Dianne Nicol*

Public Trust, Intellectual Property and Human Genetic Databanks: The Need to Take Benefit Sharing Seriously

Introduction

The last decade or so has seen major advances in two key areas of biomedicine: new genetic technologies, including genomics, proteomics, transcriptomics, metabolomics and the like; and stem cell technology. Both are touted as offering much promise in terms of our understanding of basic biological process and in the translation of this basic science into mainstream medical practice. But in both areas much further research must be done to realise this promise, and this hinges on the appropriate and adequate supply of essential research tools, particularly human tissue, human cells and human genetic information, which are referred to collectively here as *human biological material*. Tissue collections, banked cell lines and databases of genetic information, which will be referred to collectively here as *human genetic databanks*, are vital stores of these research tools. The people who supply the tissue, cells and genetic information to these databanks (collectively referred to here as sources) play a pivotal role in the success of this research endeavour. Hence, its success is, to a large extent, premised on the trust that sources have in it. Increasingly, entire populations of *sources* are being recruited to provide human genetic material for databanking; in such circumstances, individual source trust becomes synonymous with public trust.

Whilst it is recognised that the issues associated with trust in human genetic databanking are complex and multifaceted, this article focuses on the particular problems associated with trust in the commercialisation of biomedical research utilising human biological materials stored in human genetic databanks. Commercial development of new health care products is a key outcome of the research endeavour. Hence, there is a need for human genetic databanks to have adequate and appropriate intellectual property and access policies that provide some certainty in the rights and obligations of all parties involved. It will be argued that one essential requirement for such policies is that they should explicitly make provision for benefit sharing arrangements from two distinct perspectives: general benefit to society at large; and specific benefit to the sources of the original human biological material and/or their social groupings.

The nature of human genetic databanks

Many human genetic databanks have been in existence for long periods of time, having been established for non-research purposes, for example as stores of pathological samples.[1] Other genetic databanks established for particular research projects also continue to store collections of human biological material. In fact, vast numbers of these collections of biological material are in storage around the world.[2] It has been estimated that 350 million tissue specimens are stored in repositories in the US alone,[3] with a further 20 million added each year.[4] It is now well recognised that these banks of tissue, cells and information can have significant value for research, both now and into the future.

A number of organisations have been established with the specific purpose of coordinating storage and distribution of these stores of biological material. A good example is the American Tissue Type Culture Collection (ATCC), a world-wide repository for biological material, including micro-organisms,

---

* PhD (Biology), LLM, Senior Lecturer, Faculty of Law, University of Tasmania. I would like to thank Don Chalmers, Margaret Otlowski and Mark Stranger for commenting on early drafts and Jane Kaye for helpful discussions and providing me with access to her materials. This research was supported by Autralian Research Council Dicovery Grant DP 0559760.

Dianne.Nicol@utas.edu.au

1 *Jean E McEwen*, 'DNA Sampling and Banking: Practices and Procedures in the United States' in *Bartha Maria Knoppers, Claude M Laberge* and *Marie Hirtle* (eds) Human DNA: Law and Policy International and Comparative Perspectives (The Hague: Kluwer Law International; 1997) at 414.

2 See, for example, *Jon F Merz*, 'On the Intersection of Privacy, Consent, Commerce and Genetic Research' in *Bartha Maria Knoppers* (ed) Populations and Genetics: Legal and Socio-Ethical Perspectives (Netherlands: Koninklijke Brill NV; 2003) at 257-258.

3 Ibid.

4 *Karen Birmingham*, 'An Inauspicious Start for the US National Biospecimen Network' (2004) 113 Journal of Clinical Investigation 320.

cell lines and recombinant DNA materials.[5] Some of the major research organizations around the world store and make available their tissue via the ATCC. For example, Johns Hopkins University provides its Special Collection of Biological Materials for research purposes via the ATCC catalogue.[6] The Wistar Institute also makes available its Special Collections of various cancer cell lines and hybridomas in this way.[7] In Australia, the Western Australian Research Tissue Network carries out a similar function, providing a facility for banking biological materials in that state.[8] To date, its collections of samples primarily relate to various forms of cancer, including breast, ovarian, prostate, colorectal and gastric. The network also has ethical approval to collect and manage health information related to its collected materials.

The lack of consistency as to methods of collection and storage and access policies has also encouraged the creation of more informal tissue or biospecimen networks, bringing together organisations that have pre-existing tissue collections. The aim of these networks is to standardise policies and procedures for storing and accessing the material rather than to provide actual storage facilities. In Australia and New Zealand, for example, the Australasian Biospecimen Network has been established to provide a forum to address technical, legal and ethical, and managerial issues relevant to human biospecimen repositories within Australia and New Zealand. The Network is a non-profit scientific organisation with voluntary membership.[9]

There is also a growing trend to create new large-scale population human genetic databanks for use as research tools in wide ranging research projects.[10] In the UK, for example, the Biobank Project aims to collect tissue samples from 500,000 participants aged between 45 and 69 and to use the genetic information extracted from those samples to identify links between genetic and environmental factors in common diseases. It is described as the world's biggest resource for the study of the role of nature and nurture in health and disease.[11]

One of the first of the large scale population databanks was established in Iceland, and it has generated a large amount of publicity and academic debate because of the way it is structured, with a distinctly commercial make up.[12] In 1998 legislation was passed for the establishment of a nationwide databank of blood samples and genetic information, which is linked to other health and genealogical information. deCODE Genetics, a for-profit company based in Iceland, has been given an exclusive licence from the Icelandic government to manage the databank.[13] The company is entitled to use the databank for its own research and to on-licence to other researchers.

CARTaGENE is a project based in Quebec in Canada, the aim of which is to recruit 50,000 individuals to provide blood samples and anonymised health information. It will be under the management of a non-profit institute.[14] The Estonian Genome Project Foundation is a hybrid between the Biobank and CARTaGENE models and the DeCode model. The Foundation is a non-profit organisation that has been set up under legislation to manage a national databank of tissue and genetic, health and genealogical information in that country. In addition, a for-profit company, EGeen, has been given the right to sell access and information.[15]

Aside from the databanks described above and others of the same nature that store human tissue and frequently combine it with personal genetic and health information,[16] there are also increasing numbers of databases of more generic DNA

5 For further information see: http://www.atcc.org/ (last accessed 25 January 2006).

6 See: http://www.atcc.org/common/specialCollections/JHU.cfm (last accessed 25 January 2006).

7 At: http://www.atcc.org/common/specialCollections/wistar.cfm (last accessed 25 January 2006).

8 At: http://www.waimr.uwa.edu.au/etc/page.cfm/SID/11/PID/64 (last accessed 25 January 2006).

9 For further information see: http://www.abrn.net/ (last accessed 26 January 2006).

10 *Geneviève Cardinal* and *Mylène Deschênes*, 'Surveying the Population Biobankers' in *Bartha Maria Knoppers* (ed) Populations and Genetics: Legal and Socio-Ethical Perspectives (Netherlands: Koninklijke Brill NV; 2003).

