Whose Genes, Whose safe, How safe?
Publics' and professionals' Views of Biobanks

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By Edna Einseidel, *Whose Genes, Whose Safe, How Safe? Publics' and Professionals' Views of Biobanks*.

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INTRODUCTION

If genomics is the science of the 21st century, genetic information is its defining idea. Like many defining ideas, genetic information has currency when it is transformed into knowledge. This knowledge centers on elucidating the meanings of this information. From whom this information is obtained, how it is obtained, how it is interpreted, and how it is used become critical questions for society.

The completion of the human genome project in 2001 was not an end in itself; it marked a starting point for programs of research designed to understand more fully what the information coded in the human genome means and how this knowledge could be used for improving human health. With the mapping of the human genome and the further development of molecular technologies, a different way of examining and unlocking some of the secrets of disease and health has developed. From this genomic map, the interest in understanding gene functions and characterizing the influences of genes and environment was a next logical step, with the realization that collection of genetic samples from populations could provide a powerful tool for this understanding. This has intersected with the availability of technologies to store and allow investigations of large masses of data. In a nutshell, the idea of biobanks emerged from these developments and interests.

Earlier research on genetics used diseases as starting points, working "backwards" by tracking the inherited patterns of these diseases, then trying to identify the genetic changes that might have been responsible for the condition. Clinical geneticists have been doing these family studies for some time, investigating disorders that might be explained by single genes, familial patterns of cancers or more common diseases. The new genetics, on the other hand, has been touted as promising more precise diagnostic capabilities, providing a better understanding of genetic influences on disease, and promising eventual treatment possibilities. As increased knowledge of human genetic variations and gene-disease associations has been gained, there has also been a greater realization of the complexity of gene-environment interactions and a corresponding interest in understanding the nature of these interactions.

This paper will address the following general question: **what are the views of publics and professionals of biobanks?** What are the publics' views and concerns about genetic research? More specifically, what are publics' views on the confidentiality of genetic information, human rights issues, the use of secondary data, and commercialization of such information? What do publics think about donating samples to a DNA database and the conditions under which they would or would not donate to such an enterprise?

It is recognized that "publics" could include a variety of groups -- members of the general public, patients and patient groups, other advocacy organizations. Even within the so-called "general public," there are many voices, many different interests. Our primary focus in this paper is on the general public as well as advocacy organizations, keeping in mind the caveat that we are referring to the "unorganized public" and that this term further includes many different subgroups.

The views of professionals are also of interest with regard to: informed consent, confidentiality of genetic information, human rights issues, the use of secondary data, commercialization, and other social, moral and ethical considerations. For purposes of this paper, "professionals" includes geneticists, genetics researchers, genetic counselors, research coordinators, members of research ethics boards or institutional review boards, physicians, ethicists, legal experts and epidemiologists.

For the purposes of this research, the term "biobanks" is defined as a collection of physical specimens from which DNA can be derived and the data that can be derived from these DNA samples" (CBAC, 2002). These physiological samples (portraying an individual's genotype) are typically connected with other data about that individual relating to illness (via medical records), lifestyle patterns (obtained, for example, via questionnaires) and, in some cases, inheritance patterns (e.g., through genealogical records). Although the term "biobank" is relatively new, blood and tissue banks have been around for a long time. For example, these could include (a) repositories collected by academic scientists studying genetic disorders; (b) commercial repositories offering DNA banking to researchers or people who might have a reason for storing their DNA; (c) DNA forensics banks; (d) military DNA banks, typically created for identification of human remains; (e) samples collected for clinical diagnosis which are then retained, such

as cancer tissue banks; (f) newborn screening cards (Lysaught, et.al., 1998). What is "new" for those fluid or tissue banks that have been in existence for some time is the analysis of DNA from these types of samples for examining the genetic bases of disease, gene-environment interactions, hereditary patterns of illness, and genetic variations of illness among population groups. The efforts to map the human genome, along with advances in gene technology such as the polymerase chain reaction (PCR) and other new technologies that have become routine for molecular biology, have provided a major impetus for some countries to start regional or national projects to collect samples for analysis. As discussed below, this is the case for such countries as Iceland, Tonga, Estonia, and the U.K.. For other countries which have been collecting fluid or tissue samples for some time (e.g., Sweden, the U.S.), genetic analysis of these long-standing samples has become a more recent activity.

The following are examples of national biobank initiatives that have been set up or are being launched. For the most part, they are population-based efforts to collect, store and analyze genetic information.

- In December, 1998, **Iceland**'s parliament passed the Health Sector Database Act which granted a for-profit corporation, deCode Genetics, an exclusive licence to create a database of the medical records of all Icelandic citizens and one of DNA samples. A third database of genealogical records already exists, allowing for the linking of these three databases. While the government can use the medical records database for policy and planning purposes, the licensed company controls access to the database for commercial use for 12 years. Medical records are included in the data bank unless the individual "opts out" by notifying his physician. While public support of this effort in Iceland appeared to be high, the establishment of this biobank generated considerable domestic and international debate, providing "a type of ethical laboratory that helps identify the major issues involved in population-based genetic research." (Annas, 2001; Winickoff, 2000).

- **U.K. BioBank** was set up in April 2002 with funding from the Wellcome Trust, medical foundation, the Medical Research Council and the Department of Health. The objective is to analyze samples from 500,000 volunteers aged 45-69 and follow their health over 10 to 15 years to understand how genetic and environmental factors combine to influence susceptibility to disease. Random selection procedures will be employed to ensure geographic representativeness. Doctors will invite selected patients to participate and after explanation of the study, those who indicate willingness to participate will then be asked to provide informed consent. Ethical oversight will be provided by an independent

committee. Operating under the common law of confidentiality, the Secretary of State for Health has the power to authorize processing of medical data without consent for essential health service activities considered to be in the public interest and for which it would be impractical to obtain consent or to use anonymized data. (http://www.ukbiobank.ac.uk/; also Wellcome Trust, 2002).

- For the last three decades, the **Centers for Disease Control and Prevention (CDC) in the U.S.** has been running national surveys on health and nutrition called the National Health and Nutrition Examination Surveys (NHANES). A laboratory was also established in conjunction with these surveys to hold blood, serum, and urine samples. These samples are collected from a representative sample of the population and are now being used for DNA analysis to establish prevalence data for genetic diseases and investigate gene-environment interactions. This genetic research program is being overseen in collaboration with the National Center for Human Genome Research at the National Institute of Health (http://www.cdc.gov/nceh/dls/dnabank.htm).

- **Estonia** has approved a project proposed by the Genome Centre Foundation, a not-for-profit Estonian organization, to compile DNA profiles of 75% of the country's 1.4 million citizens (Frank, 2000). In contrast to Iceland, where data are maintained anonymously (donors do not have access to their own information), Estonian DNA samples will be identified through a coded system, but will belong to the state-controlled foundation. Donors must also give their informed consent for the use of these samples and, if they change their minds and want out of the database, their samples will be destroyed (Frank, 1999; Frank, 2000).

- As of Jan. 1, 2003, **Sweden**'s new legislation regulating the use of human biobanks will be in place. The Act on Biobanks in Health Care mandates explicit informed consent at the original point of collection. If the samples are to be used for new purposes, informed consent will normally be obtained, but if used for research, a research ethics committee can grant exceptions to this requirement. The donor can withdraw consent, at which point the sample must be destroyed or "depersonalized" so it can no longer be traced back to the donor. The Swedish government has established Foundations for Technology Transfer to fund collaborations between businesses and universities. The Foundation in Umeå, which currently manages the region covering Västerbotten, Västernorrland and Jämtland, financed the company **Umangenomics,** a collaboration between Umea University and regional health care authorities, with the company having exclusive rights to commercial use of Umea's medical bank of blood samples. Because it remains under public authority, university researchers still have access to the bank's samples. The bank has been collecting blood samples from the entire region of Västerbotten, an isolated region, since 1985. It currently has more than 100,000 samples from 60,000 individuals who have also provided information about their health and lifestyle (Nilsson and Rose, 1999).

- The island nation of **Tonga** signed an agreement with Autogen, an Australian biotechnology company, to establish a health database aimed at identifying genes that cause common diseases. The kingdom of Tonga has 108,000 people of Polynesian descent. Under the terms of this agreement, Autogen was to provide annual research funding to the Ministry of Health and pay net royalties on revenues generated from any commercialized discoveries. In return, it would have had exclusive access to the database. Autogen has had a long-standing interest in diabetes and obesity, cardiovascular disease, hypertension and ulcers. The company has a strategic alliance with Merck. (Fitzgerald, 2001).
- The **Singapore** Genomics Programme was set up in June 2000 with an initial mandate to focus on novel genes and their related molecular targets. Of interest are such diseases as liver cancer which have a relatively high prevalence in Singapore and Asia. The program expects to become a broad-ranging database in the longer term, expanding to cover health-related information on the general population because of Singapore's racial mix, including a large number of Indians and Malaysians in addition to the majority Chinese. This has been seen to offer advantages over relatively homogeneous populations such as Iceland and Estonia, providing researchers an opportunity to follow responses of difference ethnic groups to a given drug (Cyranoski, 2000).

