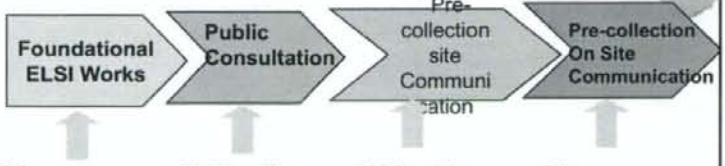
Possible Corrective Efforts

Enhancing the Cooperation between BIO & ELSI Disciplines



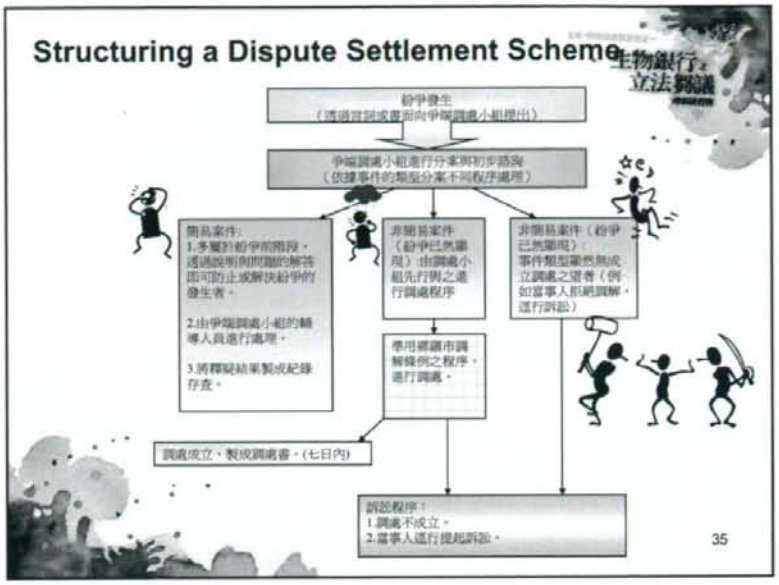
ELSI
- Expansion of Networks
- Design of Special Consent Mech.
- Personnel Training (Nurses, Volunteers & Intellectual People)

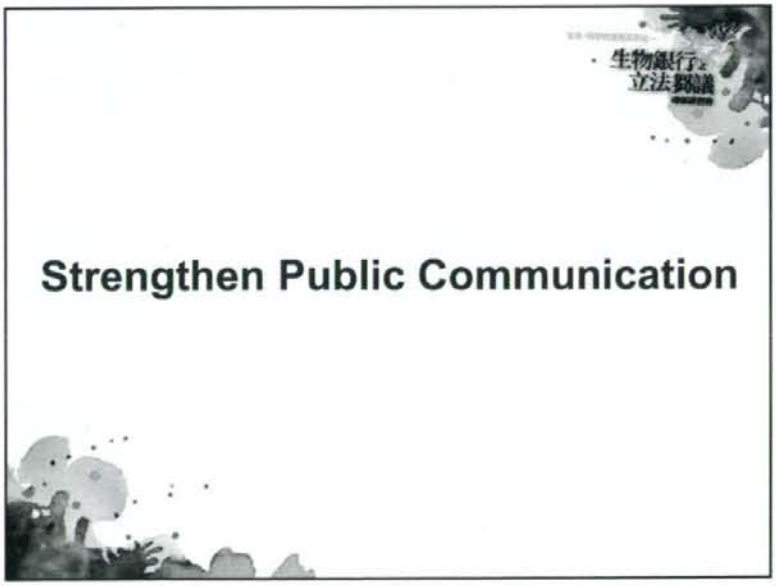
ELSI + Bio
- Public Consultation for Recruitment

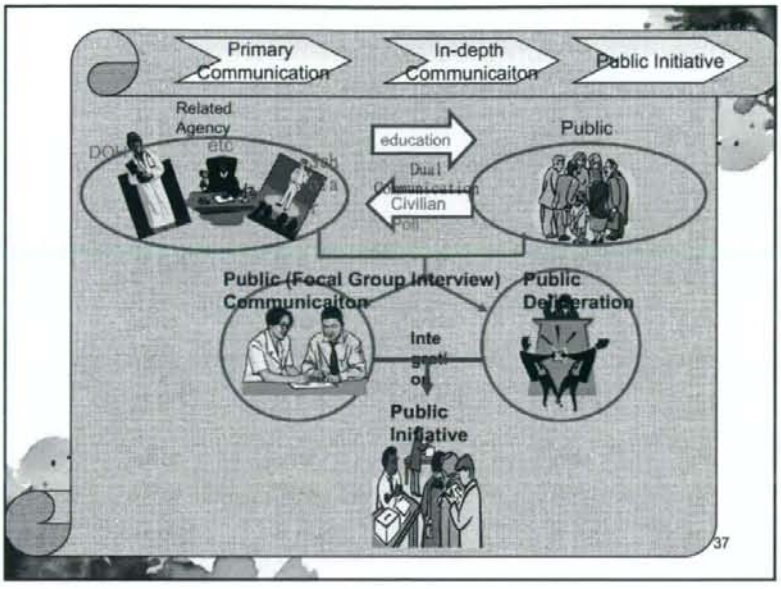
ELSI + Bio
- Tel Contact
- Other Supporting Channels for Conducting Informed Consent