11 For further information on the UK Biobank Project, see: http://www.ukbiobank.ac.uk/ (last accessed 24 January 2006)

12 See, for example, *Jane Kaye* and *Paul Martin*, 'Safeguards for Research Using Large Scale DNA Collections' (2000) 321 British Medical Journal 1146; *Hilary Rose*, The Commodification of Bioinformation: the Icelandic Health Sector Database (London: The Wellcome Trust; 2001),

13 Ibid at 1147.

14 At: http://www.cartagene.qc.ca/index2.cfm?lang=1 (last accessed 26 January 2006).

15 At: http://www.egeeninc.com/public/ (last accessed 26 January 2006).

16 For a full list as at 2004 see *Hans-E Hagen* and *Jan Carlstedt-Duke*, 'Building Global Networks for Human Diseases: Genes and Populations' (2004) 10 Nature Medicine 665.

sequence information.[17] The most comprehensive and well known is GenBank, the publicly accessible repository of the sequence information produced by the Human Genome Project.[18] Many proprietary databases also exist. For example, Celera Genomics, the company that raced against the Human Genome Project for completion of the human DNA sequence, offered access to its sequence database for a fee.[19] In addition to the Human Genome Project, there are a number of other international collaborative sequencing ventures, notable examples of which are the SNP Consortium and the HapMap Project. Both also make sequence information available in publicly accessible databases.[20]

Ethical considerations

Debate about the appropriate rules for regulating human genetic databanking is intensifying around the world as their number, size and scope increases. Consent by a source to the storage and use of their tissue, cells and genetic information is always likely to be a paramount ethical concern because of the acute privacy and discrimination issues raised by the use of identifiable genetic information. Such matters have been debated extensively in the academic and policy literature, and countries around the world are putting in place procedures to alleviate some of these concerns. For example, the aim of the HapMap project is to map common patterns of human genetic variation and to determine linkages with common diseases like diabetes, cancer and stroke. The early pilot study involved collection of samples from four representative populations in Africa, Japan, China and northern and western Europe, and hence it was highly ethically sensitive.[21] Considerable attention was paid to these ethical sensitivities to ensure that the project had the ongoing support of the populations involved and society as a whole.

There are likely to be ongoing ethical problems relating to the use of materials in databanks that are already in existence, primarily resulting from the inadequacy of consent requirements that were in place at the time that the material was collected.[22] These problems can be alleviated to some extent by ensuring that the material is properly de-identified before it is supplied to researchers. However, it is debatable where any material containing human genetic material can ever be truly de-identified.[23] As there is now better recognition of the importance of securing proper consent to store and use material for research purposes, any research projects using materials from more recently created databanks are likely to pose less problems from this perspective.[24] Nevertheless, the precise nature of the requirement for valid consent to unspecified future research use remains problematic.[25]

---

17 *Michael G Tyshenko* and *William Leiss*, 'Current Trends in Publicly Available Genetic Databases' (2005) 11 Health Informatics Journal 295 at 296.

18 Available at: http://www.ncbi.nlm.nih.gov/ (last accessed 25 January 2006).

19 However, Arti Rai notes that the availability of the public data placed a ceiling on what Celera could charge and ultimately resulted in the company moving out of databanking and into drug development: *Arti K Rai*, 'Open and Collaborative Research: a New Model for Biomedicine (2004) Duke Law School Legal Studies Research Paper Series Research Paper No 61 at 26-27.

20 One of the lead funding agencies of both projects, the Wellcome Trust, describes these ventures as two global partnerships that are characterising variations in the human genome. It states that single nucleotide polymorphisms ('SNPs') are changes to single letters of the DNA code, which occur in about one in every 1000 nucleotides. The SNP Consortium is mapping these SNPs, whereas the HapMap Project is investigating the combinations of SNPs that are inherited together: Wellcome Trust, The SNP Consortium and the International HapMap Project (2005) at: http://www.wellcome.ac.uk/doc_WTD003500.html (last accessed 25 January 2006). See also Dave A Chokshi and Dominic P Kwiatowski, 'Ethical Challenges of Genomic Epidemiology in Developing Countries (2005) 1/1 Genomics, Society and Policy 1.

21 For an account as to how these ethical issues were dealt with see International HapMap Consortium, 'Integrat-ing Ethics and Science in the International HapMap Project' (2004) 5 Nature Reviews Genetics 467.

22 *Mary R Anderlik*, 'Commercial Biobanks and Genetic Research Ethical and Legal Issues' (2003) 3 American Journal of Pharmacogenomics 203 at 205.

23 In Australia, the second draft revision to the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (as at January 2006) provides at page 26 that: 'with advances in genetic knowledge and data linkage, and the proliferation of tissue banks of identified material, human tissue samples may always be regarded as, in principle, potentially re-identifiable.' Although that draft has not yet been approved, it does provide some indication of new ways of thinking about this contentious issue of identifiability.

24 See, for example, Lorraine Sheremeta, Population Biobanking in Canada: Ethical Legal and Social Issues (Canadian Biotechnology Advisory Committee; 2003) at 8. Available at: http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/en/ah00482e.html (last acces-sed 30 January 2006).

25 For a critique on the ongoing focus on informed consent and individual rights see *Garrath Williams*, 'Bioethics and Large-scale Biobanking: Individualistic Ethics and Collective Projects' (2005) 1/2 Genomics, Society and Policy 50.

Alongside this issue of consent to use for research purposes, there are other equally valid and growing concerns about the direct commercial use of databanked material and the more indirect commercial use of the results of research that has utilised databanked material. These concerns are inextricably linked to the consent question, because arguably fully informed consent requires disclosure of both of these direct and indirect commercial dealings with human genetic material.

Although the willingness of sources to continue to provide their materials is vital for most biomedical research,[26] payment for supply is rarely considered to be a serious option, because of the long-standing revulsion that society has about the commodification of human biological material. This sentiment is reflected in a number of official international bioethics documents. For example, the Council of Europe's *Convention on Human Rights and Biomedicine* provides in Article 21 that: 'the human body and its parts shall not, as such, give rise to financial gain'[27] and the *Universal Declaration on the Human Genome and Human Rights* similarly states in Article 4 that 'the human genome in its natural state shall not give rise to financial gains'.[28]

At the same time, there is growing awareness that private companies could make millions of dollars from the exploitation of inventions developed using tissue and information that has been freely donated. The situation becomes increasingly complex when the managers of human genetic databanks and the researchers themselves become involved in the commercialisation processes. There is ample evidence of the increasing commercialisation of the storage and research phases of these endeavours. Although many databanks are non-commercial in nature, an increasing number of companies are establishing themselves in this role, deCODE being the prime example.[29] Researchers and research institutions are also becoming increasingly involved in the commercial side of biomedical research and development. They are some of the most prolific filers of patents in the areas of gene and stem cell technology and often have partnerships with industry to facilitate commercialisation of their research.[30]

In such situations, where everyone but the source appears to have a financial interest, it is not difficult to see why the source may feel somewhat marginalised, and even exploited.[31] Whilst some would argue that this problem could be solved by paying sources a fair price for their material,[32] this view is not widely supported. On the contrary, in addition to the potential for this to impact on the cost of doing biomedical research, there is concern that it could lead to coercion of the most vulnerable sectors of society.[33] Lori Andrews and Dorothy Nelkin point out that there is a widespread view that this process of turning tissue, cell lines and DNA into commodities not only violates bodily integrity, exploits powerless people and intrudes on community values but also distorts research agendas and weakens public trust in scientists and clinicians.[34]

---

26 Because of this, *John Harris* has made the rather controversial argument that individuals actually have an ethical obligation to participate in such research. See *John Harris*, 'Scientific Research is a Moral Duty' (2005) 31 Journal of Medical Ethics 242.

