Regulating Genetic Information In The Genome Era

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Medical practice is being, and will continue to be, transformed by genetic research. Francis Collins, the Director of the National Human Genome Research Institute, coined the expression the "Genome Era" as a descriptor of the period since the announcement of the mapping of the human genome in 2001[1]. The genome era is generating vast amounts of data and information from large-scale multi-centre trials, that would have been considered inconceivable a decade ago. This data and information is gradually uncovering and confirming genetic links to many common human genetic diseases. This individual genetic information is driving a new trend in "personalised medicine", which has a number of themes. In the pharmaceutical area, individual genetic profiles are being used to develop new drugs, to better match drugs to individual patient and to minimise adverse drug reactions for individual patients. There is an increasing range of direct–to-customer (DTC) genetic tests available, which have raised concerns amongst the National Institute of Health (NIH) and other national regulatory authorities. In medical technology, CT or MRI scans will be supplemented with individual whole- genome scans. The promise of genetic research, in the Genome Era, is considerable. The successful translation of this research into personalised medicine will depend, in part on access to personal genetic information and tissue samples of large numbers of patients and research participants. In turn, access to genetic information raises issues of privacy and public trust in ensuring that research and personalised medicine develop in accordance with high ethical and legal standards.

This article considers the exponential growth in genetic information and some of the transformative changes in genetic research, particularly in the expansion of biobanks as significant repositories of genetic information. This article will also discuss the nature of genetic information and the challenges for society and medical practice and the ways in which sensitive and predictive genetic information should be regulated.

THE GENOME ERA

Building on the work of Avery and others as well as relying heavily on the early X-ray crystallography photographs of Rosalind Franklin, Watson and Crick[2] published their influential and foundational paper on the double helix structure of DNA in 1954. With the advance of understanding of mapping the genomic sequence by the Sanger method and acceleration in computer power, a group of scientists and scientific centres around the world came together to map the human genome; the international collaborative Human Genome

[1] Sulston J and Ferry G (2003) *The Common Thread* London Corgi Books
[2] See Watson, J. *The Double Helix,* Penguin, 1953 and Black D, *An Invitation to Medicine*, Basil Blackwell, Oxford, 1987.

Project (HGP) was started[3]. This work was challenged and by the maverick, former NIH scientist, Craig Venter and the private company, Celera using the fast-track and controversial shotgun technique for mapping the human genome. The first draft of the sequence of the whole genome through the joint efforts of the HGP and Celera was jointly published in 2001[4]. The Human Genome Project and Celera joint publication did not turn to be the "Holy Grail"[5] but a significant *starting point* for further genetic research and work to understand the relationship between this genetic information and common diseases. It has also been the start of a longer journey towards therapies and treatments for these diseases. It was quickly realised that the map of the human genome was only one step in the genetic research journey; it was a beginning not an end.

The HGP and Celera work, however, did prompt a radical revision of basic genetics. Rather than the estimated 100,000 human genes, the HGP and Celera publication concluded that the total number of human genes is between 30,000 and 40,000. This considerable reduction was a "humbling" result that the late Stephen Jay Gould described as "the collapse of the doctrine of one gene for one protein, and one direction of causal flow from basic codes to elaborate totality, marks the failure of reductionism for the complex system that we call biology…"[6] Similarly, Dr Graig Venter declared dramatically that the notion that one gene produces one protein or equals one disease was rapidly "flying out of the window"[7]. The human genome sequence has branched into many offshoot disciplines such as structural genomics and proteomics (gene identification, protein structure); functional genomics and transcriptomics (genetic variation, gene expression monitoring); metabolomics; epigenetics (changes in phenotype (appearance) or gene expression caused by mechanisms other than the DNA sequence or by environmental factors) and targeted drug discovery and pharmacogenomics (for treatment of diseases with a genetic component).