Bio
- Reconfirm before Participant's Signing on the Consent Form

34


Structuring a Dispute Settlement Scheme
生物銀行之立法芻議
爭端發生
（透過買賣或要求向爭端調處小組提出）
爭端調處小組進行分案與初步篩選
（依據事件的類型分案不同程序處理）
簡易案件：
1.多屬於紛爭前階段，透過說明與問題的解答即可防止或解決紛爭的發生者。
2.由爭端調處小組的輔導人員進行處理。
3.將釋疑結果製成紀錄存查。
非簡易案件（紛爭已然顯現）：由調處小組先行與之進行調處程序
非簡易案件（紛爭已然顯現）：事件類型顯然無成立調處之望者（例如當事人拒絕調解，逕行訴訟）
準用鄉鎮市調解條例之程序，進行調處。
調處成立，製成調處書。（七日內）
訴訟程序：
1.調處不成立。
2.當事人逕行提起訴訟。
35


生物銀行之立法芻議
Strengthen Public Communication


Primary Communication
In-depth Communicaiton
Public Initiative
Related Agency
education
Public
Civilian
Public (Focal Group Interview) Communicaiton
Public Deliberation
Public Initiative
37


Thank you for your attention

International Symposium
Biobank and Genomic Research
- Bioethics of Genomic Medicine

Ethics, Law and Governance of Biobanks

Professor Don Chalmers

KYOTO, 22 March 2009

UTAS

Centre for Law & Genetics

Overview

- Biobanks – Definition
- Biobanks – National and International
- Biobanks and Genomic science
- Research uses and Personalised medicine
- Technical challenges for Biobanks
- Legal and Ethical challenges for Biobanks
- Governance Principles
- Conclusions

1 Biobanks - Definitions

- Biobanks are specifically created collections of human tissue samples established with the specific aim of conducting **research**.
- UK "Biobank"; Latvia -"genebank"; French National Ethics Consultative Committee -"biolibraries"

1 Biobanks -Existing Collections?

- Existing collections of human tissue (eg Pathology samples; blood banks) with **primary** aim for diagnostic and clinical purposes
- These collections may be used for **secondary** purpose of research
- Are these Biobanks? Generally no but may be organised with proper governance arrangements.
- Existing collections have only specific and limited consent regimes.

2 Biobanks- National

- *National* UK Biobank (**500,000**) DeCode (Iceland);Estonian Genome;Karolinska Institutet (Sweden); CARTaGENE (Quebec); GenomEUtwin (Finland); Danubian Biobank Foundation (six countries in Central Europe); KORA-GEN(Germany); LifeGene (Sweden); Generation Scotland; INMEGEN (Mexico); LifeLines (Netherlands); National Heart, Lung and Blood Institute (NIH USA); Centre for Integrated Genomic Medical Research (UK).
- Japan and Taiwan
- *Australia*: WA Genetic Health project (Busselton);Victoria cancer consortium;Tasmania Menzies Centre

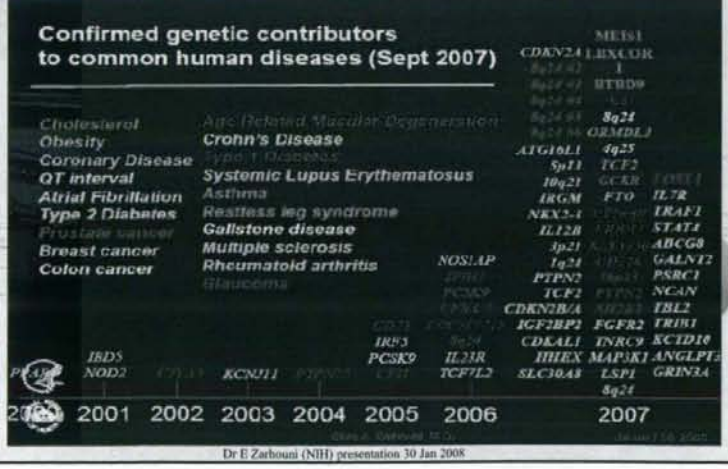
2 Biobanks:International

- *International Haplotype Mapping Project:* USA, UK, Japan, Nigeria, China and Canada collaboration after Human Genome Project to study/find genes that affect health, disease and medication responses
- *Public Population Project in Genomics* (P3G); genome Canada not-for-profit public database for biobank/genomics community, (motto - *transparency and collaboration*)- Consent forms; Guidelines; P3G Observatory; 22 Charter; 13 Associate; 152 members (41 countries, **10.5 million participants**
- PHOEBE (Promotion and Harmonization of Epidemiological Biobanks in Europe)
- Translational Genomic Research in the African Diaspora (TgRIAD)

