, health and environmental information from Quebec's population aged 25- 69 years of age].

Caulfield T. Upshur R. & Daar A. (2003) DNA Databases and Consent: A suggested Policy Option Involving an Authorization Model. *BMC Medical Ethics* 4,1. [Good overview of the difficulty of consent in biobanking].

Council of Europe, Convention on Human Rights and Biomedicine. (Oviedo April 4, 1997).

[Available online at: http://conventions.coe.int/treaty/en/treaties/html/164.htm. Article 11 refers to prohibition of discrimination and Article 12 refers to predictive genetic testing stating that it can only be undertaken for health purposes or for research that is linked to such purposes].

Deschênes M. Cardinal G. et al. (2001) Human Genetic Research, DNA Banking and Consent: A Question of 'Form'? *Clinical Genetics* 59 (4), 221.

Estonian Genome Project [See online http://www.geenivaranu.ee for details of the population project which are focuses on returning information and benefit to individuals].

European Commission. (2004). *Ethical, Legal and Social Aspects of Genetic Testing; Research, Development and Clinical Applications*. Brussels: European Commission.

[The] European Parliament and The Council of the European Union. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 *on setting standards of quality and safety for*

the donation, procurement, testing, processing, storage and distribution of human tissues and cells. Off. J. Eur. Union 47. L102/48-L102/58.

French National Advisory Bioethics Committee (CCNE). (2003). *Ethical Problems Raised by the Collected Biological Material and Associated Information Data: 'Biobanks', 'Biolibraries.* Paris: French National Advisory Bioethics Committee.

German National Ethics Council. (*2004). Biobanks for Research: Opinion. Nationaler Ethikrat: Berlin* [Presents a comprehensive overview of biobanking issues].

Godard B. Schmidtke J. et al. (2003). Data Storage and DNA Banking for Biomedical Research: Informed Consent, Confidentiality, Quality Issues, Ownership, Return of Benefits. A Professional Perspective. *Eur. J. Hum. Genet* 11(2), 88.

Greely, H. T. (2001) Informed Consent and Other Ethical Issues In Human Population Genetics. *Annu.Rev.Genet* 35, 785.

Greenberg v. Miami's Children's Hospital and Reuben Matalon (October, 2000). [Plaintiff's action was for damages and equitable and injunctive relief to redress defendant's breach of informed consent, breach of fiduciary duty, unjust enrichment, fraudulent concealment, conversion and misappropriation of trade secrets.]

[The] Health Information Act, R.S.A. 2000, c.H-5 [Alberta Act speaks specifically of public benefit].

Hellman D. (2003). What Makes Genetic Discrimination Exceptional? *American Society of Law and Medicine* 29, 77. [Argues that special legislation is warranted to prohibit genetic discrimination].

Human Genes Research (2000). Official translation, passed December 13, 2000, State Gazette (RT1 I 2000, 104, 685) December 29, 2000, entered into force January 8, 2001) [The main objective of the Estonian Act is to regulated scientific research in the field of human genetics. By incorporating the principles pf voluntary donorship and informed consent and creating rights to donor access and less restricted access to researchers, it is regarded by some as more comprehensive]

Human Genetics Commission (2002), *Inside Information: Balancing Interests in the Use of Personal Genetic Data.* London: Human Genetics Commission. [UK government independent advisory committee on social and ethical issues in human genetics. Provides conclusions and recommendation based on wide inquiry].

Human Genome Organization (HUGO) Ethics Committee. (2000). *Statement on Benefit Sharing.* London: HUGO. [Refers to an emerging international consensus that groups participating in research should, at a minimum, receive some benefit.]

Human Genome Organization (HUGO) Ethics Committee. (2002). *Statement on Human Genomic Databases*. London: HUGO.

Knoppers B. M., Joly Y. et al. (2006). The Emergence of an Ethical Duty to Disclose Genetic Research Results. *Eur. J. Hum. Genet*. 14 :11, 1170.

Icelandic Database Project. [Attracted attention in part because a national law ratified a public-private partnership. [See Act on Biobanks, no.110-2000; Act on Health Sector Database no.139/1998; deCODE website, online: < http://www.database.is>; Mannvernd Website, online: www.mannvernd.is who represents opposition to the bank].