- Newfound Genomics, in partnership with researchers in **Newfoundland and Labrador**'s Memorial University, recently launched three province-wide studies focusing on weight, diabetes, and inflammatory bowel disease. The population of Newfoundland and Labrador is considered relatively unique in terms of having descended from a "founder" population of 20-30,000 English, Scottish, and Irish immigrants and its increased incidence of certain diseases such as diabetes. The family orientation of this region and the relatively larger size of families have been touted as features that promote research into extended and multi-generational family units (www.newfound-genomics.com).

Literature Base for this Study

The issue of genebanks or biobanks is a relatively recent one. This means the majority of the literature base on the subject has developed only in the last decade. The developments and controversies over these population databases have been covered by the key weekly journals, *Science* and *Nature*, providing additional helpful background information for this report. Furthermore, many of the papers have been commissioned and are in the form of reports, which we have accessed on the internet.

Many of these papers and reports grew out of two particular undertakings: the first is the Iceland Health Sector Database and the second is the U.K. Biobank. The consideration and passage of the law on biobanks in Iceland followed a short, but highly

controversial, period of public debate in the country and which continued over the next two years internationally. The Icelandic case became an international flashpoint for heated discussions on genetic information and genebanks. Not surprisingly, this was reflected in a spate of social scientific, legal and philosophical studies as well. As sociologist Hillary Rose (2001,31) observed,

> It is the very fact of the Icelandic Health Sector Database legislation and the visibility of its processes which has exposed the immense innovation of genomics in that country to vigorous public debate not just nationally but internationally. This conflict has served to put the ethical issues concerning the commodification both of bioinformatics and of nature as human tissue onto the international cultural and political agenda.

Perhaps taking a page from Iceland's experience, the framework for U.K. Biobank was developed with an eye to understanding stakeholder concerns and a number of studies were commissioned accordingly.

PUBLICS' PERSPECTIVES

Public Awareness and Understanding of Genetics

There is an on-going discussion in the literature about how publics are "constructed" by policymakers and researchers. Researchers who measure the public's "scientific literacy" are charged with working from a "public deficit" model, with the public's ignorance of science issues as something needing correction (see Irwin and Wynne, 1996). A different approach promotes the public as active negotiators in making meaning of information and the social world, of providing another variety of "expertise" in decision-making born out of experience, social values, and life savvy.

I have suggested elsewhere that these are not necessarily mutually exclusive images (Einsiedel, 1998); there are occasions when the public knows little or nothing about a subject (and this includes scientists as well) and that this so-called ignorance may stem from simple constraints of time, resources or interest or even a choice not to know or not to be engaged with particular sorts of information – "a willed non-engagement" (Durant, Hansen and Bauer, 1996). There are other occasions when public ignorance may be counter to some larger collective interest. The issue of AIDS is a good example where

lack of knowledge about the causes of the disease can lead to larger societal problems of discrimination or to individual high-risk behaviours. In sum, the ability of publics to understand scientific knowledge has been given short shrift by being viewed through narrow, technocratic lenses. So have the reasons for publics to have limited understandings. When we talk about publics and their understandings of genetics then, it must be understood in the context of the need for examining how knowledges are used and interpreted, by whom, and the contexts in which these processes occur.

A national survey on the U.K. public's perceptions to and attitudes toward human genetic information showed that this public had a broad understanding of genetics and human genetic information. There was also a broad understanding of a range of human characteristics and illnesses being explained by some balance between nature and nurture. There was considerable support for the use of such genetic information to improve diagnosis of and susceptibility to disease and to develop targeted drugs (Human Genetics Commission, 2000).

A more specific and in depth study on attitudes of publics toward human biological samples done for the Wellcome Trust and the Medical Research Council in the U.K. was carried out through focus groups with the general public and in-depth interviews with people with diseases and their family members, religious and community leaders, and special interest organizations. Again, in this instance, medical research was found to enjoy a broadly positive image. Genetic research was less familiar but also supported, especially by those who had a better understanding (Porter, et al., 2000). While the general public knew little about the use of human biological samples, there appeared to be broad acceptance of their use, provided this takes place with the informed consent of donors or their representatives. Participants also stressed the importance of regulations governing collection, storage, use, and disposal of samples and preferred oversight of these processes by an independent body (Porter, et al., 2000).

The public's understanding of genetics has been interpreted to be limited in terms of inheritance(Richards, 1996). For example, interviews with a random sample of adults in South Wales who did not carry genetic disorders thought inheritance patterns typically skipped generations (Davison, Frankel, and Smith, 1989; Richards, 1997), that there are resemblances between those who get the disease, or that genes are only passed on by

females (Richards, 1997). At the same time, these beliefs also showed a sophistication in terms of understanding the complexities of the social and cultural contexts of quality of life. Focus group studies in the U.K. showed lay discourses to be sensitive to technical, methodological, institutional and cultural forces around the new genetics (Cunningham-Burley, S., A. Amos, and A. Kerr, 1998). Health status and social position also influences what people knew or the information they sought and considered relevant (Kerr, Cunningham-Burley and Amos, 1998). Patients who claimed not to know about medical science displayed relatively detailed understandings of their condition, a case of "situated knowledge"; that is, the individual's social and personal contexts help to locate that individual in particular knowledge situations, allowing that individual to navigate between personal and authoritative or institutional forms of knowledge (Lambert and Rose, 1996).

On a larger scale, the 1996 Eurobarometer surveys in Europe examined beliefs about inheritance of a series of traits including musical abilities, criminal tendencies, intelligence, athletic abilities, mental illness and so forth. These surveys showed respondents tending to cluster certain traits together. That is, respondents who tended to attribute musical abilities to inheritance were also more likely to make the same attribution for intelligence, mental illness, and body size. About a fifth of European respondents attributed all five of these characteristics to inheritance. A second factor grouped together criminal tendencies, attitudes to work, happiness, and homosexuality; this second set was less widely considered to be genetically based (Gaskell, et al., 1996). This study found wide variations among countries. For example, roughly a quarter of Italians and Austrians but fewer than one in ten of the Swedes and the Danes think criminality is mainly inherited. Interpretations of survey findings such as these are, of course, limited in terms of one's ability to explore the nuances of these attitudes and the fact that the response sets in this instance are from a forced choice response between a trait being "mainly inherited" or mainly from one's upbringing. When a continuum is provided to respondents, as was the case in the extensive study done by the Human Genetics Commission, responses are more likely to reflect the public's grasp of the idea of variations in the balance between environmental and genetic factors depending on the type of condition (Human Genetics Commission, 2000).

When it is familiarity with "scientific facts" that is investigated, wide variations are found depending on the topic being investigated. For instance, about half of European adults were aware that more than half of human genes are identical to those of chimpanzees. More than three-quarters were unaware that animal genes can be transferred to plants in the 1996 and 1999 surveys. On the other hand, close to eight in ten knew that Down's syndrome could be detected in the first few months of pregnancy (Gaskell, et al., 2001), perhaps indicating greater familiarity with health and medical information in general.

Focus group research in the U.S. on the issue of race and genetics demonstrated this contextualized knowledge. African-American and white participants' discussions showed understanding of such ideas as differentiating between people having different genes (they were aware that people are genetically similar) and that there are different variations of the same gene (Condit, 2003). They also showed familiarity with the notion of different degrees of gene expression and different levels of dominance among genes even though these ideas were articulated in common-sense understandings rather than in the vocabulary of scientists. , This study acknowledges that the resources with which publics could fully understand connections between race and genetics were incomplete, but discussions surfaced a general consensus that an essential but small genetic difference might exist between races, mainly expressed in visible traits (Condit, 2003).

In sum, public awareness of genetics shows broad understanding of some key ideas in genetics. Depending on their situations and needs, some subgroups show a very good grasp of genetics issues, while other groups show more limited knowledge. These findings suggest uptake of information is dependent on many factors, not least of which is relevance of the information.