3 Biobanks and Genomic Science

- Francis Collins NHGRI "The Genome Era"
- Exponential increase in 2007 in information about genes implicated in complex genetic disorders.
- New paradigms are emerging how genes and gene-gene interactions (e.g. networks in obesity) might function.
- New analytic research platforms allow multi-centre collaborative "blockbuster" type association studies to identify even more about gene activity

3 Biobanks and Genomic Science



Dr E Zarbouni (NIH) presentation 30 Jan 2008

3 Biobanks and Genomic Science

- Example of blockbuster study: breast cancer susceptibility genome-wide association study involving 28 centres in 12 countries and 50,000 samples
- 'The detection of further loci will require….larger numbers of cases and controls…[and] results across multiple studies"(Easton)-from *individual* to *population*

3 Biobanks and Genomic Science

- Taichi Sakaiya – *Knowledge-Value Revolution*
- Convergence of technologies -HGP and collaborations; computers and bioinformatics; microarrays; new tests; proteomics and metabolomics; national biotechnology policies; increased funding (eg President Obama in USA $20 billion); Commercialisation and Partnerships

3 Biobanks and Genomic Science


GEN
Genetic Engineering & biotechnology News
Biotechnology from bench to business
Liquid Chromatography
OMICS | Drug Discovery | Translational Medicine | Bioprocessing | Biobusiness
Pushing Toward a $1,000 Genome
Stepwise Technological Evolution Will Continue, but Disruptive Spurts Are Also Forecast

4 Research Uses of Biobanks

- Large scale research and biobanks and rising health costs (cancer, diabetes, heart diseae).
- Large scale genetic epidemiology studies; Disease gene/proteomic discovery studies
- "Biobanks are increasingly seen as an essential tool in translating biomedical research into real improvements in healthcare" (*Genetic Engineering News* , 2005)

4 Research Uses of Biobanks

- Personalised medicine -Pharmacogenomics - (1)match drug to patient for effectiveness (Herceptin), and
- (2)Minimise patient adverse drug reactions (ADRs)
- (3) *Combinatorial* therapy (eg stem cells and drugs).
- Failure to improve clinical evaluation [of genetic tests] would undermine the development of personalised medicine in the 21st century, and lead to a new generation of medical technology of unclear clinical value. (Melzer et al. *Phg Foundation Research Report* Feb 2008)

5 Technical Challenges of Biobanks

Rand Corporation study -inconsistencies

- Number of data points to be collected for each individual sample
- Coding of the collected sample and protection by encryption codes (Privacy Enhancement Technology –PETs)
- Access only to authorised biobank employees.
- Collection/testing facilities accreditation standards.
- Sample collection and storage must be quality assured and not tainted by human/process error

5 Technical Challenges of Biobanks

- Industry standards for biobanks,
- *First-Generation Guidelines for NCI-Supported BioRepositories (*National Cancer Institute, National Institutes of Health, U.S Health /Human Services)
- *International Society for Biological and Environmental Repositories* (ISBER).

6 Ethical/legal Challenges

1 Privacy and Confidentiality

- Preventing improper access or release
- *Privacy legislation* information be relevant to the purpose for which it is collected *and* access to personal genetic information.

2 Public Consultation and Engagement .

- Public engagement a major feature of the developments eg biobanks (See OECD (2007) particularly Chapter 3.5 *Public Engagement in the Establishment of a Population Database).*
- Public trust and accountability

6 Ethical/legal Challenges

3 Consent: Future biobank projects - re-contacting participants for new information, new uses, or new research.

- (1) *Limited /specific consent* for research for use of sample for a specific project, or
- (2) *Qualified/follow-up* consent where participant wishes to be contacted in future if there is any extension or substantial variation from original research project, or
- (3) *Full/unspecified* consent to use of sample in all future research ("blanket'/"broad" consent is major issue)
- Children (UK not recruiting –Consent at 18?)

6 Ethical/legal Challenges

4 Health Related Information Policy required on whether to reveal health information to participants during research (UK Biobank does not as a policy).

5 Withdrawal from project at different levels,

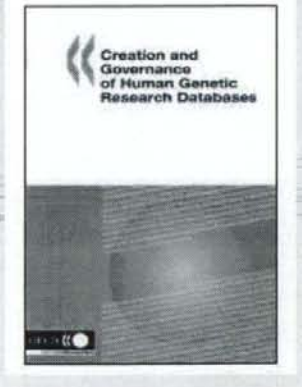
- (!)complete withdrawal and destruction of samples;
- (2)allow use of sample but not participate in any way;
- (3)retention of sample with withdrawal from future projects.

7 Governance

Establishment and Proper Research Governance
-governance structures appropriate for primary research focus and protection of the interests of the research participants.

- UK Biobank, *Ethics and Governance Framework*, Version 2.
- OECD *Creation and Governance of Human Genetic Research Databases* (2007)
- Good governance as a condition of broad consent?