The Genome Era is also driven by substantial developments in the enabling technologies of computer systems to handle this massive information and microarray genechips and bioinformatics[8] This has come around largely because of a convergence of technologies, the information from the HGP and also the collaborative interaction between research centres. There has also been an enormous increase in computer power and bioinformatic analysis. The development of micro arrays enables 10s of thousands of individual tests on the one micro array. The $1000 genome wide microarray is predicted to be available in the next few years.[9]

However, the rate at which human genetic information can be translated to treatments should not be overestimated. A report by the UK Human Genetics Commission reflects this view in stating that the Commission was set up and "its Terms of Reference were shaped at the end of the 1990s when there was a very real expectation of a genetics revolution within a few years". However, the report goes on to comment that "the reality has been slower than anticipated but developments in human genetic knowledge are now increasing'[10]

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[3] For a good account of the development of genomics, see Sulston J and Ferry G (2003) *The Common Thread* London Corgi Books

[4] Venter C "The Sequence of the Human Genome" (2001) 291 *Science* No 5507:1304-51 and also Lander E Initial sequencing and analysis of the human genome. (2001) 409 *Nature* 6822:860-921

[5] Chalmers D " The Challenge of Human Genetics" in Freckelton I (ed) *Controversies in Health Law* Federation Press, 1999

[6] Editorial, (2001) New York Times cited in (2001) *GeneWatch* May 14: 5.

[7] Venter, C., (2001) Financial Times cited in Vol Gene *Watch* May 2001 14:5.

[8] See Nicol, D. and Neilsen, J (2001) "The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development" *Sydney Law Review* 23:347 74

[9] Reported in (2007) *GEN* Genetic Engineering&biotechnology News Vol 27 No 19, November 1 at 1,34

[10] UK Human Genetics Commission (2008) *Light Touch Review of the Human Genetics Commission* at 19

INCREASING UNDERSTANDING OF HUMAN GENETIC INFORMATION

The vast expansion in microarray and computer technology has enabled a concurrent expansion in the volume of human genetic information. This exponential increase in information about genes and DNA variations, implicated in complex genetic conditions is a defining feature of the Genome Era. Researchers are finding new paradigms on how genes and gene interactions function. Between 2001 and 2005, there was slow development the understanding of the confirmed genetic contributors to certain human genetic diseases. The understanding of the confirmed genetic contributors to certain human genetic diseases has had a significant growth in 2007.[11]

Human genetic research has expanded beyond genes to other varieties of different possible alterations (mutations) in DNA sequences that may explain the genetic link in some common diseases. Studies have established differences between individual DNA through single nucleotide polymorphisms (SNP). Now differences are being recognised through the development of understanding of insertion/deletion (indel) variant polymorphisms where a particular nucleotide base is inserted or deleted in the sequence. These "… insertion-deletion (indel) variants have received considerable recent attention, partly because of their phenotypic consequences." [12] In addition, some 1500 copy number variations (CNVs) have been identified so far that cover significant areas on the genome, estimated at 12% of the entire genome. Each individual is estimated to have an average of 70 CNVs and within the CNV regions are to be found may genes, which are involved in metabolism and immunology. "Genetic diseases are caused by a variety of different possible alterations (mutations) in DNA sequences.,,,,,,, We do not know what proportion of genetic disease is caused by copy number variation (CNV), but ….[a] range of promising new technologies should, for the first time, allow us to scan the entire human genome for CNV in a single experiment. We are comparing these new technologies for screening hundreds of apparently healthy individuals for CNV."[13]

Scientific research in the Genome Era is showing that the human population contains an enormous level of variation and an understanding that the genome is not stable. There are continuous changes occurring in all genomes and these are passed on to the next generation. Similarly, understanding of epigenetic factors, including environmental interaction, is increasing.