Areas of Concern for Publics

Many publics regard genetic information as unique and therefore worthy of extreme care and protection (Human Genetics Commission, 2002). In this regard, even before discussing areas of concern for publics with regard to *how* DNA banks should be set up, it should be noted that, for some groups, a preceding question is *whether* biobanks should be set up. This point of view ought to be recognized. For example, the Institute

for Science in Society in the U.K. has questioned the lack of information about the biobank initiative and the value of focusing on genetic factors, concluding that "it is hard to see how there can be significant findings from the Biobank project that could justify the huge investments called for" (Institute for Science in Society, 2002, p. 2). Views such as these and the experience in Iceland, where the limited amount of time provided for public reflection and discussion was roundly criticized, emphasize the concern for addressing the premises behind such major projects *before* they are underway.

Following this, we elaborate on concerns expressed by various publics in a number of studies on how biobanks ought to be designed and implemented. It is important to note that this breakdown of issues is useful for analytical purposes. In practical terms, many of these issue areas blend together or are not so easily disentangled.

Informed consent. This was seen as crucial by every group studied, regardless of whether it was the general public (Porter, et al., 2000; Uraneck, 2001; Human Genetics Commission, 2001), patient groups (Porter, et al., 2000), religious leaders (Porter, et al., 2000), or special interest groups (People Science and Policy, 2002). There are two critical points at which informed consent in relation to biobanks comes into play: the first is at the point of donation, the second is consent for subsequent or future uses. Another type of information for which informed consent comes into play is patient records, which are governed by confidentiality and privacy rules. These records could become part of some database to be used for purposes other than those for which the information in the records was originally obtained.

More than eight in ten Americans consider the use of patient records for medical research without prior permission to be unacceptable (Institute for Health Care Research and Policy, 1999). While comfort levels increased if the information released could not be identified with individual patients, a third said it was still "not at all acceptable" for researchers to be able to use this information without patient consent (Institute for Health Care Research and Policy, 1999). As a result of growing concern among its constituent publics, the U.S. Congress introduced a privacy rule in 2001 into its Health Insurance Portability and Accountability Act of 1996. This rule required researchers using the country's tissue banks to obtain consent when using patient-specific information such as

medical information (Uraneck, 2001). This was in response to mounting public concerns over privacy.

In the U.K., the vast majority (about 9 in 10) maintained that permission should always be sought prior to blood or tissue being used in genetic tests and that fresh consent needed to be obtained before new research was allowed on existing samples (Human Genetics Commission, 2001).

In Canada, most Canadians regard genetic information as different from other types of personal information (90% agree or strongly agree with this idea of genetic information being different) and want to see stricter rules for governing access to such information (Pollara and Earnscliffe, 2001). Despite these concerns, more than three quarters of Canadians were agreeable to health information being released to governments and researchers, *provided their consent had been obtained*, with 42% strongly agreeing to this (Canadian Medical Association, 2000). Fewer than half agreed that this information could be released without their consent even with any identifying information having been removed.

The question of how informed consent was to be secured for future uses of samples was considered potentially problematic, especially when these future uses involve new techniques still to be developed, but there is little disagreement on the importance of informing donors about the possibility that their samples might be used for other studies in the future.

A U.K. advocacy organization, GeneWatch, has identified five questions it maintains are crucial for potential participants to ask as part of the informed consent process:

- What research is going to be carried out on my sample?
- What are the benefits and dangers of this research?
- Will my sample ever be used for research I don't agree with?
- Will any of my genes be patented and will I be informed about it?
- Can I change my mind?

People Science and Policy Ltd., 2002, p. 9

Feedback. Among groups consulted on the issue of potential participation, the question of participants receiving feedback on their personal profile has been raised. Among participants in the U.K. focus groups and interviews, some thought it would be important for donors to have the right to be informed on anything that emerged from their own samples (Porter, et al., 2000). Other consultations demonstrated a mixed response. That is, some members of the public understood and accepted that feedback would not be provided at the individual level. Others thought this would be problematic and could pose a barrier to participation (People Science and Policy, Ltd. 2002).

In the United States, focus groups conducted by the National Bioethics Advisory Committee (NBAC) showed most participants not objecting to research which linked demographic information to stored tissue samples; they were also only slightly more concerned about links to medical histories. These findings were in the context of notification in the event that medically helpful information was discovered (NBAC, 2000).

The other kind of feedback that could potentially be provided is on general project findings. In this regard, there was interest in receiving information on discoveries or developments made from the research (Porter, et al., 2000).

Confidentiality. Two thirds of Canadians say genetic information is "most private and confidential, i.e., information they would not want others to have access to without their consent" (Canadian Medical Association, 2000). There has been significant concern about donors' anonymity and how this was to be protected. There is some unease about records being made available for research purposes and these concerns are particularly heightened by the possibility of employers and insurers obtaining and misusing this information (Canadian Medical Association, 2000). These concerns seem to be allayed when participants receive explanations of why the information is useful, how the information is to be used, and the safeguards in place to guard against unauthorized access (Human Genetics Commission, 2002).

Differential trust in who ought to be granted access to genetic information is evident in a recent survey in Canada (Einsiedel, forthcoming). As Table 1 demonstrates, access to personal genetic information for purposes of diagnosis and treatment is readily

accepted by close to eight in ten. What is surprising in a country with universal health care where health records are already centralized is the large number – three in five – who do not think health ministries should have access to this sort of information. Another striking thing about these results is the finding that hardly anyone demonstrates uncertainty or lack of opinion on this question of who can have access to genetic information.

Table 1: Canadians and Genetic Information

	Agree	Disagree	Don't Know
Doctors and surgeons' access to genetic information	78%	19%	3%
Health Canada or provincial health Ministry's access to genetic information	37	60	3
Private insurance companies' access to genetic information	12	87	1
Police access to genetic information to help solve crimes	63	34	3

(N = 1500; survey undertaken January, 2003)

In the U.S., privacy and security rules in the Health Insurance Portability and Accountability Act (HIPAA) of 1996 were updated with additional guidelines put in place by the Department of Health and Human Services. This update requires that researchers using tissue banks obtain authorization when they use patient-specific information such as medical histories (Uraneck, 2001). Civil and criminal penalties can be applied for violations. These rules were in response to mounting public concerns about loss of privacy and fear of discrimination as a result of abuse of sensitive health information. For instance, 85% of Americans surveyed in 1995 were either "very concerned" or "somewhat concerned" that insurers and employers would gain access to and misuse genetic information. Another survey in 1996 showed that fewer than one in

five considered the use of patient records for medical research without prior permission to be very acceptable; fewer than a third indicated that identifiable health information used for research without patient consent was unacceptable (Uraneck, 2001).

Table 2 summarizes informed consent and privacy arrangements for DNA banks in five different countries. It shows some differences in approaches to both these issue areas.

Table 2. Comparison of Consent and Confidentiality Arrangements

Country	Scope	Ownership	Consent	Privacy/Confidentiality
Iceland	National	Private monopoly	Presumed consent of population. "Opt out" for those refusing consent.	Strict confidentiality; while opt out possible, information stays in database.
U.K.	National 500,000 adults 45 +	100% Public	Broad	Strict confidentiality; opting-out provisos being considered.
Estonia	National (1M or 75%)	Public w/ private investment	Broad; can be withdrawn, samples destroyed	Strict confidentiality; data linked, providing donors access to own information
U.S. CDC	National	Public	Obtained at original collection; samples anonymized for subsequent research	Strict confidentiality; data anonymized.
Sweden	National and regional	Public	Required at each use but REB also has discretion to decide	Strict confidentiality; opt-out possible any time and information can be withdrawn from database.

Ownership and Control of Data bases. There was a strong sense among British national sample respondents that medical databases should not be owned by commercial interests. That these databases should be publicly owned was favoured by three in five respondents (Human Genetics Commission, 2000). Public ownership of new products developed from using genetic information was also overwhelmingly favoured, with three-quarters expressing this view.

Among Canadians, more than seven in ten were of the opinion that legislation designed to protect privacy of health information should be applicable to **both** public and private sectors (Canadian Medical Association, 2000).

The issue of who controls these data bases and who reaps the benefits that might accrue from them has already ignited controversies internationally, the case of Iceland being one of the more prominent. Domestically, a controversy in Newfoundland also serves to signal that this issue raised public concerns. Scientists from Baylor University in Texas had flown to St. Johns to study an extended family that had ARVC, a type of congenital heart disease that left its victims prone to cardiac arrest from a young age. The scientists spent a weekend collecting DNA samples and left without making provision for any follow-up treatment or genetic counseling, without providing local researchers or physicians access to the data, and sending thank you notes to the participants without letting them know whether they were at risk (Staples, 2000). This incident was dubbed another instance of "biopiracy" (Staples, 2000).