7 Governance



7 Governance

- OECD -*Creation and Governance of Human Genetic Research Databases* (2007)
- Chapter 2. Human Genetic Research Databases
- Chapter 3. Establishment of a HGRD (Public Engagement in the Establishment of a Population Database)
- Chapter 4. Data and Sample Collection and Management
- Chapter 5. Database Management and Governance
- Chapter 6. Commercialisation Considerations
- Chapter 7. Conclusions
- Note *Guidelines* expected in mid 2009 (Draft circulated for comment late 2008)

Conclusions

- OECD Creation and Governance of Human Genetic Research Databases *Guidelines* awaited
- The need for a "chain of responsibility" (German/French Declaration)
- Consent
- Solidarity & Benefit Sharing –Research and health care products?) UNESCO *Universal Declaration on Bioethics and Human Rights* 2005
- Harmonisation

私は非常に感謝する

- 私は非常に感謝する
- To Professor Ida and to Kyoto University
- To Ministry of Health (MHLW) for this Symposium
- To the Japan Society for Promotion of Science, sponsors of the Basic Law of Bioethics in Japan Project
- To colleagues in this Symposium

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References

- Chalmers, D "The Governance of Biobanks and Databases for Research -Towards an international consessus on Ethical Principles" (2007) 3 *Taiwan Journal of Law* and *Technology*.
- OECD *Creation and Governance of Human Genetic Research Databases* (2007) http://www.oecd.org/document/50/0,3343,en_2649_34537_37646258_1_1_1_1,00.html
- Rand Corporation study Eiseman E, et al Case Studies of Existing Human Tissue Repositories: Best Practices for a Biospecimen Resource for the Genomic and Proteomic Era, National Cancer Institute National Dialogue on Cancer (Arlington VA: Rand Science and Technology).
- *First-Generation Guidelines for NCI-Supported BioRepositories* April 2006, National Cancer Institute, National Institutes of Health, U.S Department of Health and Human Services http://biospecimens.cancer.gov/biorepositories/First%20Generation%20Guidelines%20042006.pdf
- *International Society for Biological and Environmental Repositories*(ISBER). "Best Practices for Repositories I: Collection, Storage, and Retrieval of Human Biological Materials for Research" (2005) 3 *Cell Preservation Technology* 1, 5-48.
- UK Biobank, *Ethics and Governance Framework*, Version 2.0) Wellcome Trust and Medical Research Council and Department of Health UK, July 2006 http://www.ukbiobank.ac.uk/ethics/egf.php
- German National Ethics Council and the French National Consultative Ethics Committee for Health and Life Sciences, *Joint Declaration*, The European Group on Ethics (EGE) in Science and New Technologies to the European Commission Ethically Speaking Newsletter, Issue 5, August 2005 at 27

International Symposium

Biobank and Genomic Research

- Bioethics of Genomic Medicine -

Ethics, Law and Governance of Biobanks

Donald Chalmers,
University of Tasmania

22nd March, 2009

Kyoto University Clock Tower International Exchange Hall III

Professor Don Chalmers*

Faculty of Law School, University of Tasmania

1 INTRODUCTION

This chapter examines the legal principles and rules for human genetic research with particular emphasis on the development of collections of tissue samples and data held in human genetic research databases. This century has been described by Francis Collins as the Genome Era[1] in science and medicine, acknowledging the volume and intensity of genomic research[2] in both the public and private sectors. Human tissue samples are essential tools for genomic research and "translating biomedical research into real improvements in health care"[3]. The German National Ethics Council[4] has noted the potential of biobanks for the identification of causes of disease and for breakthroughs in medical and pharmaceutical research and the "particularity of biobanks, which…lies in their twofold character, as collections of

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* Professor and Dean, Faculty of Law, University of Tasmania. Chair Australian Gene Technology Ethics Committee, Deputy Chair Embryo Research Licensing Committee, Member Human Genetics Advisory Committee. Director Centre for Law and Genetics, past Chair Australian Health Ethics Committee 1993-2000.

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[1] *Australian Biotechnology News* July 4 2003 at p 8.

[2] Knoppers, BM and Chadwick, R "Human Genetic Research: Emerging Trends in Ethics" (2005) 6 *Nature Reviews Genetics* 75-79. See also the special issue of (2007) 18 *King's Law Journal*, 201-311 with articles by Gibbons, SMC, Kaye, J "Governing Genetic Databases: Collection, Storage and Use" at 201-208 ; Caulfield, T "Biobanks and Blanket Consent: The Proper Place of the Public Good and Public Perception Rationales" at 209-226 ;Campbell, AV "The Ethical Challenges of Genetic Databases: Safeguarding Altruism and Trust" at 227-245;Brownsword, R "Genetic Databases: One for All and All for One?"at 247-273; Beyleveld D, "Data Protection and Genetics: Medical Research and the Public Good" at 275-289; Knoppers, BM, et al "Genomic Databases and International Collaboration" at 291-311

[3] Genetic Engineering News Vol 25:No 3 (2005) at 1.