Research in the Genome Era is increasingly global. New analytic technologies and platforms enable enormous blockbuster association studies to identify even more about gene activity and interaction. As an example, a large multi-centre research project examined breast cancer susceptibility genes. This is a genome wide association study involving some 28 centres in 12 countries involving 50,000 samples. The project has noted "the detection of further loci will require larger numbers of cases and controls and results across multiple

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[11] Francis S. Collins, M.D., Ph.D. "Physician Assistants and Personalized Medicine" National Human Genome Research Institute, PAEA Annual Meeting, October 27, 2007 www.paeaonline.org/ht/a/GetDocumentAction/i/67540 (visited 31 July 2009)

[12] Bhangale TR, Stephens M, Nickerson DA (2006) "Automating resequencing-based detection of insertion-deletion polymorphisms." *Nat Genet.* 38(12):1457-62.

[13] For an explanation of copy number variations in disease studies, ee The Wellcome Trust Sanger Institute, The Copy Number Variation (CNV) Project, http://www.sanger.ac.uk/humgen/cnv/

tudies".[14] Even 10 years ago, a single laboratory team did much research. The post-genome era is remarkable for these multi-centre international blockbuster type studies.

Research is confirming that the diversity of populations is increasingly underlining diversity of the human genome. This research is also tempering and toning down some of the early expectations and optimism of the Genome Era. The interpretation of genetic data, its connection to common diseases and the development of treatments will be a long road. In simple terms, the promise of genetics has often been much greater than its results. This is classically illustrated in the area of stem cell research where the promise is still greater than the actual therapies produced[15]. Human genetics is now entering into a more reflective and complex Genome Era.

THE NATURE OF HUMAN GENETIC INFORMATION

In the early 1990s, many commentators argued that human genetic information was exceptional. It was exceptional and different from other health information because of its prophetic potential. Genetic information about one individual was exceptional because it had implications for the family members and, also, there was a real fear about its potential to stigmatise and victimise. USA *Task Force on Genetic Information and Insurance*[16] considered these factors in detail in its 1993 report but rejected the 'exceptionalism' case.[17] This view is less accepted. There is a greater understanding that genetic information is valuable for research; it is sensitive but not exceptional. Though not exceptional, human genetic information can be predictive and reasonably conclusive for some monogenetic conditions. But the monogenetic diseases are not the main target for current research, which has expanded to a host of other common diseases, such as heart disease, diabetes and cancers. Genetic information may be predictive for some but not for other conditions. For example, at one stage the risk assessment on BRCA-1 was particularly high in relation to the susceptibility to cancer for carriers and an equally high susceptibility to pass on the gene to offspring. Later research has substantially revised the risk level. Importantly, genetic information is generally treated like other medical information as sensitive but not exceptional.[18]

Genetic information has become an important commodity in the Genome era. The private, commercial for-profit sector is conducting much of the increased research effort in genomics. Companies, sometimes in public-private partnerships with universities, are involved in research with the aim of securing intellectual property rights and profits through licensing or spin-off companies. National biotechnology strategies also see genetic research as a key strategy to improve the health as well as to build their economies to create valuable jobs in the modern "knowledge-value" economies of the Genome era[19]. Patents are seen as

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[14] Easton, D et al (2007) "Genome-wide association study identifies novel breast cancer susceptibility loci" *Nature* 447, 1087-1093

[15] Chalmers D "Stem Cell Technology: From Research Regulation To Clinical Applications" in Campbell A and Capps B *Bioethics and the Global Politics of Stem Cell Science: Medical Applications in a Pluralistic World* (forthcoming)

[16] Task Force Report (1993)*: Genetic Information and Insurance*, Bethesda, Maryland: Genetic Information and Health Insurance, National Institutes of Health, National Center for Human Genome Research

[17] Lazzarini, Z. (2000) What Lessons Can We Learn From the Exceptionalism Debate (Finally)? *Journal of Law, Medicine and Ethics*, 29:149-151

[18]Chalmers D " The Challenge of Human Genetics" in Freckelton I (ed) *Controversies in Health Law* Federation Press, 1999

[19] Saikaya T (1993) *The knowledge-Value Revolution* Kodansha Press

"…a winner-take-all game, with no glory or comfort for the also-ran".[20] They are the preferred protection for invention and discovery in new technologies, but there a many who believe that human life should be exempt, on moral grounds from patent protection.[21] Also health officials, in Australia and elsewhere expressed concern about the potential costs to the health care system from medical patents and licences.