Advocacy organizations have been at the forefront in raising concerns about ownership and control of genetic information. As was pointed out in critiques of the Human Genome Diversity Project, "without a doubt, the most politically explosive aspect of the project is the question of ownership of knowledge and patents" (GenEthics News, 2001). The international non-government organization ETC group, formerly the Rural Advancement Foundation International (RAFI), has been at the forefront of the campaign against what they have called an epidemic of "biopiracy" or "biocolonialism," pointing out that people in developing countries and indigenous communities who provide biological material receive very little benefit, much less share in the profits (ETC, 1998; see also Indigenous Peoples' Council on Biocolonialism at http://www.icpb.org).

Commercialization of Genetic Information. Commercialization of genetic information is proliferating. A decade ago, the "tissue industry" revenue totaled $20 million; by 2003, revenue is estimated to rise to $1 billion U.S. (Beck, 2001). There are companies, which rely on hospitals or medical centres to recruit patients to donate blood or tissue samples. Others solicit samples online, relying on the altruism of donors who

want to help fight disease. Some samples are obtained through doctors who are remunerated for their efforts (Hawkins, 2002).

A Belgian biobank that went bankrupt had 500 saliva swabs donated for research. These samples, alongside the office equipment, were sold because they were considered "assets" (Hawkins, 2002)

Public concern about commercialization issues where publics are concerned range from commodification of the human body to inappropriate or misleading marketing and advertising to consumers, inappropriate implementation (e.g., wrong timing or providing insufficient or misleading information), costs to the individual and the system, and ownership issues that include public or private sector ownership and patenting. They also include such questions as "who's doing the research?" and "who's paying for these activities?". (see Caulfield, 1998 and Caulfield and Williams-Jones, 1999 for discussion of these issues). In some instances, there will be conflicting consumer interests between the push for more health products and services (increasing commercialization) and concerns about this very trend. As posed by Caulfield (1998), "Can we regulate the potentially adverse impact of market forces while still allowing the rapid dissemination of genetic innovations?" (p. 155).

The issue of patenting is one on which some public opinion surveys have been done. A variety of groups in Japan, including the public and scientists, were asked whether "people should be able to obtain patents and copyrights" with regard to *new* plant varieties, *new* animal varieties, *existing* plant/animal genes and *existing* human genes. Support for patenting fell among both groups as the focus moved from new plant and animal varieties to patenting existing plant/animal and human genes (Macer 1992). This hostility towards patenting genetic material already in existence was also evident among members of the New Zealand public (Couchman and Fink-Jensen 1990).

The Canadian public has demonstrated high levels of support for the mapping of the human genome and, with the success of this enterprise, has shown increased support for the idea of patenting genes. Concerns have been raised, however, about the possibility of patents driving up prices of medical products and reducing accessibility. Most Canadians associate genomic research with these products and have indicated in a national survey that equality of access should be the primary guiding principle in

commercialization, including patenting of these products (Pollara and Earnscliffe, 1999). Another concern is in the area of patenting higher life forms. Half of Canadians asked about the Harvard oncomouse said they were "not very comfortable" or "not at all comfortable" with the earlier Appeals Court decision which granted a patent on the mouse (Pollara and Earnscliffe, 1999).

Swedish perceptions of commercializing genetic information reveal similar concerns (Høyer, 2002). In assessing responses to commercializing technology, it was clear that, while respondents had little concern over commercializing information technology, gene technology posed serious concerns about "ethics," chief among them the idea of commercializing such information (Høyer, 2002). In some instances, however, the possibility exists of framing an effort that involves commercialization of genetic information in ways that might allay such concerns. UmanGenomics in Sweden has tried to promote the idea that they are <u>not</u> in the business of selling genes, only information, framing their venture in the context of an "ethical" transaction (Høyer, 2002).

It is clear that concerns about commercialization are prevalent among many publics. It is likely that, because genetic information impinges on personhood and identity, generating concerns about privacy and a desire to exert control over one's person, anxieties about ownership and commercialization are felt most keenly. At the same time, the tantalizing potential of finding cures for disease and improving human wellbeing, when combined with some assurance that protection can be provided to guard privacy and confidentiality, seems to entice some people to participate in commercial transactions. DNA Sciences, a company recruiting volunteers to provide blood samples for genetic studies, says in its website: "The information you give us would make a difference in the fight against dozens of genetic diseases and conditions. It is nothing less than a chance to be a part of history" (DNA Sciences GeneTrust project at http:www.dna.com/landing/landing.jsp?link=GeneTrust.htm).

Human rights issues. Some individuals go to some length to protect themselves from potential stigma or discrimination or simply the possibility of their privacy being invaded. In the U.S., one in seven Americans have admitted to taking extraordinary steps to keep their medical information confidential to avoid embarrassment, stigma, and

potential discrimination. These steps include withholding information from their health care providers, physician-hopping so as to prevent building of a consolidated medical record, making out-of-pocket payments normally covered by insurance or avoiding health care altogether (Institute for Health Care Research and Policy, 1999). In another survey on the privacy of genetic information, close to two thirds of Americans (about 63%) reported they would not take genetic tests for diseases if insurers or employers could access these tests (Institute for Health Care Research and Policy, 2001).

In Canada, only one in ten (11%) admitted to holding back information from a health-care provider because of concerns about whom it would be shared with or the purposes it might be used for. (Canadian Medical Association, 2000).

Are there reasons for these public fears? At least in the U.K., there appears to be some basis for these anxieties. A Wellcome Trust survey of patients and their families showed 13 % reporting problems in obtaining insurance among those whose genetic disorder did not represent any adverse actuarial risk and who should have been able to obtain insurance protection. These individuals, who were healthy carriers of recessive genetic or sex-linked conditions, healthy non-carriers of genes for late-onset disorders, and parents of children whose condition is the result of a spontaneous mutation, reported being refused insurance outright, or having higher premiums imposed, or being required to have unnecessary medical examinations (Low, King and Wilkie, 1998).

Among indigenous populations, the issue of genetic information and human rights in a collective or community context is a particularly sensitive one. For historical and cultural reasons, genetic testing has been approached with a certain amount of skepticism, if not outright resistance, by some communities. These perceptions are based in part on the conflict perceived by some groups between science and the maintenance of tradition; others fear the scientific establishment cannot be trusted with their genetic resources. Concern regarding retention of control over genetic material is evident in such declarations as the Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples (http://users.ox.ac.uk/~wqtrr/mataatua.html).

The Need for Public Information. Another concern expressed by some publics was the lack of information available. Three quarters of U.K. adults said they received

too little information on regulations governing biological developments and close to the same number expressed little or no confidence that these regulations were keeping pace with research developments (Human Genetics Commission, 2001).

Recruitment and Participation

A study by a U.K. research firm showed that willingness to participate appears to be mediated by how much information members of the public have and how much trust they have in the medical profession and government institutions (Cragg Ross Dawson, 2000, cited in Haimes and Whong-Barr, 2002). While initially expressing willingness to donate samples to a biobank, survey respondents (members of the "general public") became concerned when informed about wider issues. These concerns includedpossible misuse of information by employers, insurance companies, the police, and pharmaceutical firms; safeguards to protect confidentiality and their reliability; trustworthiness of the consent mechanisms when there was uncertainty about the future use of samples; and the right of donors to receive feedback on their samples (Cragg Ross Dawson, 2000, in Haimes and Whong-Barr, 2002).

Two empirical studies specifically interviewed or surveyed potential participants. The first was a study of participation and non-participation in the North Cumbria Community Genetics project (NCCGP) commissioned by the Wellcome Trust (see Haimes and Whong-Barr, 2002) and the second examined a small sample of 12 patients in Tayside and Fife, Scotland for possible inclusion in the U.K. Biobank ~~UK~~ project (Marsden, et. al., 2002). These patients were recruited for demographic considerations; those terminally ill with genetic diseases were excluded.

The NCCGP project investigated the perceptions of women who had been asked to donate tissue samples (in this case, blood and tissue samples collected from the umbilical cord of newborns and, subsequently, maternal blood specimens) and complete a health and lifestyle questionnaire. The NCCGP had a very high response rate, with close to 90% of the pregnant women approached agreeing to provide the samples. This study found that two primary themes predominated among those who agreed to participate: the desire to help and the recognition that provision of this help did not entail much effort.

Interestingly, this discourse of helping was also evident among non-participants; that is, the women who did not participate also portrayed themselves as willing to help but just not in these particular circumstances. Reasons given ranged from not having enough information about the project to not wanting to provide access to medical records because of the uncertainty surrounding how they were to be used. Similar results were found in Sweden in a study of participant and non-participant mothers in a neonatal research screening project (Gustafsson, et al., 2002). Again, the attitude of altruism or benevolence was demonstrated as a basis for participation, with these positive attitudes extending to the research to help children's health, the contribution of survey information as well as blood samples, and to the implementation of intervention programs in response to research results. Concerns were focused primarily on the storage of these materials and the right to be informed of any project results.