[4] Nationalcr Ethikrsat , Opinion on Biobanks for Research Berlin 2004 at http://www.ethikrat.org

both samples and data".[5] Pharmacogenetic research into genetic variability in drug response may be substantially advanced by biobanking.[6] Tissue samples, in the form of DNA or RNA samples, cell lines, tissues, cell preparations or plasma/blood samples, are essential tools for pharmacogenomic research and analysis that aims to identify potential biomarkers[7] or drug targets by any of the new generation genomic tests utilising DNA marker, RNA expression level or protein activity. Unsurprisingly, many pharmaceutical companies operate biobank collections for research purposes and to enrol suitable clinical trial recruits so as to minimise side effects and achieve better results. Biobanks are important resources for medical health research that may benefit current patients but are also aimed at long-term research for future benefits[8].

Ethical and social issues[9] surround biobanks, apart from the technical and scientific issues. Human tissue samples held in human genetic research databases will usually be coded, making the samples potentially re-identifiable[10]. This raises the issue of privacy of the genetic information. Patient identification may be required for follow-up of results or result validation. There are doubts whether de-identification is realistic as a link back to the patient may be required, particularly in disease identification studies. Such distinctions are critical in the design, conduct and reporting of human genetic research and pharmacogenomic studies. It has been recognised that complete guarantees of individual privacy are unrealistic in health research. Participant re-contact may also be required by the biobank[11] to collect new information or to seek consent for new approved research uses or a new study.

[5] Ibid at 21

[6] See Shastry,B "Pharmacogenetics and the Concept of Individualized Medicine" (2006) 6 *The Pharmacogenomics Journal* 16-21. The Generation Scotland project, which is run by a consortium of the medical schools in Scotland with Scottish Executive funding, has this as an explicit objective: http://www.generationscotland.org

[7] A bio-marker is a physiological response or a laboratory test that occurs in association with a pathological process that has possible diagnostic and/or prognostic utility.

[8] Kaiser J "Biobanks: Population Databases Boom, from Iceland to the U.S." (2002) 298 *Science* (5596), 1158-1161.

[9] Cambon-Thomsen, A, et al "The social and ethical issues of post-genomic human biobanks" (2004) 5 *Nature Reviews Genetics*, (11) 866-873.

[10] The term is not precise as has been noted by Knoppers, BM and Saginur, M "The Babel of genetic data terminology" (2005) 23 *Nature Biotechnology* 925-927

[11] See UK Biobank, Ethics and Governance Framework, Version 2.0 Wellcome Trust and Medical Research Council and Department of Health UK, July 2006 at 10 http://www.ukbiobank.ac.uk/ethics/egf.php

Linkage may also be required to enable recontact of participants for future research projects, to follow up a participant to pass on clinically significant results or, possibly to recruit for a prospective clinical trial. There has to be an effective balance between individual interests in privacy with the public interest in promoting high quality public health research. Apart from the important legal issue of participant privacy, there is also a mixed range of legal issues[12] dealing with participant consent, research governance, human tissue, material (tissue) transfer agreements, employee confidentiality, commercialization, benefit-sharing and international collaboration.

It is essential that all human research be conducted with integrity and according to the highest ethical standards. This is even more important where large genetic research database collections have been assembled. Public trust[13] is an essential pre-condition for the successful operation and future research benefit of human genetic research databases, sometimes referred to as biobanks.

This chapter considers the regulation required to balance individual interests in privacy with the public interest in effective and reliable research. This issue is particularly salient in relation to genetic research databases where the balance must be made between the proper protections of those recruited as tissue sample providers with the public interest. This chapter does not discuss forensic DNA banks for criminal investigations[14] or "problems that might arise because of other

[12] For a helpful list of ethical tensions and issues in biobanking, including consent, ownership and IP, governance, public engagement, data-sharing, research access, security, privacy, benefit-sharing, commercialisation, discrimination, public good, cultural sensitivity and international harmonisation, see Cambon-Thomsen, A, et al, "Biobanks for genomics and genomics for biobanks" (2003) 4 *Comparative and Functional Genomics*, (6) 628-634; Caulfield, T "Biobanks and Blanket Consent: The Proper Place of the Public Good and Public Perception Rationales" at 209-226 Caulfield, T "Biobanks and Blanket Consent: The Proper Place of the Public Good and Public Perception Rationales" at 209-226

[13] Campbell, AV "The Ethical Challenges of Genetic Databases: Safeguarding Altruism and Trust" (2007), 18 *King's Law Journal*, 2 at 237-245.see also Chalmers D and Nicol D "Commercialisation of biotechnology: public trust and research" (2004) 6 *International Journal of Biotechnology* , 116-133; On the importance of public trust see Bovenberg J "Towards an International System of Ethics and Governance of Biobanks: A "Special Status" for Genetic Data?" (2005) 15 *Critical Public Health* 369-383. See also J Bovenberg "Inalienably Yours? The New Case for an Inalienable Property Right in Human Biological Material" (2004) 1 *SCRIPT-ed* 545.