27 The Convention was signed by the member states on 4 April 1997.

28 The Declaration was adopted by the General Conference of UNESCO on 11 November 1997.

29 See, for example, Anderlik, above n22; Merz, above n2 at 263. It has been suggested that a charitable trust rather than a private company may be a more appropriate governance structure for human genetic databanks: see David E Winickoff and Richard N Winikoff, 'The Charitable Trust as a Model for Genomic Biobanks' (2003) 349 New England Journal of Medicine 1180. However, such a model is not problem free: see Andrea Boggio, 'Charitable Trusts and Human Research Genetic Databases: the Way Froward?' (2005) 1/2 Genomics, Society and Policy 41 and a further response: David E Winikoff and Larissa B Neumann, 'Towards a Social Contract for Genomics: Property and the Public in the 'Biotriust' Model' (2005) 1/3 Genomics, Society and Policy 8.

30 *Merz*, above n2 at 262.

31 It should be recognised that human genetic databanking, of itself, is not necessarily a profitable enterprise. Indeed, a survey of databankers across Europe in 1999-2000 revealed that most such activities are not profitable and need to be subsidised: A Cambon-Thomsen et al, 'An Empirical Survey on Biobanking of Human Genetic Material and Data in Six EU Countries' in *Bartha Maria Knoppers* (ed) Populations and Genetics: Legal and Socio-Ethical Perspectives (Netherlands: Koninklijke Brill NV; 2003) 141 at 153.

32 *John C Bear*, '"What's My DNA Worth Anyway?" A Response to the Commercialization of Individuals' DNA' (2004) 47 Perspectives in Biology and Medicine 273-289.

33 Irish Council for Bioethics, Report of the Working Group on Human Biological Material (20005) (the Irish Report), at 62. Available at: http://www.bioethics.ie/publications.html (last accessed 30 January 2006).

34 *Lori Andrews* and *Dorothy Nelkin*, 'Homo Economicus: Commercialization of Body Tissue in the Age of Biotechnology' (1998) 28 Hastings Center Report 30 at 31.For a contrary viewpoint see Bear, above n32 at 284-285, where he argues that an individual's DNA sequence information associated with information about his or her health status has commercial value and that payment is an obvious implication of this fact.

Hence, although the contribution that sources make to the research endeavour needs to be better recognised, serious questions have to be asked about the appropriateness of financially rewarding sources for supply of human biological material and also about any further commodification of human genetic databanking and biomedical research. Having said this, there are still good reasons why the involvement of private companies in the development of biomedical technology is justifiable, principally because this is likely to be the only way to bring products to the healthcare market. The whole endeavour of databanking human biological material and utilisation of that material for biomedical research and development is only likely to succeed if these conflicting interests can be accommodated. The word *trust* perhaps best encapsulates the challenge that lies ahead. Sources of biological material are only likely to be willing to continue to provide their material if they have *trust* that appropriate ethical safeguards are in place to protect them. But it is increasingly being recognised that source trust goes beyond this. Sources also need to be assured that others are not unduly profiting from their willing participation[35] and that adequate benefit arises out of their participation, whether from their own perspective, or that of the societal group to whom they belong or the public as a whole.

Similarly, it is likely that researchers will only continue to collect, supply, maintain and utilise databanked material if they have *trust* that they will receive adequate and appropriate benefit, whether this is in the form of broad scientific advancement resulting from the research endeavour, proper acknowledgement of their research input or more overt forms of compensation for their intellectual input. Private companies will only be interested in supporting the endeavour and commercially developing research results if they have *trust* that these actions are in the best interests of their shareholders. In particular, they will need some assurance that they are able to recover their investment in research and development, which will usually require some guarantee of clean ownership of any intellectual property rights arising out of the endeavour. More generally, and perhaps even most importantly, the broader public will only support human genetic databanking, research and commercial development if they have *trust* in the whole enterprise, both from the perspective that that an appropriate balance has been achieved between these diverse and potentially conflicting needs to secure benefits in one form or another and also from the perspective that inappropriate commodification is avoided. As Jon Merz puts it:

> there are open issues about how such ventures [like large scale population genomic databases] should be best structured to provide incentives for the development of useful public resources while avoiding unjust appropriation of public goods ...[36]

Benefit sharing is being mooted both as an ethically appropriate means of balancing the conflicting interests involved in genetic databanking and also as a potential solution to the problem of loss of public *trust*.

The problem of loss of public trust

It is probably fair to say that public trust in biomedical science is slowly (or even, in some areas, rapidly) eroding.[37] The last few decades have not only seen the erosion of trust in the profession of medicine, but also in government and science. Well-publicised organ retention scandals in British hospitals have added to this general malaise. The most recent uncovering of fraud by one of the most esteemed teams of stem cell scientists is likely to erode the fragile layer of trust that may have been forming around this technology. The collection of medicinal plants from developing countries for the purpose of drug development has led to widespread use of the phrase biopiracy. When the same methods were use to collect samples of blood and hair from indigenous peoples around the world in the mid-1990s this became known as the *Vampire Project*. The term *helicopter genetics* has also been coined to describe the process whereby research teams fly in to a remote location where a particular genetic condition may be prevalent, take family histories, bleed local residents and return to the host laboratory to analyse the samples, never to be seen or heard from again.[38]

---

35 A recent review of public perceptions of genetic databanking found that concerns about commercialisation are prevalent among many publics. Edna Einsiedel, Whose Genes, Whose Safe, How Safe? Publics' and Professionals' Views on Biobanks (Canadian Biotechnology Advisory Committee; 2003) at 17. Available at: http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/en/ah00511e. html (last accessed 30 January 2006).

36 *Merz*, above n2 at 263. See also *Mark Stranger*, *Don Chambers* und *Dianne Nicol* 'Capital, Trust and Consultations: Databanks and Regulation in Australia' (2006) 15 Critical Public Health 343.

37 On this point see also *Kaye* and *Martin*, above n12 at 1146.

38 Newfoundland and Labrador Department of Health and Community Services, Policy Implications of Commercial Genetic Research in Newfoundland and Labrador (January 2003) (the Newfoundland Report) at 12. Available at: www.nlcahr.mun.ca/research/

The negative impact of such activities on public trust is likely to be most acute where there is commercial involvement. The industry sector probably will always be viewed with some scepticism by the public because of its perceived 'profit at all costs' mentality. The pharmaceutical industry, in particular, is seen as being predominantly profit driven, even though (or perhaps because) it is developing products to serve the public good. The increased commercialisation of human genetic and stem cell research is likely to further threaten public trust in this sector, particularly if there is the perception of conflict of interest, where profits come before patient care or free exchange of research results.[39] Graeme Laurie and Kathryn Hunter argue that represents a break down in the traditional altruistic gift model for organising medical research.[40]

It seems that the problem is most acute when the language of *ownership* is introduced. For example, in 2000 the Australian biotechnology company Autogen Ltd entered into negotiations with the government of Tonga to set up a population database on this small Pacific Island. The project was abandoned in 2002 following public opposition. According to Geneviève Cardinal and Mylène Deschênes, one of the reasons for the failure of the project was concern about 'the conversion of the islanders DNA into corporate property through patent monopolies'.[41] The whole notion that biobanked material can be the subject of commerce, to be bought and sold like any other commodity is deeply troubling for many members of society.[42]

Would public trust be restored simply by allowing sources of human genetic material to enter the world of commerce and be paid for their contribution? Is this really what we mean when we talk about benefit sharing? Would it be better to free the research endeavour as far as possible from the fetters of commodification rather than encouraging further proprietary claims? Would it be fair to allow the downstream developers of new healthcare products to reap the benefits of the endeavour, without having to provide a share to other participants? Is benefit sharing the one right answer to this complex web of questions? According to one recent report, the concept of benefit sharing does not attempt to denounce commercialisation, but it seeks to promote the idea that those who directly financially profit ought to contribute to the donors of the material, without such donation amounting to an inducement.[43] Teasing out an appropriate mechanism to achieve this end requires further exploration.