Marsden, et al. (2002) found that there was limited knowledge of genetics and genetic research among patients. The general belief was that genetic research would be about "finding cures" for illnesses. However, when asked about willingness to donate blood samples, all the patients interviewed said they were willing to give a blood sample, considering this a routine medical procedure they had undergone before. These patients also had no reservations about filling out a lifestyle questionnaire, but asked questions about its length and depth or the type of questions that would be asked. Most of these participants were also unconcerned about the prospect of a research nurse going through their medical records *as long as these records remained in the medical offices of their doctors and as long as they were clear about the purpose for doing this* (as suggested by the frequently posed question, "What would they be looking for?"). Similarly, these patients all wanted to know more about how the larger project (i.e., U.K. Biobank) would work and for what purpose.

This interest in participation was motivated by altruism, underlined by the belief that participation in genetic research would contribute to finding cures for diseases and would be inherently "a good thing". These patients' concerns focused primarily around the possible uses that could be made of the database and who would have access to it. These participants were most fearful of misuse by insurance companies and the police and were in favour of denying these institutions access.

The Iceland Health Sector Database project provides another illustration of actual participation rates -- in this case, of a national population. In this instance, the public's participation was presumed and Icelanders were given six months after passage of the Act to "opt out" of the plan. Six months later, by June 1999, only about 9,000 of the country's 270,000 residents (about 3 %) officially opted out (Lewis, 1999). By May, 2000, some 18,000 had opted out (Mannvernd, 2000). Polls had shown that close to nine in ten Icelanders supported the database early on (Lewis, 1999). One poll of 600 randomly selected citizens published in the Icelandic newspaper *Dagur*, found three quarters of respondents did not think the data would be misused (Lewis, 1999). Such high levels of support have been variously attributed to the public's lack of awareness of the full implications of the project – only 13% of a representative sample said they understood the bill a month before its passage (Lewis, 1999) -- and to Iceland's long history of the commodification of nature (Rose, 2002). That is, among supporters of this database project, the exploitation of genes in Iceland has been compared favorably with Norway's successful exploitation of its oil (Specter, 1999; Rose, 2001).

The Media's Role in the Public Arena

It is difficult to talk about public views and attitudes without also addressing the role of the media. As Dorothy Nelkin observed, "Media messages matter. As an important source of information about science -- the only source for many people -- mass culture helps to create the unarticulated assumptions and fundamental beliefs underlying personal decisions, social policies, and institutional practices" (Nelkin, 1999). While there is not a one-to-one correspondence between what appears in the media and public perceptions, the impact of the former tends to be more pronounced in instances where the public is unfamiliar with an issue. On new issues such as stem cells, for example, publics surveyed have readily pointed to the media as their primary source of information (ABC News-BeliefNet, 2001). The increasing attention paid to events involving privacy of information, more typically abuses of privacy of information, has likely played a role in sensitizing the public to these issues.

The sensitivity of genetic research has made for some critical stories alerting the public, primarily to abuses of privacy and confidentiality, the issue publics are perhaps most sensitive to. For example:

- In Sweden, a series of articles in a national tabloid reported that samples and information from a university tissue bank had been passed on to a private company through its collaboration with a researcher from that university's pathology department. The company had access to the codes linking patients to samples and the researcher's links to the company had not been disclosed to responsible ethics committees.
- Media coverage in the U.K. has been extensive around the issue of organ retrieval from dead babies and questions around appropriate consent (Sanders, C., 2002).
- In the US, there have been many press reports of breaches of confidentiality. For example, there was considerable consternation when the press reported the pharmaceutical company Eli Lilly had accidentally disclosed the e-mail addresses of 6,000 patients who were taking Prozac (Pew Internet and American Life, 2001). There are also documented instances in the media of misunderstanding and misinterpreting genetic information, resulting in unnecessarily penalizing people. Private insurers confused a person's being a carrier of an altered gene with actually suffering from the gene-associated disease, categorized them as suffering from "pre-existing conditions" and cut off their benefits (Sankar, 1997).

What makes "a story" for the media is not going to be the fact that bank deposits are safe. The story will be those instances when there have been breaches of safety; and it is these instances that publics will recall more readily.

Summary of Publics' Perspectives

Perhaps with the exception of Iceland, most publics are unaware of developments in genomics and the growing international interest in gene banks. That said, publics are already highly sensitized to the issues of privacy and consent with the increasing prominence of electronic commercial transactions, data gathering and surveillance mechanisms, and the greater exposure to and use of information technologies in general. Because publics also consider genetic information to be unique and deserving of special

protections, it is not surprising that the issues of consent and confidentiality are foremost in most people's minds.

Concerns about commercialization, though less prominent, are also frequently articulated. In general, there seems to be greater comfort with and trust in public ownership of biobanks. Having said this, some populations (Icelanders and Estonians, for example) appear to have accepted commercialization arrangements for their national genebanks for reasons that include pride in a national enterprise and the opportunity to contribute to finding cures for diseases.

For certain population groups, considerations of commercialization, consent, and confidentiality, are also embedded in broader concerns for human rights, potential discrimination or stigmatization, and the protection of collective identity and culture.

PERSPECTIVES OF PROFESSIONALS

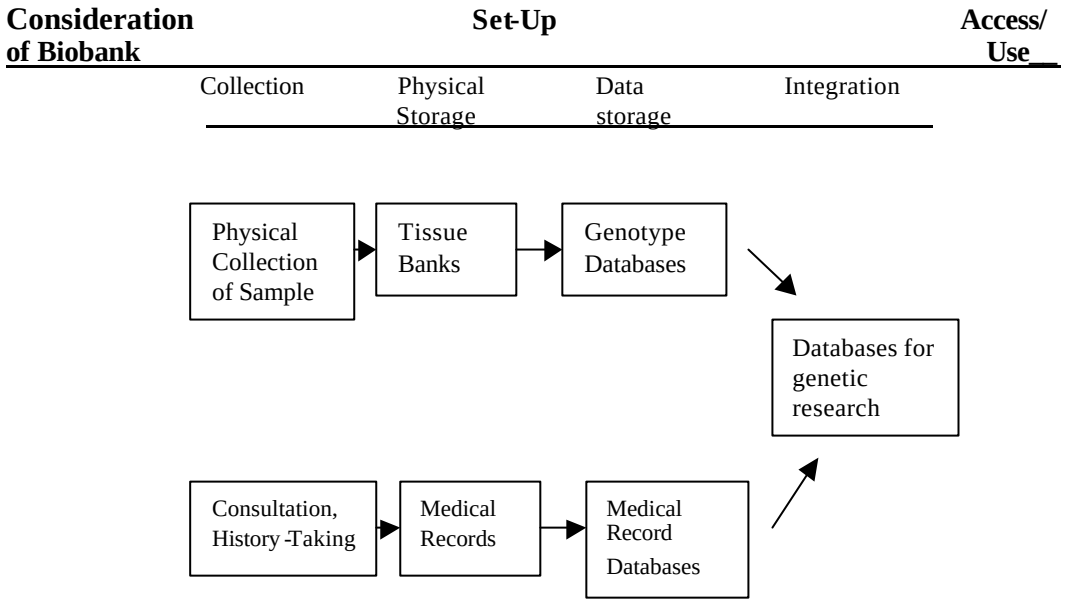
The scope of groups described as "professionals" for the purposes of this paper is necessarily broad. Different professional groups are involved with the issue of DNA banks, from the health professionals and geneticists who are directly involved with a patient to ethicists, policy and legal scholars who have been writing on this issue. The literature that has developed around the issues of privacy and consent alone is a burgeoning one and illustrates the challenges of trying to provide a picture of the "views of professionals." The portrait provided below will admittedly not necessarily be comprehensive as much as it will be an attempt to portray the range of views within an admittedly widely disparate group. The objective here is to understand which views are prevalent in which professional community and how professionals' views may be similar to or divergent from the views of publics. Similar arenas of concern will be described, as will additional areas or issues not necessarily discussed by publics.

Informed Consent

Obtaining informed consent is relevant at different points in the consideration of biobanks. As illustrated in Figure 1, the idea of consent can be extended to the three stages in the "life" of a biobank: the idea stage, the set-up stage and the usage and

maintenance stage. Much of the discussion on informed consent has focused primarily around the second and third stages, but the necessity of public consent even before the idea of the biobank is carried out is equally relevant. This is critical regardless of whether entire national populations are involved (as is the case with Iceland, Tonga, Estonia) or specific subgroups (indigenous populations, subgroups with high levels of genetic diseases). At national population levels, when public funds are committed to such efforts or when repositories collected with public funds are targeted for commercial exploitation, the need for public assent or dissent is rather obvious. The lack of public debate and consultation was seen to be among the most contentious issues surrounding the Iceland database proposal.