Kohane S. & Altman R.B. (2005). Health Information Altruists – as a Potentially Critical Resource. *N.E.J.M.* 353:19. 2074. [Giving patients control of the use of their health data will provide a practical mechanism for harnessing volunteerism of populations and gathering research data].

Laurie, G. (2004). Privacy and Property? Multi-Level Strategies for Protecting Personal Interests in Genetic Material. *Genomics, Health and Society: Emerging Issues for Public Policy (*eds. B. M. Knoppers & C. Scriver), *Canada; Government of Canada, Policy Research Institute.*

Lemmens T. Joly Y. &. Knoppers B. M. (2004). Genetics and Life Insurance: A Comparative Analysis. *GenEdit* 2:3, 2.

Lemmens T. (2003). Genetics and Insurance Discrimination: Comparative Legislative, Regulatory and Policy Developments and Canadian Options. Special Edition: Precedent and Innovation: Health Law in

the 21st Century,) *Health Law Journal* Special Supplement 41. [Overview of initiatives in the context of insurance with respect to the prohibition of genetic discrimination].

Lemmens T. Lacroix M. & Mykitiuk R. (2007, forthcoming). *Reading the future? Legal and Ethical Challenges of Predictive Genetic Testing.* Montreal: Thémis. [Looks at pitfalls of a genetics specific approach].

Martin P. & Kaye J. (1999). The Use of Biological Sample Collection and Personal Medical Information in Human Genetics Research: Issues for Social Science Research and Public Policy. *Background Paper for Wellcome Trust Workshop on 'The Collection of Human Biological Samples for DNA and other Analysis*' London: Wellcome Trust.

McInerney v. MacDonald [1992] 2 S.C.R. 138. [Leading case on confidentiality in Canada].

Merz J. F., Magnus D. et al. (2002). Protecting Subjects' Interests in Genetics Research. Am. *J. Hum.Genet* 70, 965. [Emphasis on Greenberg case and benefit sharing].

Moore v. Regents of the University of California (1991) 793 P.2d 479 (cal.1990), *cert denied* 111 S.Ct. 1388 . [Court denied property interests in excised cells that were used to develop a new product without the knowledge of the donor].

Ontario Personal Health Information Privacy Act S.O. 2004, c.3, Schedule A.

Pate v. Threkel 661 So.2d 278, 282 (Fla. 1995). [Court limited obligation of physician to telling patient about the importance of contacting family members]

Personal Information Protection and Electronic Documents Act (PIPEDA).S.C. 2000, c.5.

Porter G. (2004). The Wolf in Sheep's Clothing: Informed Consent Forms as Commercial Contracts. *Blood and Data, Ethical, Legal and Social Aspects of Human Genetic Databases, (eds.* G. Árnason. S. Nordal & V. Árnason), 85. Reykjavik, Iceland: University of Iceland Press and Center for Ethics.

[The] President's Commission for the Study of the Ethical Problems in Medicine and Biomedical and Behavioural Research. (1991). *Screening and Counselling for Genetic Conditions: The Ethical, Social and Legal Implications of Genetic Screening, Counselling and Education Programs*. Washington, D.C.: Government Printing Office.

PXE International. [See online: <http://www.pxe.org/>. Unique example of disease advocacy group that has become leader in partnering with researchers].

Ragnhildur Gðumundsdóttir v. The State of Iceland [Available at

http://www.mannvernd.is/english/lawsuits/Icelandic_Supreme_Court_Verdict_151_2003.pdf. which provides a legal translation of the case by a court authorized translator. The court noted that extensive information is found in medical records and that is it unclear what information from the medical records would be encrypted. Even though provisions of the HSD stipulate that the health information is non-personally identifiable, the Court felt that it is far from clear that this objective will be achieved.]

Rao R. (2000). Property, Privacy and the Human Body. *Boston University Law Review* 80, 359 [Privacy protects spiritual relationships as opposed to market relationships in the case of property].

Renegar G., Webster C. J. et al. (2006). Returning Genetic Research Results to Individuals: Points to Consider. *Bioethics* 20:1,24. [There is a trend for participants to be permitted access to their personal data if they so choose. Special considerations apply to returning data in context of drug development trials].

Rule J.B. (2004). Toward Strong Privacy: Values, Markets, Mechanisms and Institutions. *Univ. of Toronto L.J*. 54,183.