Theoretical rationale for benefit sharing

Both from the ethical analysis outlined above and, a matter of common sense and decency,[44] there are strong grounds for arguing that, at the very least, researchers, databanks operators and other individuals involved in genetic databanking have the following moral obligations:

- to sources, to properly recognise their willing participation;
- to vulnerable members of society, to avoid coercion;
- to the scientific community as a whole, to disclose and make available the results of research using databanked materials; and
- to society as a whole, to ensure that the benefits stemming from research using databanked materials are shared by all, with particular focus on the needs of disadvantaged groups in both developing and developed countries.

Do any of these obligations equate with a moral obligation to share in the financial rewards derived from research and development utilising databanked human genetic material? Ruth Chadwick and Kàre Berg express the view that although intuitively, sharing of economic benefits seems morally desirable, it is also difficult to identify any specific reason why the pharmaceutical industry should be obliged to share the revenue from their genomic research.[45] Indeed, Berg further argues that any rule requiring sharing of economic benefits may be in conflict with other rules that state that the

---

reports_search/DP_Final__Report.pdf (last accessed 30 January 2006); Rose, above n12 at 9.

39 *Don Chalmers* and *Dianne Nicol* 'Commercialisation of Biotechnology: Public Trust and Research' (2004) 6 International Journal of Biotechnology 116

40 *Graeme Laurie* and *Kathryn G Hunter*, 'Benefit-sharing and Public Trust in Genetic Research' in Gardar Árnason, Salvör Nordal and Vilhjámur Árnason (eds), Blood & Data: Ethical, Legal and Social Aspects of Human Genetic Databases (Reykjavik: University of Iceland Press & Centre for Ethics; 2004) 323 at 323.

41 Above n10 at 61, citing *B. Burton*, 'Proposed Genetic Database on Tongans Opposed (2002) 324 British Medical Journal 443.

42 *Sheremeta*, above n24 at 53.

43 Irish Report, above n33 at 64.

44 Emerging international principles, discussed later in this article, also add strength to this argument.

45 *Ruth Chadwick* and *Kàre Berg*, 'Solidarity and Equity: New Ethical Frameworks for Genetic Databases' (2001) 2 Nature Reviews Genetics 318.

human body should not be a source of income.[46] In his view, the difficulty for individual sources is that they have not done anything *valuable* with their biological material, and, if there is a duty to pay, the rights of the scientists that have made the sample valuable may exceed those of the source. He concludes that: '*specific* strong arguments for financial compensation to individuals are hard to find' [his emphasis].[47]

Others have also commented on the difficulty in finding some underlying normative justification for benefit sharing.[48] According to Richard Gold and Tim Caulfield, these problems arise because the focus of the analysis remains based in property rhetoric and the obligation to compensate for contribution.[49] In the alternative, they support justifications based on distributive justice, that everyone has the right to share in scientific advances and their benefits.[50] Berg uses the language of solidarity, which extends from a responsibility to make one's biological material available for research to support for people in need to a duty to help the needy or to help countries develop.[51] Some policy documents also provide support for the applicability of both of these principles when attempting to find justifications for benefit sharing, adding further that recognition that the human genome is the common heritage of humanity[52] requires that benefits accruing from genetic research should benefit all the people.[53]

These principles provide solid justification for sharing of benefits across society, but they do not provide a great deal of support for arguments that individual sources or the groups to whom they belong deserve to receive special benefits. In addressing this problem, Charles Wiejer argues that what really is required is a new ethical principle, the principle of respect for communities.[54] But whether benefit sharing actually needs some form of normative ethical justification is a moot point. Laurie and Hunter sensibly bring the debate squarely back to the issue of trust.[55] They argue that, aside from these normative principles, lack of trust of itself is sufficient rationale for benefit sharing. In support of this argument, they suggest that benefit sharing: 'allows the normatively appealing gift model while redressing the palpable imbalance of power in the researcher-subject relationship' by providing a 'continuing obligation to ensure that financial benefit (profit) to the researcher is shared in some way with the participant or her community' [their emphasis].[56]

Accepting that there is a strong linkage between trust and benefit sharing, and that some form of benefit sharing is desirable both practically, to promote trust, and also (perhaps more arguably) from the normative perspective, the difficult issues of determining what benefits should be shared and how they should be allocated remain. Mark Rothstein notes that calls for benefit sharing arose in the first place because of actual or perceived exploitative behaviour.[57] Clearly, this problem needs to be addressed. However, he also expresses concern about what he refers to as 'true benefit sharing', which, he says, would require a restructuring of the biomedical research system, technology transfer laws, and intellectual property laws.[58] Kàre Berg also raises a number of practical difficulties with sharing of financial benefits. In particular, he cautions against creating a general rule that financial compensation should be paid at the outset because of the difficultly in predicting success and the stultifying effect that this could have on university research.[59]

The benefit sharing obligation does not necessarily have to be restricted in this way, to focus exclusive-

---

46 *Kàre Berg*, 'The Ethics of Benefit Sharing' (2001) 59 Clinical Genetics 240 at 242-243.

47 Ibid at 243.

48 See, for example, *E Richard Gold* and *Timothy A Caulfield*, 'Human Genetic Inventions, Patenting and Human Rights (Justice Canada; 2003) at 45-46. Available at: http://www.cipp.mcgill.ca/db/published/00000006.pdf (last accessed 30 January 2006).

49 Ibid. See also Kadri Simm, 'Benefit-sharing: an Inquiry regarding the Meaning and Limits of the Concept in Human Genetic Research' (2005) 1/2 Genomics, Society and Policy 29.

50 *Gold* and *Caulfield*, above n48 at 47.

51 Berg, above n46 at 242.

52 Note that UNESCO's Universal Declaration on the Human Genome and Human Rights (adopted on the report of Commission III at the 26th plenary meeting, 11 November 1997) refers in Article 1 to the human genome as being, in a symbolic sense the heritage of humanity.

53 Irish Report, above n33 at 63.

54 *Charles Weijer*, 'Benefit-sharing and Other Protections for Communities in Genetic Research' (2000) 58 Clinical Genetics 367 at 368.

55 Above n40 at 325.

56 Ibid.

57 *Mark A Rothstein*, 'Expanding the Ethical Analysis of Biobanks' (2005) 33 The Journal of Law, Medicine & Ethics 89 at 97.