Figure 1: The Creation and Use of Genetic Databases (adapted from Martin, 2001)



Public Consultation	-Consent/Use -Confidentiality -Access -Ownership	-Consent/Use -Confidentiality -Access -Ownership	-Consent/Use -Confidentiality -Access -Ownership	-Consent/Use -Confidentiality -Access -Ownership	-Consent/use -Confidentiality -Access -Ownership

Informed Consent at Original Sample Collection. Health care professionals who may be on the front lines for recruiting participants are adamant about consent being obtained at the point of collection and for subsequent uses (Hapgood, Shickle, and Kent, 2001-focus group study with 26 general practitioners and nurses). Each collection of information and each new test on DNA that was seen as falling outside of the broad descriptions initially provided at recruitment needed new consent, particularly if the data collected are sensitive or different qualitatively from that which the participant was informed about at recruitment (Hapgood, et al., 2001).

The issue of informed consent for the collection of genetic information is also of increasing concern to research ethics committees, particularly around secondary use of samples. Some are starting to review their procedures. In instances where commercial companies have voluntarily submitted protocols and indicated interest in seeking patents, committees have found that patients' understanding of these issues was neglected by researchers. Concepts of genetic risk or commercial gains that might result from DNA analysis were inadequately explained and protocols included patient sheets that treated DNA collection from blood or tissue as incidental to the research (Rigby, Taylor and Khoaz, 2001).

A survey of researchers and those who bank tissue in Canada in the mid 1990's demonstrated that information concerning ownership and control options, storage conditions (e.g., duration of storage) and sharing of samples with other researchers were often not shared with tissue donors. Fifty six% did not specify ownership information, only 15% specified storage duration, and six in ten admitted to sharing samples with other researchers (Verhoef, Lewkonia, and Kinsella, 1995). Information on more recent practices is unfortunately not available.

The issue of informed consent in the context of a culture where these practices have not been normative has also been raised. In the case of Estonia, the argument has been made that a "paternalistic tradition" in postcommunist Baltic States "makes it difficult to ensure that informed consent and non-directive counseling of individuals are carried out properly" (Frank, 1999, p. 1263). Ellis, Lerch and Whitcomb (2001) present a set of information, which they recommend should be referenced at the time the DNA sample is originally stored.

Figure 2: Suggested Information at Original Donation (from Ellis, Lerch, and Whitcomb, 2001)

1. Description of where the DNA sample will be stored.
2. The minimum time period for which that DNA will be stored.
3. To whom does the sample itself and indeed the sequence information belong?
4. Who will be allowed access to that stored DNA sample?
5. Can the sample be moved, shared or stored by any other DNA storage facility?
6. If clinically significant findings arise from testing the DNA sample, who should be told and to whom should the results be given?
7. In the event of the person's death, who will have ownership and decision-making rights over that banked DNA sample?
8. Will medical doctors or specified researchers be allowed open access, and others only for a specified reason?
9. Other uses to whichthat sample may be put, e.g., on an anonymous basis for research.
10. Who will own any commercial benefits or patents that arise from DNA tests on that individual's genetic sequence?

Consent to Future Uses. The idea behind biobanks is their availability for multiple uses. Consent laws in many countries require researchers to obtain informed consent for the use of all identifiable genetic information and to repeat this process for new projects (Caulfield, 2002). While blanket consent for current and future uses might be convenient for researchers, their vagueness ultimately diminishes their legal significance (Caulfield, 2002). IRBs could consider this potentially problematic in the context of their current practice of requiring informed consent documents to disclose all of the ways the specimens or medical records of an individual might be used by the researcher seeking approval (Rothstein, 2002). The NBAC in the U.S. has suggested one approach, which is for the researcher to provide the potential research subject with a menu of possible uses. The research subject can then authorize the uses he or she

consents to (NBAC, 1999). Other bioethicists disagree (see Annas, 1998). Still others have proposed a position in between. Greely, for example, proposes a process allowing for consent to unforeseen research uses, but only if conducted within a well defined regulatory framework. This work stipulates conditions for recontacting the donor, providing an absolute right of withdrawal and time limits, setting limits on accesss by third-parties, provisions for group permission in addition to individual permission, disclosure of commercial interests and specifying community benefits. (Greely, 1999).

In Sweden, consent has to be obtained at every use although provision is made for the researcher to obtain clearance from an ethics committee if the secondary use does not deviate significantly from the uses the donor had originally consented to. In the UK, if the personal information is anonymous, if an ethics committee has given approval, and if the research is considered not to result in harm, consent was deemed not to be required. This established practice, however, is being questioned in light of more recent court rulings which consider these practices illegal (Martin and Kaye, 1999).

Confidentiality and Privacy

The extent to which participants are identifiable is dependent on the donor population pool and the regulations that may be put in place governing confidentiality and anonymity. Typically, blood or tissue samples can be linked back to their donors for banks dealing with specific diseases; when samples are provided to researchers, this is usually without identifying information (Balleine, Humphrey, Clarke, 2001).

The British Medical Research Council has described anonymized samples or data as those which "have had any identifying information removed, such that it is not possible for the researcher using them to identify the individual to whom they relate." There are two types of anonymized samples: linked anonymized samples where data are

> fully anonymous to the people who receive or use them (e.g., the research team) but contain information or codes that would allow others (e.g., the clinical team who collected them or an independent body entrusted with safekeeping of the code) to link them back to identifiable individuals." Unlinked anonymized data or samples have no information that would allow linkage back to the donor (Medical Research Council, 2001a.).

One potential approach to this problem is to anonymize irreversibly the samples by stripping off all labels. Arguments against this are that information derived could later be of benefit to the patient; the patient and/or physician might later request access to data; and finally, this system would prevent prospective addition of samples or clinical data from participants in the future if long-term research were contemplated (Knoppers, Hirtle, Lormeau, Laberge, and Laflamme, 1998). The second approach, used in the Iceland DeCode project, is to provide a third-party encryption system which acts as a firewall between those who store data and those who use it (see Gulcher, et al., 2000). Iceland's Data Protection Commission was created to ensure data security by approving procedures for collection, registration and processing of personal data during the setting up of the database and its subsequent use. This Commission is charged with carrying out encryption and coding of data and overseeing procedures linking different databases of health information, genealogies, and genotypes (Kaye and Martin, 2000). The privacy security afforded by this system has been questioned, however, with some arguing that "in reality, anonymity does not exist in databases such as the Icelandic health sector database that have large amounts of information from which contextual inferences about personal identity can be drawn" (Arnason, 2002).

In sum, there is disagreement among professionals about the conditions for confidentiality and the viability of technical solutions to provide answers.

Feedback

In the process of analyzing a subject's medical records or DNA, a researcher may find something of interest to that individual – this could relate to that individual's past (e.g., questions of paternity) or his future (e.g., disease risk). What are the obligations of researchers in these cases? While researchers in the U.S. have the choice of telling their research subjects whether they will return information to them as part of the informed consent process, many choose not to return information and let subjects know this, an option which, while legally convenient, could potentially pose problems for the researchers and their institutions (Greely, 2001). This is a question that concerns some researchers who have argued that, in their rush to protect research subjects, those advocating restrictive policies end up hamstringing research. The additional worry is that

subjects in research on one gene who have said they want results might be provided findings by well-intended researchers concerning genes not covered in consent forms such as breast or colon cancer genes (Holzman, D., 1996).

A survey of 3600 counselling and allied health professionals in the U.S. showed that more than two/thirds of the health professionals support autonomy in situations where clients choose not to be told the results of genetic testing. At the same time, 29% would place limits on autonomy when clients refuse to tell at-risk relatives the results of genetic testing and think that health professionals should contact and inform relatives. This dichotomy raises a potential conflict between the professionals' obligations to maintain client confidentiality and the ethical duty to warn at-risk relatives about genetic disease susceptibilities (Lapham, et.al.,1997).

Human rights considerations

Biobanks are seen to be an important basis for pharmacogenomics, or individualized medicine. As such, human rights concerns have been raised with regard to the implications of this approach to medicine and health care. For example, a European Parliament study has flagged the potential exclusion of certain groups from healthcare if they react to a large number of drugs and alternatives are not economic to produce. Additionally, the role of ethnicity in pharmacogenomics could be problematic since some medical problems and drug reactions might be specific to certain ethnic groups. (Webster, A., N. Brown, B. Rappert, P. Martin, R. Frost, and A. Hedgcoe, 2001).

At the same time, some professionals have also commented on the complexities of race and ethnicity as they observe the difficulties of "wanting it both ways," referring to the impulse to regard race as a biological fiction (both as a result of the genetic similarities demonstrated between groups of people and especially in the context of the history of race and biology) and to the clinical reality of differential rates of disease or different responses to drugs by different ethnic groups (see, for example, Satel, 2001; see also Wade, 2001).