There were early clashes between gene researchers about free access to results. The HGP had a strong policy to open access but other commercial researchers (Celera in particular) thought that their "discoveries" should be patentable. There were real tensions between the public and private sectors working on the genome sequence before the joint publication. The public sector based HGP supported open access to data in their *Bermuda Declaration* and released sequence data within 24 hours[22]. This did not prevent something of a "patent rush" before the joint publication[23]. The problem came under control when the United States *Patent and Trade Mark Office* declared the application of a higher test of "utility" for the backlog of applications. The stricter test was in line with the stricter test in the EU countries[24]. There is a continuing debate about patenting of genes. The Australian Law Reform Commission conducted an inquiry on the subject and concluded that "no radical overhaul of the patent system"[25] was required but recommended a number of changes to be achieved by guidelines and changes in practice, such as

- Improving patent law and practice concerning patenting genetic materials and technologies, including amendments to the *Patents Act* and changes in the practices and procedures of IP Australia, patent examiners and the courts;
- improving patent law and practice concerning the exploitation of gene patents, including in relation to a new defence to claims of patent infringement, Crown use, and compulsory licensing of gene patents;
- ensuring that publicly funded research, where commercialised, results in appropriate public benefit, including through the adoption of appropriate patent practices;
- establishing mechanisms for monitoring the implications of gene patents for research and healthcare so that governments have the ability to intervene where gene patents are considered to have an adverse impact, either in specific cases or systemically.[26]

ETHICAL, LEGAL AND SOCIAL CHALLENGES OF GENETIC INFORMATION

The explosion in human genetic information has been accompanied by ethical, legal and social concerns, which have been debated by international organisations. As early as 1997,

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[20] Jasanoff S (1993) "Innovation and Integrity in Bio-medical Research" *Academic Medicine* 68:at 95.

[21] See Australian Law Reform Commission *Genes and Ingenuity* Report 99, 2004

[22] Financial Times cited in Gene *Watch* May 2001 Vol 14:5.

[22] Sulston J and Ferry G (2003) *The Common Thread* London Corgi Books

[23] At the outset of 2000 9,364 patent applications were filed worldwide for inventions relating to the human body and some 126,672 applications for whole or partial human gene sequences. By the end of the year gene sequence applications had increased by 34,500 applications. One company, Incyte Genomics filed applications covering portions of more than 50,000 gene sequences including 7,000 full length genes. Some 500 gene-related patents were granted that year Nicol, D. and Nielsen, J. (2001) 'The Australian medical biotechnology industry and access to intellectual property: issues for patent law development', *Sydney Law Review*, 23:347-374.

[24] Ibid Nicol, D. and Nielsen, J. (2001)

[25] Ibid at 14

[26] Ibid 14-15 and see Recommendations 6-3; 9-1; 10-2; 11-1; 13-1; 19-4

the UNESCO *Declaration on the Human Genome and Human Rights* provided that "research, treatment and diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment of the potential risks and benefits" with the informed consent of the person and after the research protocols have been submitted for prior review (Article 5).

Privacy Privacy has been an enduring concern with genetic information, especially as computer power in national health systems can, or are planning to, link doctors' records, hospital records and government records. There are continuing concerns that sensitive genetic information may be accessed by insurance companies, employers or police and misunderstood or misapplied. The UNESCO *Declaration on the Human Genome and Human Rights* recognised the potential for discrimination and provided that "No-one shall be subjected to discrimination based on genetic characteristics…"(Article 6). Genetic discrimination in employment or insurance and pension scheme has been a matter of ongoing international concern and was the subject of a major inquiry by the Australian Law Reform Commission.[27] Their Report on the human genetic information in 2003 laid down a range of recommendations to improve genetic privacy, regulate genetic testing and research and databases, to prevent the improper access to this information by insurers, employers, police and other law enforcement agencies and to restrict genetic testing in arguments about parentage. The Commission recommended the establishment of a national Human Genetics Advisory Committee that has operated for three years and implemented many of the report's recommendations.[28]. It should be noted, however, that an empirical study in Australia found that cases of discrimination have been rare.[29] Much of the literature about genetic discrimination describes the unique American medical system that is the only OECD nation *without* a public universal health care system. It is clear that privacy law principles, which are generally internationally harmonised, are a sound foundation adequate to meet the challenges of genetic information. European nations must implement legislation to comply with the European Union (*EU) Data Protection Directive* (95/46/EC). Privacy law now has a major influence in the regulation of medical research generally. Privacy legislation applies across a range of principles from the collection through to the storage and use of data.[30]