58 Ibid at 96.

59 *Berg*, above n46 at 241-242

ly on direct financial benefits. The umbrella of benefit sharing could also include more indirect benefits, such as preferential access to new healthcare developments, as well as genuine efforts to fully disclose all relevant information, particularly information about the process of commercialisation, and to explicitly recognise the input that sources have made. It could be argued that the promise of new healthcare developments is sufficient to satisfy any obligation to provide benefits to participants in biomedical research. However, for Laurie and Hunter, such abstract promises, that are only likely to benefit future generations, are not enough.[60] It is argued here that if benefit sharing is a desirable end in this area of human genetic databanks then it must be addressed in a genuine way. If researchers and databank operators try to satisfy obligations to provide for benefit sharing by means of trite statements of future possibilities, then rather than promoting trust, they could further erode it. This is not to say that the only benefit that should be considered is financial benefit.

Emerging international principles

A number of international principles provide some guidance in clarifying the concept of benefit sharing and the obligations that it might entail in the area of human genetic databanking.[61] Some guidance can be obtained from the *Convention on Biological Diversity* (the CBD) and associated guidelines in relation to access to non-human genetic resources.[62] Article 15.7 of the CBD calls for fair and equitable sharing of the results of research and development and the benefits arising from the commercial and other utilization of genetic resources. It is important to note that the CBD and associated guidelines only apply to non-human genetic resources. However, it has been argued that they, nevertheless, provide a rational starting point in determining how benefit sharing could apply in the context of human genetic material.[63] The *International Treaty on Plant Genetic Resources for Food and Agriculture*, adopted by the Food and Agriculture Organisation in November 2001, also has similar provisions. The Treaty's objectives are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of benefits derived from their use, in harmony with the CBD, for sustainable agriculture and food security.

Although the benefit sharing provisions in these instruments have caused concern in some quarters, they do make good common sense. Kàre Berg has commented that there would be an almost universal feeling that it would be unfair to take natural resources to make marketable products without giving something back.[64] He argues that the same is true where research on genes in a family leads to marketable products and revenues for the pharmaceutical industry and the family is given nothing back.[65] Yet there is much less support in international law for benefit sharing in respect of human genetic material.

UNESCO's *International Declaration on Human Genetic Data*[66] is perhaps the most influential normative statement on benefit sharing in relation to biomedical research. It provides that:

> benefits resulting from the use of human genetic data, human proteomic data or biological samples collected for medical and scientific research should be shared with the society as a whole and the international community.[67]

Notably, it adds that special assistance may be provided to the persons and groups that have taken part in the research.[68] The Declaration goes on to provide some further clarification of the forms that benefit sharing may take,[69] but does not provide any further specific guidance as to the nature of the special assistance mentioned above. UNESCO's earlier *Universal Declaration on the Human Genome and Human Rights* also emphasises the importance of international collaboration and free exchange of knowledge,[70] but is silent on benefit sharing as such.

The Human Genome Organisation (HUGO) Ethics Committee's *Statement on Benefit Sharing* provides

60 *Laurie* and *Hunter*, above n40 at 325.

61 For a helpful summary see *Bartha Maria Knoppers*, 'Biobanking: International Norms' (2005) 33 The Journal of Law, Medicine & Ethics 7.

62 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation (Decision VI/4 from the sixth meeting of the Conference of the Parties to the Convention on Biological Diversity in 2002)

63 *Bartha Maria Knoppers* and *Lorraine Sheremeta*, 'Beyond the Rhetoric: Population Genetics and Benefit-sharing' (2003) 11 Health Law Journal 89.

64 Berg, above n46 at 240.

65 Ibid.

66 UNESCO, International Declaration on Human Genetic Data. Adopted on 16 October 2003 by the 32nd session of the General Conference of UNESCO.

67 Ibid Article 19(a).

68 Ibid Article 19(a)(i).

69 Ibid Article 19(a)(ii)-(vii).

70 See particularly Articles 12 and 18.

more explicit guidance on the appropriateness of benefit sharing and the obligations it entails, both from the broad societal perspective and the more specific perspective of the source and/or their social group.[71] The statement recommends that:

- all humanity should share in, and have access to, the benefits of genetic research;
- benefits should not be limited to those individuals who participated in such research;
- there should be prior discussion with groups or communities on the issue of benefit-sharing;
- even in the absence of profits, immediate health benefits as determined by community needs could be provided;
- at a minimum, all research participants should receive information about general research outcomes and an indication of appreciation; and
- profit-making entities should dedicate a percentage (e.g. 1% - 3%) of their annual net profit to healthcare infrastructure and/or to humanitarian efforts.

The first five dot points encapsulate some of the key concerns that have been raised earlier in this article. The last dot point is more controversial. It clearly puts the issue of financial benefit sharing onto the agenda, and it avoids the problem of coercion by recommending that profits should be dedicated to healthcare infrastructure or other humanitarian needs. However, on the one hand, this may not provide adequate specific benefit to the source or to their social group and on the other hand, the obligation to provide a fixed percentage irrespective of the actual success of the product may be seen as too significant an impost for some commercial entities.

The Statement does provide some further clarification that benefit means more than financial benefit. It defines benefit as:

> a good that contributes to the well-being of an individual and/or a given community (e.g. by region, tribe, disease-group...). Benefits transcend avoidance of harm (non-maleficence) in so far as they promote the welfare of an individual and/or of a community. Thus, a benefit is not identical with profit in the monetary or economic sense. Determining a benefit depends on needs, values, priorities and cultural expectations.

There is support in the academic literature for including in this broad definition of benefit sharing such scientific benefits as: prompt diffusion of research results, collaboration with members of the scientific community and attribution of licences for patented inventions; and such general and specific social benefits as: access to future treatments resulting from the research, donation of part of the profits to a local humanitarian organisation and financial support for research or contribution to health technology infrastructures.[72]

There are some international instruments that provide further specific guidance on benefit sharing in relation to human genetic databanking. As with the more generalist instruments, there are two aspects that need to be balanced. One aspect focuses on the need to share benefits amongst the community as a whole, rather than at the level of the particular individual or the group. Indeed, there is a growing trend to describe databanks as global public goods rather than as collections of individual pieces of property.[73] UNESCO's *Statement on Human Genomic Databases* describes databanks in this way, and in recommendation 3 it states that the free flow of data and the fair and equitable distribution of benefits from research using databases should be encouraged. At the same time, Recommendation 6 recognises that researchers, institutions and commercial entities have a right to a fair return for their intellectual and financial contributions.

There is also some support at the international level for the more specific aspect of benefit sharing at the level of the individual or group. The World Health Organisation (WHO), for example, emphasises that, in recognising the potential value of human material and human genetic information, it is also necessary to recognise the inherent value of the person from whom the material or information is derived. [74] Hence, it suggests that, in exchange for the supply of materials, there should be an undertaking that some kind of benefit will ultimately be returned, either to the individual from whom the material is taken or the general class of people to whom the individual belongs. The stated rationale for this conclusion is that intellectual property

---

71 Human Genome Organisation Ethics Committee (2000) Statement on Benefit Sharing, Available at:http://www.hugo-international.org/Statement_on_Benefit_Sharing.htm (last accessed 30 January 2006).

72 *Cardinal* and *Deschênes*, above n10 at 60. See also *Mylène Deschênes*, *Geneviève Cardinal*, *Batha Maria Knoppers* and *Katherine C Glass*, 'Human Genetic Research, DNA Banking and Consent, a Question of Form?' (2001) 59 Clinical Genetics 221 at 229.