[14] See Chalmers, D (Ed) *Genetic Testing and the Criminal Law* (ed) UCL Press London 2005. On legislation, see, for example, *Criminal Investigations (Blood Samples) Act* 1995 authorizing New Zealand's national DNA databank. For a UK perspective see the forthcoming report from the

utilisations, for civil or criminal purposes or for employment or insurance"[15] This chapter focuses on the legal responsibilities and obligations for biobank administrators and researchers in dealing with human tissue and data collections and biobank research participants.

1.1 What are Human Genetic Research Databases and Biobanks?

The OECD generally uses the term 'genetic databases' or 'Human Genetic Research Databases (HGRDs)' to describe large-scale collections of human tissue for research. The OECD Committee for Scientific and Technological Policy produced a Report on Human Genetic Research Databases that provides an excellent outline of the procedures to establish an HGRD, to collect and manage samples, to manage and govern databases and commercialisation aspects.[16] Apart from the terms HGRDs and biobanks, the Estonian Genome Project uses "genome database", the Latvian Genome Project uses "genebank" and the French National Ethics Consultative Committee uses "biolibraries".[17]. The term "biobank" is used in this sense and is largely synonymous with the term "human genetic research database". All involve the storage of human tissue.[18] For this reason, genetic registers[19] of personal and family genetic information and histories are usually not included in a discussion of HGRDs because they generally do not require any collection or storage of human tissue.

Nuffield Council on Bioethics, *The Forensic Use of Bioinformation: Ethical Issues*, September 2007.

[15] Ethical issues raised by collections of biological materials and associated information data;"biobanks' and "biolibraries"Opinion 77, Comité consultatif national d'éthique pour les sciences de la vie et de la santé, France, 2003 at 3 www.ccne-ethique.fr/english/start.htm

[16] OECD Committee for Scientific and Technological Policy: Working Party on Biotechnology *Tokyo Workshop Report: Human Genetic Research Databases: Issues of Privacy and Security, DSTI/STP/BIO* (2005) 14.

[17] Ethical issues raised by collections of biological materials and associated information data;"biobanks' and "biolibraries"Opinion 77, Comité consultatif national d'éthique pour les sciences de la vie et de la santé, France, 2003 http://www.ccne-ethique.fr/english/start.htm

[18] For a discussion of terminology, see Tutton, R and Corrigan, O, *Genetic Data Bases: Socio-Ethical Issues in the Collection and Use of DNA* Routledge London2004 at 2-4.

[19] Special health registers may include the Perinatal Registers, Cancer Registry and Mental Health Register. Some registers may be governed under specific legislation,which defines the type of data to be collected, the method of collection,and restrictions on its use and availability.

However, a distinction can be drawn between the generic OECD term HGRDs and biobanks. In the case of HGRDs, many existing collections of human tissue were developed primarily for diagnostic and clinical purposes (without consideration of research or with research later considered as a secondary purpose). Moreover, many HGRDs were developed for specific limited research purposes only with specific and limited consent regimes. There are, therefore, some unique considerations in relation to research using existing tissue collections.[20] In contrast, biobanks have been established generally with the specific aim of conducting research. Biobanks have also been established with careful efforts to ensure that participant's consent has been obtained to cover research generally including variations to the original purpose for future research. In this sense, if there is a difference between the two terms "HGRD" and "biobanks", a biobank tends to refer to a collection of human tissue, specifically created for research. However, the term "biobank" is often used interchangeably with HGRD to describe any collection of human tissue, which can and is used for research purpose. Both HGRDs and biobanks have the twin goals of facilitation of genomic research balanced with the protection of the welfare of the biobank sample contributors[21].

1.2 Genetic research and Privacy

Genetic tests and research can provide information not only about a person's genes, but also information about the person's parents, siblings and children and even cousins and other more distant blood relations[22]. For this reason some forms of genetic information have:

1. predictive potential;
2. implications for family members; and
3. potential to stigmatise.

[20] See section 3 below.

[21] See National Bioethics Advisory Commission Report Research involving Human Biological Materials: Ethical Issues and Policy Guidance Vols 1& II Bathesda, Maryland August 1999 http://www.georgetown.edu/research/nrcbl/nbac/pubs.html. See also National Bioethics Advisory Commission Report Ethical and Policy issues in Research involving Human Participants Vols 1& II Bathesda, Maryland August 2001 at http://www.georgetown.edu/research/nrcbl/nbac/human/overvol2.html.

[22] Or possibly unrelatedness in the case of, say, parentage testing.