Individual rights versus the collective or community.

The proposal of Australian biotechnology company Autogen to establish a health database in Tonga using the population's genepool sparked regional and international outrage among human rights and church organizations. The director of the Tonga Human Rights and Democracy Movement called the arrangement an attempt to colonize their resources (Burton, 2002). The Tongan National Council of Churches, supported by the Geneva-based World Council of Churches, convened a conference on bioethics in the Pacific region and resolved that "the conversion of lifeforms, their molecules or parts into corporate property through patent monopolies is counterproductive to the interests of the people of the Pacific." The church groups insisted that decisions to exploit genetic material needed to consider the collective rights of the extended family (Burton, 2002).

The history of the Human Genome Diversity Project has again provided a plethora of writing on its collection of genetic material from indigenous communities around the world. The question of informed consent is typically discussed in the context of western notions of personal autonomy, but many indigenous groups have social structures, which are based on the collective rather than the individual. How will the process and the assumptions behind these processes of informed consent be modified to accommodate these different social and cultural contexts (Greely, 2001)?

Other Social and Philosophical Concerns

Commodification of the human body. Most ethical problems that arise in biomedical research with human body parts concern the legal and moral status of those body parts, but there are also important larger issues implicated around this subject. What are a particular culture's ideas about human dignity? How is the body or its parts conceived in jurisprudence and what are the differences between countries in their legal frameworks and their connections with cultural and social values? Should the body be commodified? What moral arguments over commodification of body parts are raised and how are these addressed? (see Meade, 2001).

The question of ownership of the body (or its parts) and the associated question of commodification is one on which there are different views within the professional community. Some have argued that objectification and commodification of the body

negatively impacts individual concepts of personhood (Williams-Jones, 2000). Others point out that "the image of the body as property relies on a sense that *parts* of the body, such as organs, gametes, or cellular tissues can be transferred to, acquired, and manipulated by, others" (Campbell, 1992). From an ethical perspective, many ethicists argue that people have a right to treat their own body parts as property and they should further be fully informed as to what, if anything, will be done with their donated (or removed) biological material (Dekkers and Ten Have, 1998). It is, however, more frequently the case that "providing general information about storage and use of human body parts is virtually non-existent in most research and healthcare institutions.(Dekkers and Ten Have, 1998, p. 61).

Questions of identity. , The Human Genome Diversity project was designed to address questions about the origins of humans. However, considerable controversy arose about a number of ethical issues, which the project was criticized for not addressing adequately (see National Research Council (1997).~~not least being~~ One of these criticisms related to how researchers interacted with indigenous populations. The emphasis placed on genetics often reflected on the identity of population groups, an identity which ~~. The question~~ anthropologist Jonathan Marks suggested could be threatened: ~~posed is one that remains important to ask today~~ (2002, p. 7):

> Do scientists have the right to study whatever they want, without regard to the wishes or sensibilities of relevant people? The pragmatic question is, how then do you honestly secure the participation of the very people whose ancestors, relics, relations or blood you wish to study, when your research agenda is constructed to undermine their beliefs?

Complexity and Reductionism. The Human Genome Diversity Project has made the claim of reconstructing the evolutionary pattern of the human species. Opposition to the aims and methods of this research program and criticisms by respected bodies such as the National Academy of Sciences (NAS, 1997) included the idea that the complexity of evolutionary patterns cannot be reduced to simple molecular biological explanations

(see Marks, 2002). A similar trend has been identified in the case of explanations for disease, with diseases being categorized into sub-groups with or without genetic components. Such diseases as certain cancers (e.g., breast cancer), diabetes or asthma are reclassified according to their genetic bases, further amplifying the shift towards genetic explanations (Martin and Kaye, 1999).

Health Professionals' Concerns.

General practitioners and nurses in the U.K. interviewed for a Wellcome Trust-funded study expressed concerns about the possible impact of consent requirements on their practices. This included time commitments, costs and remuneration, and the additional burden and responsibilities of explaining the project to patients they may be recruiting (Porter, et al., 2000; also Hapgood, Shickle, Kent, 2001).

A majority of health professionals support the use of genetic technology to learn whether or not a fetus would be born with a disease or disability, 29% would use technology to prevent obesity, 9% to increase a child's intelligence, 4% to select gender and 1% to clone humans. These findings indicate the need for increased genetics education of health professionals about the ethical issues of emerging genetic technologies and their impact on the public. Genetics professionals need to be aware of the views of counselling and allied health professionals and how they may influence clients' participation in genetics testing and research. Informed voices are needed from health professionals and the public to make policy decisions about use of the continuously evolving new genetics (Lapham**,** et. al., 2000).

Primary care physicians and clinicians play a key role in clinical research with their involvement primarily in the identification of patients who might meet certain demographic or clinical criteria (e.g., patients with a particular disease). Frequently, it is the physician who might ask the patient and/or his family to participate in the research project. Such a role places the physician in the position of providing the patient with information about the research project and, in the event of a negative outcome, the physician and the investigator could be held liable by the patient (McInnis, 1999). In this instance, the physician assumes a responsibility to her patient to be informed not just about the benefits, but also the potential risks entailed. The ethical conduct of medical

research is most directly spotlighted in this doctor-patient relationship. It was in this context that the Icelandic Medical Association advised the government that the interests of the patient were being jeopardized by the Health Sector Database law with its unacceptable arrangements regarding informed consent (Icelandic Medical Association, 2000).

Commercialization Issues

As mentioned earlier, fluids and tissues available for genomic investigation can come from samples collected for the purpose of establishing a biobank or whichcollected by institutions as part of surgeries, biopsies or autopsies. These samples have been billed as "hot commodities" (Ready, 2000). Some hospitals have jumped into the commercialization market while others have hesitated or been reluctant to do so. For example, two teaching hospitals in Massachussetts have an agreement with a biotechnology company to supply tumors and other tissue (with patient consent); in return, the company will process the material into products (e.g., DNA, RNA arrays) which are then sold to commercial scientists for a profit and to academic researchers at cost (Ready, 2000). Other hospitals have simply limited access to academic researchers (Ready, 2000), but with increasing ties between academe and industry and the increased financial pressures on hospitals, commercial arrangements may become more commonplace.

In addition to population-based initiatives sponsored by governments, there are similar efforts occurring in the private sector. For example:

- The Mayo Clinic has entered into partnership with IBM to create a database of medical records from 6 million existing patients and the 500,000 new patients who are checked into the clinic each year, correlating phenotypic (e.g., a diagnosis of hepatitis) with genotypic (e.g., a test for hepatitis) data.
- DNA Sciences in California has signed up 13,000 people via the internet in its "Gene Trust" Program. The volunteers will contribute their blood samples for research purposes, allowing these participants to opt out if they choose.
- Massachussetts General Hospital and Brigham Women's Hospital have also announced a database similar to that of the Mayo clinic (Uehling, 2002).
- Genset in Paris announced an exclusive two-year research collaboration with Technion Bruce Rappaport Faculty of Medicine in Israel for the collection, banking, and analysis of DNA from patients affected by common diseases (Cancer Weekly, 1997).

In essence, the trend toward commercializing genetic information is rapidly gaining steam. This is occurring alongside the predominance of market values which enshrines consumer choice in health care, to the frequent detriment of the doctor-patient relationship, the needs of patients, and public health (Annas, 1998).

The increasing numbers of links being established between the public and private sectors have been flagged (see, for example, Human Genetics Commission, 2000), with the construction of a commercial market for human DNA and genetic data well underway (Martin, 2001). Questions that have been raised include the following:

- Should biological samples taken by public bodies or collected with public funds ever be used for commercial research?
- Under what circumstances?
- How should financial returns be shared between the public and private sectors?
- What are the rights of sample donors to commercialized products and profits made from their donated samples?
- Should third party organizations (such as insurance companies or criminal investigation bodies) outside of the biomedical research and commercial communities have access to these samples?
- How are public research agendas shaped by industry interests?
- What are the impacts of these commercial arrangements on public trust and confidence?

Other Non-Research Uses of Databases

Genetic databases established for medical research purposes could potentially also be used by third parties, including the police and the criminal justice system. Primary health care practitioners were generally opposed to the justice system having access to these databases (Hapgood, et.al., 2001).

Governance Issues

Questions around the governance of biobanks underlie many of the discussions among professional groups. Governance arrangements tend to be complex, in part because the issues tend to be complex. Policy developments around genetic information

have a recent history and are still evolving; the practical ramifications of having and managing the use of genetic information are not completely understood. Complexity also arises from the fact that the oversight functions relating to genetic information concern a diversity of actors: legislative bodies, federal and provincial or state governments, health authorities, professional bodies, foundations and granting councils, and ethics boards.