73 See *Knoppers*, above n61 at 11.

74 World Health Organization's European Partnership on Patients' Rights and Citizens' Empowerment, Genetic Databases: Assessing the Benefits and the Impact on Human & Patient Rights (2003) available at http://www.law.ed.ac.uk/ahrb/publications/online/whofinalreport.pdf (last accessed 10 January 2005).

rights in the products of research do not 'accord an unfettered reign to the rights holder to do what they wish with the property', but rather an obligation to seek a more equitable equilibrium in the relative weighting of interests.[75]

In summary, these instruments provide support for both general and specific benefit sharing. They also provide some clarification as the nature of the benefit sharing obligation. It seems that it is difficult to divorce benefit sharing entirely from the financial realm. Having said this, there is more to it than a simple requirement to return a fixed percentage of profits. Clearly then, the actual content of the obligation still needs further elucidation. It is equally necessary to move beyond the principles and consider how the obligation actually arises and can be enforced in practice.

Existing domestic ethical and legal benefit sharing obligations

Although the number of international instruments that raise the issue of benefit sharing is growing, the same cannot be said domestically, at least in the industrialised countries that are actively promoting the development of a medical biotechnology industry.[76] In many of these countries, ethical guidelines provide no absolute obligation to inform research participants about the acquisition of intellectual property rights or about arrangements for commercial development of research findings.[77] Even more clearly, there is no obligation to return any of the profits of commercialisation to participants, because of the widely held view that offering financial inducement for participation in research is unethical.[78] A number of policy documents from around the world that have focused specifically on the appropriate regulation of human genetic databanks have consistently recommended that sources should not receive financial reward for providing their material for databanking and that they should be informed of this when asked for their consent.[79] They do, at least, recommend that when sources are asked to consent to collection storage and utilisation of their material they should be informed of any commercial objectives or likely outcomes of research using their material as part of the process of obtaining fully informed consent.[80] But they provide little guidance as to whether or not there are any benefit sharing obligations and, if such obligations do arise, what their content might be.

Similarly, although a number of domestic laws impose rights and duties in relation to the commercialisation of the results of databank research, none of these provides a great deal of assistance in determining whether there are any legally enforceable benefit sharing obligations.[81] For example, patent law provides for temporary monopolies for inventions that satisfy the requirements of novelty, inventive step and industrial applicability and that are fully disclosed. Cell lines and genes are considered to be capable of fulfilling these requirements in many jurisdictions, provided that they are in some way isolated from their natural environment.[82] Patents are made available to inventors, which might include the researchers who carry out projects using banked materials and perhaps the bankers themselves. However, there is no room in this definition to include the sources of the raw materials from which inventions are derived. Moreover, there is no requirement in patent law to inquire into the ethical appropriateness of research that leads to patentable inventions. The international Agreement on Trade-related Aspects of Intellectual Property lists the matters that members of the World Trade Organisation are allowed to exclude in their domestic patent legislation. The only exclusion that may be relevant is for inventions, the commercial exploitation of which would be contrary to pubic order or morality.[83] It is difficult to see how this exclusion would allow for inquiry into the research that *precedes* the invention. The law on ownership of human tissue and human genetic information is less emphatic on the absence of benefit sharing obligations, but nevertheless appears to be similarly unhelpful. The widely

75 Ibid.

76 Particularly focusing on North America, Europe, Japan and Australia.

77 For further details see: *Dianne Nicol*, *Margaret Otlowski* and *Don Chalmers* 'Consent Commercialisa-tion and Benefit Sharing' (2001) 9 Journal of Law and Medicine 80

78 Ibid.

79 For example, see the Irish Report, above n33, Recommendation 12

80 See, for example, the Irish Report, above n33, Recommendation 13; Medical Research Council, Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines (2001). See also *Lori B. Andrews*, 'Harnessing the Benefits of Biobanks' (2005) 33 The Journal of Law, Medicine and Ethics 22, particularly at 26.

81 See further on this point: *Nicol* et al, above n77; *Dianne Nicol* 'Property in Human Tissue and the Right of Commercialisation: the Interface between Tangible and Intellectual Property' (2004) 30 Monash University Law Review 139

82 See *Dianne Nicol*, 'On the Legality of Gene Patenting' (2005) 29 Melbourne University Law Review 1.

83 In Article 27.2.

accepted position is that both unprocessed human tissue and the human genome itself are not generally capable of ownership and there is little or no authority for a successful claim by a source to legal ownership (or interest) in any commercial product derived from their tissue.[84] The commercial product is generally seen as severed where there is an intervening and independent creative dealing with the material. However, from time to time there have been calls for recognition of sources' property rights in their biological materials. It is argued that this would facilitate ongoing control by sources of the material they provide and give them an entitlement to share in the profits arising out of commercial use of their material.[85] In effect, sources would be provided with inalienable *property* rights that cannot be waived or assigned to the director of the repository or other interested parties.[86] However, this concept of *inalienability* has been criticised because, although it would provide for ongoing control, it would inhibit profit sharing and could actually add confusion to the legal status of human biological material, rather than clarify it.[87] It is salutary to note that in Australia, a comprehensive report by the Australian Law Reform Commission and Australian Health Ethics Committee on the protection of genetic information recommended against the recognition of property rights in human biological material for various reasons.[88]

Equity may intervene if there is breach of a fiduciary obligation, for example.[89] However, even if a researcher or a databank manager were found to owe a fiduciary obligation to sources of biological material, it is most unlikely that such an obligation would extend to the downstream developers of commercial products, even if development of the products was directly linked to that particular material. Contract law could also have a role to play, particularly where benefit sharing arrangements have been specifically negotiated and agreed to.[90] However, absent a legally enforceable contract with express benefit sharing terms, it is unlikely that contract law could provide much assistance. Even if the normal consent arrangement between the source of human biological material and the researcher or databank manager could be seen as contractual in nature, it is unlikely that benefit sharing terms would be implied. In any case, concern has been expressed about the propriety of using contract law to solve such future ethical dilemmas.[91]

In summary, then, there is a lack of certainty in the extent to which relevant domestic laws could be used to impose benefit sharing obligations on databank managers, researchers and downstream users without more precision as to the nature of obligations. Despite the absence of clear legal obligations or ethical guidelines, it is argued here that the funding agencies, databank operators and researchers themselves have an ethical obligation to set their own standards providing for benefit sharing, with the assistance of adequate and appropriate policy documents. It is also sensible from the practical point of view to do so, to promote trust in their endeavours.

Human genetic databank policies

As the number and diversity of databanks burgeons, so too does the number and diversity of databank policies. Whilst consolidated facilities like the ATCC and the more informal networks are providing a greater degree of uniformity in these policies, a number of databanks still either lack formal policies or do not make their policies readily available. In this section, the key features of some of these policies are discussed, particularly as they relate to access, intellectual property and benefit sharing.
A study commissioned by the National Cancer Institute National Dialogue on Cancer provides an insight into how intellectual property and access issues are dealt with in human genetic databanks

84 On this point see generally *Nicol*, above n81.

85 See further on this point *Graeme Laurie*, Genetic Privacy: a Challenge to Medico-legal Norms (2002) at 318.

86 Ibid.

87 *Jasper A Bovenberg*, 'The New Case for an Inalienable Property Right in Human Biological Material: Empowerment of Sample Donors or a Recipe for a Tragic Anti-common?' (2004) 1:4 SCRIPT-ed.