Genetic Tests A significant challenge in the Genome Era has been the dramatic growth in companies marketing direct-to-customer (DTC) genetic tests. Companies such as 23andMe[31] and Navigenics[32] offer DTC tests to predict genetic risk of illnesses. Kaiser Permanente[33] has announced plans to study the DNA of 400,000 people. The results of DTC tests are not sent to a doctor, with the training to interpret and explain the results,[34] but go directly to the consumer. In this respect, the doctor has been bypassed and is no longer

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[27] ALRC and Australian Health Ethics Committee *Essentially Yours: The Protection of Human Genetic Information in Australia* Report 96 March 2003

[28] The HGAC is a committee of the National Health and Medical Research Council see http://www.nhmrc.gov.au/about/committees/hgac/index.htm (visited 5 August 2009)

[29] Barlow-Stewart K, et al (200) "Verification of consumers' experiences and perceptions of genetic discrimination and its impact on the utilization of genetic testing" *Genetics in Medicine* 11: 1-9

[30] Chalmers, D (2004) "Research Involving Humans: A Time for Change?"*J of Law, Medicine & Ethics* 32:583-495.

[31] https://www.23andme.com/

[32] http://www.navigenics.com/

[33] http://www.dor.kaiser.org/studies/rpgeh/

[34] Walsh K, (2009) "The gene genie: coming soon to a website near you" at http://www.superliving.com.au/storyview.asp?storyid=892350&sectionsource=IND:%20SL%20Feature (visited 5 August 2009)

standing as the gatekeeper of genetic services. With the growth of DTC kits, the question arises whether people themselves should be able to access genetic information test results without the intervention of qualified health professionals. The National Institute of Health (NIH) expressed concerns but has decided on consumer education as a major response and, in this respect treating DTC genetic tests like any other consumer product in the market[35]. A major A Phg Foundation Research Report in 2008 concluded "a failure to improve clinical evaluation of genetic tests will undermine the development of personalised medicine in this century and lead to a new generation of medical technology of unclear clinical value"[36]. Similarly, Hudson stated, "at worst, genetic testing errors can kill, at best, the result in poorly spent health care dollars, should the public begin to question the accuracy of genetic tests, personal medicine will be nothing more than a postscript on the pages of medical history. We need sensible regulation to secure the future of genetic medicine"[37]. Hudson and colleagues have gone on to argue for a mandatory registry of genetic tests as preliminary step towards quality assurance of tests[38]. The potentially wide availability of genetic information holds the challenge that the abuse of genetic information may quickly lead to an overall loss of public trust in tests and possibly in genetic research.

BIOBANKS AND GENETIC INFORMATION

One of the drivers of genetic research will come from the development of biobanks, the resources of which have the capacity to improve the accuracy and validity of genetic tests. Biobanks will also drive large- scale research projects.[39]

Biobanks are specially developed collections of human tissue samples for research. The OECD has published an important report, *The Creation of Governance of Human Genetic Research Databases*, which uses the term Human Genetic Research Databases rather than "biobank". Other countries have used a variety of other terms; the UK coined the expression, "biobank", with the idea of depositing tissue and researchers withdrawing tissue for the purposes of research. Latvia has used "genebank", but the French have preferred a very unique term of a "biolibrary", invoking the comparison of the human genome as the "Book of Life".[40] There are of course, a variety of other collections of human tissue in the form of pathology collections, researchers' private collections, police forensic DNA banks, stem cell banks and blood banks. These collections have been established with the primary aim of diagnostic, clinical or forensic purposes. They are not intended primarily for research. The popularity of biobanks can be gauged from the initial establishment of DeCode in Iceland in the late 90s. There are now major biobank facilities in the UK, Estonia, Sweden, Quebec, Finland, Germany, Scotland, Mexico, The Netherlands, to name a few.