Safer v. Estate of Pack 677 A.2d 1188, 1192 (N.J. Su per. Ct. App. Div. 1996). [Court extended duty to warn the patient as well as the patients' family members. May be based on harm rationale where FAP is treatable].

Suter S. M. (2004). Disentangling Privacy from Property: Toward a Deeper Understanding of Genetic Privacy . *Geo. Wash. Law Rev*. 72(4), 737.

Tarasoff v. Regents of the University of California (1974), 529P. 2d 533 (Cal.Sup.Ct.); (1976), 551 P.2d

334 (Cal. Sup. Ct.). [Issue of imminence. The therapist 'bears a duty to use reasonable care to give threatened persons such warnings as are essential to avert a foreseeable danger arising from his patient's condition or treatment.']

Terry S.F. and Davidson M.E. (2000). Empowering the Public to be Informed Consumers of Genetic Technologies and Services. *Community Genetics* 3(3), 148.

Thorgeirsdóttir S. (2004). The Controversy on Consent in the Icelandic Database Case and Narrow Bioethics. *Blood and Data, Ethical, Legal and Social Aspects of Human Genetic Databases, (eds.* G. Árnason. S. Nordal & V. Árnason) 67. Reykjavik, Iceland: University of Iceland Press and Center for Ethics.

United Nations Educational Scientific and Cultural Organization (UNESCO). (2003). *International Bioethics Committee, International Declaration on Human Genetic Data*.

UK Biobank, [See online:< http://ukbiobank.ac.uk> for overview of the project].

UK Biobank Ethics and Governance Framework, Version 2. (July 2006). [See I Relationship with Participants (B) Understanding Consent, (8) Expectation of Personal Gain].

Universal Declaration on Bioethics and Human Rights (UNESCO). (19 October 2005) [See http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html Article 15 refers to benefit sharing and provides that benefits resulting from any scientific research and its application should be shared with society as a whole].

The University of Washington v William J. Catalona, Case no. 4:03-cv-01065-SNL, DOC 152, filed 03/31/ 2006, U.S. District Court, Eastern District of Missouri,. rendered by Judge Stephen Limbaugh. [The case is currently being appealed in an effort to establish that donors can control their own samples. Amicus brief, filed by Lori B. Andrews and Julie A. Burger]

Wilson S. (2003). Population Biobanks and Social Justice: Commercial or Communitarian Models? A Comparative Analysis of Benefit Sharing, Ownership, and Access Arrangements. *Trames* 8(1/2), 80.

Biographical Sketches

Lori Luther is a Research Associate at the Faculty of Law, University of Toronto. She is co-coordinating an ethical, legal and social issues component of the Assessment of Risk for Colorectal Tumours in Canada (ARCTIC) project with Trudo Lemmens and writing research papers on a number of related areas, including property/ownership and benefit sharing. Lori has worked as an independent bioethics consultant, a policy analyst for Health Canada, Health Sciences Policy Division, and a lecturer/coordinator of Health Care Ethics and Law, at the University of Birmingham, Faculty of Medicine, England. She has both B.C.L and LL.B law degrees from McGill University and an MSc in Health Care Ethics and Law from University of Birmingham, England.

Trudo Lemmens (Lic. Jur., LL.M., D.C.L.) is an Associate Professor at the Faculties of Law and Medicine of the University of Toronto. He was a member of the Institute for Advanced Studies in Princeton (2003-2004); a visiting fellow of the Royal Flemish Academy of Belgium for Science and the Arts (2006-2007); and a visiting professor at both the Global Law School of the K.U.Leuven (Belgium) and the Faculty of Law of the University of Otago (New Zealand). Trudo Lemmens' research currently focuses on how law and regulation contribute to the promotion of ethical standards in the context of medical research and practice, and in the context of biotechnological innovations. He published two books: *Reading the Future? Legal and Ethical Challenges of Predictive Genetic Testing*' (Themis, forthcoming 2007, with Mireille Lacroix and Roxanne Mykitiuk) and *Law and Ethics in Biomedical Research: Regulation, Conflict of Interest, and Liability*, (University of Toronto Press, 2006, edited with Duff Waring). His publications include chapters in health law and bioethics textbooks and articles in various law, bioethics, science and policy journals. He has chaired and been a member of various advisory and ethics committees and teaches courses on Research Ethics, the Regulation of Research, Medical Law, and Privacy, Property and the Human Body.