88 Australian Law Reform Commission and Australian Health Ethics Committee Report 96 Essentially Yours. The Protection of Human Genetic Information in Australia (Canberra: Commonwealth of Australia; 2003) at 530-535 and Recommendation 20-1.

89 This was the outcome of the well-known litigation in Moore v Regents of the University of California 51 Cal. 3d 120 (Cal. 1990).

90 There is one example of a patient group (PXE International) participating in research relating to the genetic disorder pseudoxanthoma elasticum (PXE) negotiating a contractual arrangement with researchers giving the group a share in the rights to a patent application filed by the researchers. See *Donna M. Gittner*, 'Ownership of Human Tissue: a Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material' (2004) 61 Washington and Lee Law Review 257 at 315-325.

91 *Larry L Palmer*, 'Should Liability Play a Role in Social Control of Biobanks?' (2005) 33 The Journal of Law, Medicine and Ethics 70 at 76.

focusing on cancer research in the US. In 2002-2003, researchers at the RAND Corporation conducted a series of case studies on twelve tissue repositories in the US on behalf of the National Cancer Institute. The purpose of the study was to assess the usefulness of these repositories in genomics- and proteomics-based cancer research and to identify 'best practice'.[92] The final report discusses best practice in a range of areas, including privacy, ethics and law as well as public relations and marketing. For the present purposes, Chapter 8 on Intellectual Property and Legal Issues is the most relevant.

The report gives an indication of the core features that should be included in arrangements for access to deposited materials, which include the following:

- use should only be for the purpose specified in the application for access;
- no attempt should be made to obtain identifying information;
- there should be no transfer to third parties without prior written permission of the repository; and
- any publication resulting from use of the materials should acknowledge the repository.

These requirements are likely to fulfil the obligation to provide a basic level of protection to sources of deposited material. However, disappointingly, there is nothing in these requirements that specifies that the contribution of the source should be recognised in any way.

Despite a finding that it is best practice to have an intellectual property policy, not all of the repositories surveyed actually had one.[93] Nevertheless, some general trends regarding handling of intellectual property issues do emerge from the survey. It was found that most repositories do not retain any rights to downstream intellectual property produced using the material they distribute, unless they are undertaking collaborative research, in which case the intellectual property may be jointly owned.[94] As a general rule, the institution or organisation where the research is conducted claims ownership of the intellectual property rights.

The National Cancer Institute report further concludes that it is also best practice to require a material transfer agreement (MTA) to be executed in accordance with the same terms as the best practice intellectual property policy. This is important, because it gives contractual force to the terms of the intellectual property policy included in the MTA. However, the report provides no evidence of the inclusion of any benefit sharing obligations in the intellectual property policies or MTAs. Although it is generally specified that individuals who contribute material have the right of withdrawal unless stripped of identifiers, they generally have no other rights, including no right to compensation for their participation.

The UK Biobank draft *Policy on Intellectual Property and Access* is cast in somewhat similar terms.[95] It has the usual provision that intellectual property arising out of research using the resource vests in the investigator creating it. However, its access policy is somewhat unusual in that it provides that, as a general rule, researchers will not be provided with access to stored tissue. Instead, analysis will be undertaken by Biobank or a laboratory contracted by it. An access agreement has to be entered into, and an access fee has to be paid, although fees for non-commercial research are nominal. Where tissue is provided, a standard form MTA is required to be executed.

The standard ATCC MTA[96] provides the signatory with permission to make and use material, replicates and derivatives for research purposes in the signatory's own laboratory only. No permission is given to distribute, sell or otherwise transfer the provided material or replicates or derivatives. Commercial use is prohibited without authorisation. ATCC and/or its contributors retain ownership of the material, replicates and derivatives (but presumably not the intellectual property that is created from their use).

Organisations that make their collections available through the ATCC may require a separate MTA to be

92 *Elisa Eiseman*, *Gabrielle Bloom*, *Jennifer Brower, Noreen Clancy* and *Stuart S Olmsted*, Case Studies of Existing Human Tissue Repositories: "Best Practices" for a Biospecimen Resource for the Genomic and Proteomic Era prepared for the National Cancer Institute National Dialogue on Cancer (Arlington VA: Rand Science and Technology; 2003). Available at: http://www.rand.org/pubs/monographs/MG120/ (last accessed 30 January 2006).

93 Ibid at 140.

94 Ibid at 138.

95 As at 11 January 2005. Available at: http://www.ukbiobank.ac.uk/ethics/IPandAccess.php (last accessed 27 January 2006).

96 Available at: http://www.atcc.org/documents/mta/mta. cfm (last accessed 27 January 2006).

executed. For example, the Johns Hopkins University requires the execution of a Non-exclusive License Agreement for distribution to a commercial entity. The only major difference from the ATCC MTA is that it is explicitly stated that the material cannot be used for work on human subjects, including diagnostic testing. The Wistar Institute also requires a special MTA for some of its cell lines, and in this case the issue of intellectual property ownership is more explicitly provided for. In addition to the usual terms, it specifies in clause 4(b) that if the research use results in an invention, the Wistar must be notified promptly and confidentially, whereupon inventorship is to be determined in accordance with patent law (if patentable) or otherwise by mutual agreement and that the parties will cooperate regarding protection and disposition of all jointly owned intellectual property. Some Australian organisations have taken up this clause in their MTAs.[97]

These MTAs and intellectual property policies allow databank operators to retain some control over the material that they provide access to. Restrictions on transfer to third parties are particularly important in deterring inappropriate use of accessed material. In some circumstances, the databank operators will be able to claim a share of intellectual property generated through use of the material. Whilst disputes about contribution and ownership will inevitably arise, it is probably fair to say that, as a general rule, where intellectual property and access policies of this nature are in place they are likely to provide an acceptable level of clarity to promote trust by the relevant parties (databank operators, researchers and commercial developers). However, there is a marked absence of any requirement whatsoever to provide for any other form of benefit sharing, whether in the broad sense of sharing with society or in the specific sense of sharing with the source and/or their social group.

The operators of databases of human genetic information tend to be more explicit in providing for broad social benefits. The primary way that this form of benefit sharing is secured is by making the data available rapidly and without restriction. For example, the entirety of information relating to the HapMap Project is in the public domain. In the early stage of the project it was felt necessary to impose restrictions on the use of data. In order to register for access to the online database participants were required to accept the terms of the licence on the click of a button.[98] Without going into details about the scientific rationale for this, it was felt necessary because it was possible for users to capture early stage data and take out patents, thereby potentially restricting access for other users. The licence required users to undertake that they would not restrict others from accessing or using the data produced by the project. This obligation was no longer required once further data had been placed in the public domain, which occurred about 15 months into the project.