Genetic research has aroused specific privacy concerns. There are community concerns that personal information disclosed in a genetic research project may be divulged to others, such as insurance companies or employers, to the detriment of not only the research participant but also the family members and communities that share the participant's genetic profile. Such distinctions are critical in the design, conduct and reporting of human genetic research and pharmacogenomic studies. The protection of privacy of genetic information was the driver behind the joint Australian Law Reform Commission and Australian Health Ethics Committee Report, *Essentially Yours*.[23] This Report examined personal genetic information privacy in the context, amongst others, of anti-discrimination, genetic testing, health service delivery, insurance, employment, law enforcement and parentage testing

2 COLLECTION OF NEW SAMPLES FOR BIOMEDICAL RESEARCH

2.1 Governance of a Biobank

The establishment of a biobank is a complex task that will involve negotiations with health officials, researchers, governing institution(s), research funding agencies, health consumer/ community organizations and ethics experts. Biobanks can be "staggeringly expensive"[24] to establish and operate. Some biobanks have been established by national legislation setting up an operating company structure [25] or using the structure of a foundation[26] (rather than a company). For example, the Estonian database is owned and controlled by the Estonian Genome Project

[23] *Essentially Yours: The Protection of Human Genetic Information in Australia Report* 96 2003.

[24] Greely H quoted in R Longtin "Canadian Province seeks control of its genes' (2004) 96 *Journal National Cancer Institute* 1567-69. There are also critics of biobanks who question their methodological soundness and research value.

[25] *Health Sector Database Act*, 1998 (deCODE Genetics). The Icelandic Supreme Court November 27, 2003, judgment No. 151/2003 suggested that the 1998 Health Sector Database Act might be unconstitutional. In 2000, the *Act on Biobanks* No. 110/2000 was introduced for the "collection, keeping, handling and utilization of biological samples from human beings".

[26] Estonia: *Human Genes Research Act*, 2000

Foundation. In addition, some countries have enacted specific biobank legislation.[27] As biobanks will involve public benefit research, the UK Biobank is managed under the structure of a charitable company[28] with an independent Ethics and Governance Council which is an independent body charged with oversight of UK Biobank and to monitor and advise on UK Biobank's compliance with the Ethics and Governance Framework of the project [29] Similarly, CARTaGENE has an independent Institute for Population, Ethics and Governance. Some countries have established an oversight body reporting to the relevant government minister. The Scottish Executive has funded Generation Scotland, in large part, and has also established the Generation Scotland Advisory Board with an oversight function.[30]

Apart from considerations of structure, a biobank governing body will introduce guidelines[31] for the ethical operation of the biobank. The issue of participant consent to enrolment in a biobank is, and has been the most debated and vexed ethical question.[32] The governing body will introduce also standard operating procedures[33].

Biobanks are being established at regional, national and international levels[34]. At the regional level biobanks have been set up by the Karolinska Institutet (Sweden);

[27] Eg Sweden: *Biobanks in Medical Care Act* 2002 information may only be used for research purposes.

[28] A charitable trust may possibly be used, Winickoff D and Winickoff R "The Charitable Trust as a Model for Genomic Biobanks' (2000) 349 *N Eng J Med* 12 at 1180-1184. See comment in Boggio A " Charitable Trusts and Human Research Genetic Databases" (2005) 1 *Genomics Society and Policy* 41-49.

[29] See UK Biobank, Ethics and Governance Framework, Version 2.0 Wellcome Trust and Medical Research Council and Department of Health UK, July 2006 at 16-18 http://www.ukbiobank.ac.uk/ethics/egf.php

[30] http://129.215.140.49/gs/GGSAB.htm

[31] See for example, OECD Working Party on Biotechnology *Draft Guidelines for Human Genetic Research Databases* DSTI/STP/Bio(2007)17/REVI, Paris, July, 2007; Trouet, C "New European guidelines fort he use of stored human biological materials in biomedical research" (2003) 30 *Journal of Medical Ethics* 99-103

[32] Campbell, AV "The Ethical Challenges of Genetic Databases: Safeguarding Altruism and Trust" (2007), 18 *King's Law Journal*, 237 at 239-233 and see section 2.5 below

[33] See, for example, *First-Generation Guidelines for NCI-Supported BioRepositories* April 2006, National Cancer Institute, National Institutes of Health, U.S Department of Health and Human Services
http://biospecimens.cancer.gov/biorepositories/First%20Generation%20Guidelines%20042006.pdf

[34] Kaye, J, Helgason, H, Nomper, A, Sild, T and Wendel I "Population genetic databases: A comparative analysis of the law in Iceland, Sweden, Estonia and the UK" L (2004) 8 *TRAMES* 1/2, 15-33

CARTaGENE (Quebec),); the Western Australia project[35]; the National Heart, Lung and Blood Institute (NIH, USA); and the Centre for Integrated Genomic Medical Research (Manchester UK). At the national level, DeCode (Iceland) was the pioneer program that has been followed by GenomEUtwin (Finland); Estonian Genome; Danubian Biobank Foundation (involving six countries in Central Europe); KORA-GEN (Germany); LifeGen (Sweden); INMEGEN (Mexico); LifeLines (Netherlands); UK Biobank and Generation Scotland[36] that will enrol some 500,000 participantsts; and, the Lifelong Health Initiative (Canada)[37]. These regional and national biobanks have been specifically created for large-scale longitudinal genetic research projects. At the international level, the successor to the Human Genome Project, the International Haplotype Mapping Project is a collaboration between the USA, UK, Japan, Nigeria China and Canada to identify and compare genetic similarities and differences in collected human tissue samples to find genes that affect health, disease and medication responses.[38] Another international collaboration is emerging in the Public Population Project in Genomics (P3G)[39] that aims to facilitate collaboration between many national biobanks in a not-for-profit initiative to provide a public and accessible knowledge database for the international population genomics community. P3G will enable large-scale epidemiological studies to be undertaken. The regulation of biobanking has, or is being considered in a number of countries and by a range of research or regulatory organisations[40]. For