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[35] Compare in ART business in Brazier, M (1999) "Regulating the Reproduction Business" *Medical Law Review*, 7 :166-193.

[36] Phg Foundation Report (2007) *Moving Beyond ACCE: An Expanded Framework for Genetic Test Evaluation* September (Burke W and Zimmerman R)

[37] Hudson K (2006) "Genetic Testing Oversight" *Science* Vol. 313. no. 5795:1853 DOI: 10.1126/science.1134996

[38] Javitt, G, Katsanis, S, Scott,J, Hudson K (2009) "Developing the Blueprint for a Genetic Testing Registry*" Public Health Genomics* (DOI: 10.1159/000226593)

[39] Chalmers, D (2008) "Human Genetic Research Databases and Biobanks -Towards uniform terminology and Australian best practice" *Journal of Law and Medicine* 15:4 at 538-554

[40] Chalmers D (2006) "Ethical Principles For Research Governance Of Biobanks' *J Int Biotechnology law* 3:6 at 221-230

Also, in Australia, biobanks have either been established or are in the late stages of completion in Western Australia, Victoria and Tasmania. At the international level, there are also a number of initiatives. On completion of the Human Genome Project, this expertise and collaborations involved regrouped in a new collaboration between the USA, UK, Nigeria, China, Canada and most importantly, Japan, entitled the "International Haplotype Mapping Project." This project aims to identify genetic similarities and difference and to find genes that affect health, disease and medication responses. A unique project has been funded by Genome Canada, a not for profit for organisation established to promote genetic research in that country. The *Public Population Project* in Genomics entitled for short, P3G has brought together an accessible knowledge database for the international population genomics community[41]. Other collaborative organisations are setting up regularly and to mention one, the PHOEBE Collaboration is an effort to bring together biobanks for the promotion and harmonisation of epidemiological biobanks in Europe.[42]

Biobanks are seen by the research industry as representing a new opportunity for genetic information and are increasingly seen as an essential tool in translating biomedical research into real improvements in health care. They are being set up to undertake large-scale epidemiological disease research. This is seen as a major way of trying to address rising national health costs, especially in cancer, diabetes and heart disease. Equally, the biobanks are seen as research tools to advance the development of pharmacogenomics and personalised medicine.

PRINCIPLES FOR REGULATION OF GENETIC INFORMATION

There are legal and ethical principles that should guide the appropriate use of genetic information. First and most prominently, the privacy legislation will be a major vehicle for public confidence and protection. The developed countries of the OECD came together in the early 1980s and established common privacy principles, which have formed the backbone of legislation throughout the world. In summary, that legislation states that information should only be collected that is relevant for the purpose for which it is collected; it should not be used for secondary purposes; and, individuals should have access to and challenge against the personal information, in this case, genetic, held on them.

Secondly, the consent principle is a generally accepted international standard. Importantly, however, the traditional limited and specific consent for a particular project may not be sufficient. Genetic information also provides information about family members and about the future. This means that most projects will involve some follow-up with family relations or additional consents for future research. There is a real question whether a unrestricted permanent "blanket" or "broad" consent should be debated for the genetic information to be used in the future for all projects. [43] Broad consent involves consent for approved research projects but also for the use of the tissue/data for research in the *future*.

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[41] see http://www.p3g.org/ The observatory website has examples of consent forms and guidelines from its 22 Charter Biobanks, 13 Associate and some 152 individual members, representing some 10.5 million participants.