In addition to the scientific benefits likely to arise out of rapid release of information, participants in the HapMap Project claim that it offers the following benefits to society:

> it is hoped that the HapMap Project will eventually benefit the health of all people. Most of the benefits, however, will not be immediately apparent, and some might take years to materialize. So, in the short term, the main beneficiaries will not be sample donors, their families or their communities, but researchers, who will gain professional rewards, and companies, that will be able to develop drugs, diagnostic tests or other commercial products from research using the HapMap.[99]

Commentators like Laurie and Hunter would doubtless object to this statement on the basis that the benefit is too abstract in nature, and does not adequately recognise the input of sources of the original material. However, in circumstances such as this, where the material that is being provided by the databank is DNA sequence information that is essentially generic and where there are likely to be many steps between the original sequencing and

---

97 One example is the Kathleen Cunningham Foundation Consortium for Research into Familial Breast Cancer, also known as kConFab. Its Transfer of Materials Agreement gives the repository the right to vet publications, to be recognised as an author and to identify potentially patentable technology. It also specifies that inventorship is to be determined in accordance with Australian patent law (if patentable) or otherwise by mutual agreement and that the parties will negotiate an agreement regarding any jointly owned intellectual property specifying sharing of income, patent costs and the administration of any patents. Available at: http://www.kconfab.org/documents/kconfabMTA.pdf (last accessed 30 January 2006).

98 Available at: http://www.hapmap.org/cgi-perl/registration (last accessed 1 February 2006). See also *Chokshi* and *Kwiatkowski*, above n20 at 8. Free access to data is a common feature of all large scale international public sequencing projects. See: The Wellcome Trust, Sharing Data from Large-scale Biological Research Projects: a System of Tripartite Respon-sibility, Report of a meeting organised by the Wellcome Trust and held on 14-15 January 2003 at Fort Lauderdale, USA. Available at: http://www.wellcome.ac.uk/doc_wtd003208.html (last accessed 26 January 2006).

99 International HapMap Consortium, above n21 at 473.

product development, the benefit of free exchange of information together with a general promise of future benefit is probably sufficient. But the situation is quite different for the UK Biobank and like projects, where each individual source is expected to make their tissue available for research via the databank, together with other information. In such circumstances serious questions have to be asked as to whether research and the mere promise of future healthcare benefits is sufficient. Yet this is precisely what the UK Biobank intellectual property and access policy offers in its core principles of intellectual property and access.[100] The policy goes even further than this, expressly providing that, a general rule, there is no requirement to return a share of any profits generated using the Biobank resource to Biobank.[101]

There is very little evidence of any explicit requirement for specific benefit sharing with sources or their social groups in the vast majority of databanking policies throughout the world. On the contrary, some policies take great care to ensure that sources know they are not entitled to any financial benefit from their contribution to the research effort but are curiously silent on other forms of benefit. One such example is the Biorepository Protocols of the Australasian Biospecimen Network, which simply state in the section of the Protocols dealing with ethical issues associated with use of human biospecimens (or human biological material, using the terminology used elsewhere in this article) that the following information should be provided to sources on commercial issues:

> Our research is mostly directed to improving understanding of disease. Sometimes the research will lead to findings that result in the development of a commercial test or treatment that may be overseen by pharmaceutical companies. Australian law indicates that there is no financial reward or payment to you in such an event.[102]

There is no mention in the guidelines of *any* requirement to explain whether any financial or other benefit accrues to the biorepository as a result of the development of a commercial test or treatment, or whether there is any other form of benefit to the source, or any broader public benefit.

In contrast, the Quebec Network of Applied Genetic Medicine is much more explicit on the need to provide for benefit sharing arrangements in its proposed *Statement of Principles on the Ethical Conduct of Research Involving Populations*, which takes up a number of the recommendations in from the HUGO *Statement on Benefit Sharing*. It provides, in clause 7 on commercialisation, that:

> The eventual sharing of any benefits with the population should be discussed at the outset. This sharing could take different forms such as: an access to medical care, to future treatments or drugs developed; a contribution of a portion of the benefits to a humanitarian organization; support for local needs, or support for technological infrastructures or health services to the population, etc.[103]

This clause goes on to address the need for freedom of research, which it says should be promoted by respecting the principle of public access and management of the potential for conflict of interest to arise from the commercialisation process. As with the HUGO Statement, this clause encapsulates many of the key concerns highlighted earlier and it could provide a model for other databanking policy statements. Admittedly, the policy is cast in fairly broad terms and does not provide specific details as to how benefit sharing should actually be provided for.[104] But this may well turn out to be the most sensible option. It has been recognised elsewhere that a 'one size fits all' model is not appropriate and that benefit sharing policies can only provide general guidance.[105] By inviting discussions about benefit sharing at the outset, the policy encourages the parties to consider the social group's particular needs and cultural values.

A report by the Newfoundland and Labrador Department of Health and Community Services raises similar considerations, but recommends that the province should play a central role in negotiating benefit sharing arrangements, which, it further recommends, should be required for any human genetic research with commercial potential.[106] These arrangements might include free access to genetic tests for all residents of the province, for example.[107] Some of the reasons put forward to justify the proposal are: that health care is a common good and a community held responsi-

100 UK Biobank, Draft Policy on Intellectual Property and Access clause 5.1.

101 Ibid clause 8.3.

102 Australasian Biospecimen Network Biorepository Protocols (October 2005) available at: http://www.abrn.net/protocols.htm (last accessed 27 January 2006).

103 Available at: http://www.rmga.qc.ca/en/index.htm (last accessed 26 January 2006).

104 For example, it avoids the controversial requirement in the HUGO Statement on Benefit Sharing to return a fixed percentage of profits.

105 Newfoundland Report, above n38 at 52

106 Ibid at iv.

107 For further examples, see ibid at 52-55.

bility; that residents of Newfoundland and Labrador collectively share the burdens and benefits of individual genetic predispositions; and that human DNA is a communal resource.[108]

Whilst arrangements of this nature may be difficult to implement for the larger scale databanking project, they do present an interesting way of setting up the administrative framework for negotiating and enforcing benefit sharing obligations. It is likely that various other models of benefit sharing frameworks will emerge once the need to address this issue is more widely recognised.

Conclusion

There appears to be a growing realisation that research using databanked materials will be facilitated by clear intellectual property and access guidelines. However, the same cannot be said with regard to benefit sharing. There is scant evidence that this important issue is being taken seriously.

Bartha Knoppers and Lori Sheremeta have suggested that it is time to go beyond the rhetoric of benefit sharing and implement practical benefit sharing measures.[109] However, there is an even greater difficulty – for the most part, the people providing the rhetoric are not those who are most directly involved in databanking. Until policy makers, operators, researchers and commercial developers become engaged in discussions about benefit sharing, the rhetoric is empty. The theorists have presented convincing arguments as to why both general and specific benefit sharing are desirable ends, particularly from the perspective of maintaining trust. Now is the time for all parties engaged in databanking to seriously consider how to implement appropriate benefit sharing mechanisms. They should not see benefit sharing as a threat to the commercial success of the endeavour but as an important component in its success. As Sheremeta has put it:

> ... benefit sharing should be considered as a mechanism (or rather a spectrum of mechanisms) to balance the commercial interests with those of research participants in a way that is both respectful and reflective of the relative contributions to the research endeavour.[110]

It is also important to recognise that benefit sharing does not equate with paying research participants for their involvement. Nor does it equate with commodification of human tissue. But it does recognise the important contribution that participants, their social groupings and the public at large make to the research endeavour. For this reason, benefit sharing should be a mandatory consideration in human genetic databanking. Provided that all players in the databanking arena are involved in formulating best practice guidelines for benefit sharing policies and that benefit sharing arrangements are handled with sensitivity and transparency, there can be little doubt that public trust in the endeavour will be enhanced.

---

108 See generally ibid at 29-34.

109 Above n63.

110 Above, n24 at 55.