[35] For an account of Australian databases see Nicol D "Public trust, intellectual Property and human genetic Databases; the need to address benefit sharing' (2006) 3 *J of International Biotechnology Law* 89-103

[36] www.generationscotland.org and www.ukbiobank.ac.uk

[37] http://www.cihr-irsc.gc.ca/e/22982.html

[38] see http://www.hapmap.org/

[39] http://www.p3gconsortium.org/ The P3G motto is "transparency and collaboration'.

[40] Cambon-Thomsen, A, et al, "Ethical and legal aspects of biological sample banks: Synthesis, practical questions and proposals [Aspects ethiqués et réglementaires des collections d'échantillons biologiques: Synthèse, questions pratiques et propositions]" (2003) *Revue d'Epidemiologie et de Sante Publique*, 51 (1 II) at 121-126. Council of Europe, Steering Committee on Bioethics, Draft Recommendations on research on biological materials of human origin, Strasbourg, 28 November 2005; Opinion of the European Group on Ethics in Science and New Technologies to the European Commission, Ethical Aspects of Human Tissue Banking, 21 July 1998; Swedish Medical Research Council (MFR), Research ethics guidelines for using biobanks, especially projects involving genome research, June 1999; Report of the Bioethics Advisory Committee of the Israel Academy of Sciences and Humanities, Population-Based Large-Scale Collections of DNA Samples and Databases of Genetic Information, December 2002; ESRC Research Ethics Framework, Discussion Paper 2: Ethical issues raised by collections of biological materials and associated information data;"biobanks' and "biolibraries"Opinion 77, Comité consultatif national d'éthique pour les sciences de la vie et de la santé, France, 2003 The

example, the German National Ethics Council and the French National Consultative Ethics Committee for Health and Life Sciences have produced a joint Declaration of the need for a regulatory framework to ensure the development of research balanced with the protection of the individual. The Australian Law Reform Commission (ALRC) published *Essentially Yours: The Protection Of Human Genetic Information,* which recommended changes to the regulation of databases and genetic research in general.[41] In the UK, both UK Biobank and Generation Scotland have developed ethics and governance frameworks[42] to define the scope and limits of the projects nd this has been supplemented with specific human tissue legislation[43].

Once a decision to proceed has been taken, a governing body will be appointed and the governance arrangements instituted. An institution establishing a biobank must establish governance structures appropriate for and consistent with the primary research focus[44], including a separate independent ethics review board[45], to scrutinise and assess the ethical acceptability of the project. The governance

international dimension to research ethics: the significance of international and other non-UK frameworks for UK social science, April 2004; Department of Health & Human Services, Public Health Service, National Institutes of Health, National Cancer Institute, 133rd National Cancer Advisory Board, Summary of Meeting, February 16-17 2005; ESRC Economic & Social Research Council, Research Ethics Framework (REF), Discussion Paper 2, April, 2004; Working Group on DNA and Epidemiology (TUKIJA) of the National Advisory Board on Health Care Ethics (ETENE), DNA Samples in Epidemiological Research, 26 August 2002; Dr Beata Scholtz, Debrecen Clinical Genomics Center, Biobanks and Scientific Research; German National Ethics Council, Biobanks for Research, 2004.

[41] *Essentially Yours: The Protection of Human Genetic Information in Australia Report* 96 2003 Recs 18-1 to 18-3 and 14-1 to 14-5. Dr Francis Collins described the Report as "a truly phenomenal job, placing Australia ahead of what the rest of the world is doing, described this Report"Head, US National Human Genome Research Institute and Chair, Human Genome Project and International Haplotype Mapping Project News release during the XIX International Congress of Genetics Melbourne July 5-9 2003

[42] See www.generationscotland.org and UK Biobank, Ethics and Governance Framework, Version 2.0 Wellcome Trust and Medical Research Council and Department of Health UK, July 2006 at 10 http://www.ukbiobank.ac.uk/ethics/egf.php

[43] UK *Human Tissue Act* 2004.

[44] In this respect, there is a fundamental divergence between the commercial company structure and the research governance structure. Under a company structure, the accepted legal standard demands that the company owes its principal duties to the shareholders.

[45] The term Ethics Review Board (ERB) will be used generically in this chapter to refer to research ethics committees that approve human research proposals. These are nationall variously called, as examples, Institutional review Boards, human Research Ethics Committees, Local Ethics Review Committees. All have a broadly similar composition, including community members, lawyer, religious/ethicists member; researcher with no affiliation with the research project to be considered;; and, independent chair.