[42] Chalmers, D (2008) "Human Genetic Research Databases and Biobanks -Towards uniform terminology and Australian best practice" *Journal of Law and Medicine* 15:4 at 538-554

[43] Hansson M "Should Donors be Allowed to Give Broad Consent to Future Biobank Research?" (2006) 7 *The Lancet Oncology* 266-269.

Such consent must be properly and effectively obtained for all *future* research purposes. This type of consent is not common in health research[44].

Thirdly, it is clear that there should be proper research governance over genetic information. The systematic recording and storage of health records and information has been a traditional and trusted responsibility of the public health systems around the world. Public privacy laws and data protection legislation as well as specific health administration regulations and professional ethics govern public health records. Over a long period public health records have been preserved and available for epidemiological research, quality assurance procedures and legitimate disclosure. Increasingly these records are in electronic form and linked into national health information networks. All genetic information held by doctors, health services or researchers and police must deal with authorities legally and ethically. In the case of biobanks, there has already been a great deal of work done by the OECD[45] and by the NIH[46] and the ISBER[47]. In addition, the UK Biobank, which has set up a refined and sophisticated ethics and governance framework[48].

Fourthly, it is now widely accepted that public engagement is a major feature of the development of regulation schemes for genetic information. The Australian Law Reform Commission *Report on the Protection of Human Genetic Information* in 2003 was, for example, preceded by some two years of public consultation and submissions. In the case of biobanks, for example, public engagement is specifically mentioned in the OECD Report on The *Creation and Governance of Human Genetic Research*

Fifthly, global research is no longer conducted in individual labs. It involves worldwide projects and global collaborations. This requires harmonisation of regulations across jurisdictions and collaborations like the P3G initiative[49]. Harmonisation does not mean to say that all regulations are the same but they should have equivalent standards. International organisations have given guidance. For example, the OECD Report is guiding biobanks and the UNESCO *Universal Declaration of Human Genome and Human Rights* set down standards for the privacy of genetic information and reflected international agreement that some forms of cloning were unacceptable.

CONCLUSIONS

There has been a development of some new thinking in relation to ethical principles in dealing with genetic information. The recent UNESCO *University Declaration of Bioethics and Human Rights* has strengthened the idea of benefit sharing. This principle demands that there be equitable distribution of the benefits of genetic developments, either by the sharing of research results or perhaps downstream with new health care products. Interestingly, the

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[44] Caulfield, T "Biobanks and Blanket Consent: The Proper Place of the Public Good and Public Perception Rationales" (2007),18 *King's Law Journal,* 2 at 209-226.

[45] OECD *Creation and Governance of Human Genetic Research Databases* (2007)

[46] NCI (2006) *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

[47] ISBER *International Society for Biological and Environmental Repositories*. "Best Practices for Repositories I: Collection, Storage, and Retrieval of Human Biological Materials for Research" (2005) 3 *Cell Preservation Technology* 1, 5-48.

[48] UK Biobank, *Ethics and Governance Framework*, Version 2.0) Wellcome Trust and Medical Research Council and Department of Health UK, 2006 http://www.ukbiobank.ac.uk/ethics/egf.php

[49] Chalmers D (2006) "Ethical Principles For Research Governace Of Biobanks' J Int Biotechnology law 3:6 at 538-9

2005 Declaration has also promoted the notions of solidarity and human dignity as the underlying foundations for all the international declarations of human rights.

The changing nature of the social and legal debates about genetic information is well summed up by Margot Somerville in her book the *Ethical Canary*[50]. She reminded us that debates about new science developments move in fast moving "science time" where new discoveries are made daily. However, public debates and understanding is slower and follows an "ethics time". But regulators are the slowest we move behind, well behind in "law time ". But regulators must move more quickly and introduce laws that will ensure that genetic information is used responsibly to ensure public trust in the Genome Era.

[50]Somerville, M., 2000. *The Ethical Canary*: *Science, Society and the Human* Spirit. Victoria: Viking