On the legislative front, the questions that would be pertinent would relate to laws around privacy and data protection, confidentiality of medical information, ownership and patenting of human tissue, and access of third parties (such as insurance companies) to medical and genetic information. The oversight function of professional bodies would relate to standards or guidelines of such groups as the College of Physicians and Surgeons with regard to how medical research is carried out and relationships between health care providers and patients. Ethics committees would, of course, be overseeing the conduct of research and the protection of human subjects.

Issues around governance for professional communities tend to be more nuanced, if not ambivalent. For example, while some express confidence in technical arrangements for maintaining privacy and confidentiality (see, for example, Gulcher, et al., 2000), others maintain that, "given the nature of genetic information, it may prove impossible to ensure that biological samples can be truly anonymous" (Martin and Kaye, 1999, p. 55; also Arnason, 2002).

The complexity of these issues and governance arrangements suggest that the expectations of publics with regard to ensuring confidentiality and privacy, consent, and expectations about conditions of use of genetic information will be heavily reliant not just on technical/regulatory arrangements; they will have to draw on a resource that is easily abused: trust. In the end, the question of how public trust is to be maintained is one that all of these groups and bodies will have to ask themselves.

Summary of Professionals' Concerns

Because the community of "professionals" covers such diverse groups as health care practitioners, ethicists, legal scholars, social scientists, and policy groups, it becomes a challenge to try to characterize their views. This section on professionals' views of biobanks has covered a list of issues that is fairly similar to those of public

groups. At the same time, perhaps because many of these professional groups or scholars in these groups have been examining these issues for longer periods and with greater attention and intensity, it is not so surprising that their views are more elaborated and there are more distinctions between groups or even between scholars within the same professional community. Not all legal scholars or ethicists necessarily emphasize the same elements nor do they espouse the same views within their own expert communities.

On the issue of informed consent, all agree that such consent is absolutely necessary at the original point of sample collection or donation. For subsequent uses, however, differences of opinion manifest themselves. At one extreme is blanket consent at the point of donation, which permits any subsequent use. At the other extreme is requiring informed consent for every use. Most professionals tend to cluster in the middle, disagreeing primarily on the specifics of how consent might be obtained for secondary uses, with some suggesting providing donors with a menu of options and others suggesting that Research Ethics boards can evaluate applications to determine whether further consent is warranted.

On the issue of confidentiality and privacy, there is general agreement about the importance of protecting privacy and confidentiality in principle. Some researchers express confidence in legislation, ethics boards, and some agency overseeing data protection as elements that are necessary and sufficient for overseeing privacy protection. Others argue that systems of data protection and oversight mechanisms such as ethics committees will not provide adequate safeguards.

Views on providing feedback to participants are similarly dependent on the professional group. Health care professionals at least in the US have opted for not providing feedback for a variety of reasons. Others are more ambivalent, recognizing that there may be benefits to being able to provide the information to participants and their relatives, especially when they are at risk of getting a disease. At the same time, they recognize the dilemma of having access to such information when no cure or treatment is available or when there is disagreement among family members about accessing such information.

On the human rights front, again, most writers are cognizant of the need for protections against discrimination and for maintaining a health system that is fair and

equitable. At the same time, there is recognition that these principles face challenges in practice. For example, the principle of community consent has been championed widely but, at the same time, there is recognition that communities are diverse and some may have groups with conflicting interests; the issue of obtaining collective consent is a process requiring a deeper understanding of that community's culture, historical context, and political traditions.

Like publics, most professionals view the trend toward commercialization of genetic information with increasing alarm and concern. Some have proposed benefit-sharing arrangements with individuals and communities; others have suggested being clear and transparent about any potential commercial arrangements that might develop or are being developed from tissue collections.

Professionals have also written extensively on a range of philosophical-ethical concerns, from the commodification of the body to issues of complexity and scientific reductionism.

CONCLUSIONS AND RECOMMENDATIONS

Genetic information is unique and carries important symbolic significance. It tells us who we are, where we come from, the conditions of our being, and what the future might hold. The confrontation between these symbols, our desire to control our fate, and the drive for scientific progress has led to compelling questions about how we balance these sometimes competing goals.

In considering what policy recommendations might arise from this analysis, it is important to reflect on two levels: the first is the more general area of publics and genetic research and the second is the specific area of biobanks. Much of what the public knows and understands about genetics will have implications for how they think about biobanks.

Communicating with publics

In general, an understanding of genetics will help equip publics to participate more fully in policy questions and discussions on such subjects as genetic testing, risk, predispositions, genetic research, or gene-environment interactions. In order for publics

to make informed choices at personal and societal levels, public understandings need to account for both scientific validity and uncertainties and the contexts for and the social consequences of genetics-related choices. Some have already made choices about having "disease-free" or "disability-free" children. In other instances, there may be confusions about the meanings of genetic tests, the notion of probabilities, potential risks, sensitivity or specificity of these tests, or their predictive value. Professionals, not just publics, can also be confused by these topics.

The Human Genetics Advisory Commission (HGAC) in the UK has emphasized the importance of public awareness of and education on genetic issues "to enable more groups in society to participate in and follow debates about complex genetic issues." The Commission recommended a participative approach, working collaboratively with other groups such as the education sector to ensure that many groups in society "feel they are able to follow and contribute to consideration, debate and discussion of issues" (HGAC, 1998). In Denmark, where there is a high level of awareness on genetics issues, the Danish Council of Ethics and the Danish Board of Technology have played an active role in promoting public education and furthering public discussions and debate. Similar calls for public awareness have been made by the World Health Organization and the Council of Europe.

The Centers for Disease Control and Prevention (CDC) in the U.S., in its 1997 strategic plan for *Translating Advances in Human Genetics into Public Health Action*, promoted this strategy for communication about genetics:

> In collaboration with CDC's Office of Communication, conduct a comprehensive review of communication research in genetics, develop a plan for assessing the information needs of various audiences, develop messages, and select media for disseminating information about genetics and public health. Use the internet as one distribution mechanism. These activities will ensure that the dissemination of information is coordinated, accurate, and timely.

Many of the calls for public education and awareness underline the need for publics to have a more realistic appraisal of the balance between risks and benefits, to understand the limits of science, and to consider the other ethical, social, and legal dimensions of these issues. This is relevant and important but not very meaningful if the

premise behind educational initiatives is that provision of information will result in the public "coming around" or in public support. Other stakeholder groups such as scientists, health care and legal professionals, and advocacy organizations also need to be "educated" by the public about its interests, values and concerns. The provision of genuine opportunities for engagement and deliberation are critical and the Danish and Dutch experiences in engaging publics through a mix of educational initiatives and more participatory and dialogic approaches are particularly instructive (Joss and Durant, 1995; Einsiedel, 1998). *Meaningful* dialogue between scientists, other stakeholders, and the public is essential, dialogue which is "mutually informative, thoughtful, honest, and carries the possibility of being mutually transformative" (McLean, 2001).

On the more specific issue of biobanks, Iceland's experience with deCode demonstrated very clearly that people are concerned about how genetic research is done, that public involvement is absolutely necessary for genetic research, that the purposes of such research should be clearly spelled out, that international principles governing consent to and withdrawal from research should govern research on genetics (Annas, 2000).

> If there is a recurrent theme in our assessment of public interests and concerns, it is the idea of **respect**. This notion of respect includes a number of dimensions. First is respect for members of the public as citizens. Other dimensions include respect for individual autonomy, including that individual's right to make choices, respect for his or her privacy and the need for confidentiality. It also embraces respect for personhood in the context of family and community. Respect for cultural beliefs around the human body and respect for the right to information should also be recognized. Finally, it also includes respect for the vulnerable members of society. The preceding description is summarized in the following well-articulated concept of respect: (Cutter, in Weir, 1998)
>
> > To show respect for persons is to value persons by refraining from eliminating the necessary conditions of personhood, which include life, bodily integrity, freedom to make choices and to act upon them. In addition, it means acting to promote the presence of such conditions. Respect involves then a negative and a positive duty to others. On this view, respect is not dependent on the consent or rights of another. The obligation to show respect for persons is not an obligation to the person in question. It is an obligation to act in certain ways toward that person or persons. And so, on this analysis, respect is owed to the innocent and vulnerable, to communities of persons, as well as to rational agents.

One dimension of respect for citizens relates to the citizenry as active participants in a democratic polity whose voices and interests need to be heard and addressed. As citizens who support research endeavors through public funds, who benefit from, but also bear the risks of, genetic technologies, their engagement in technological decisions is also critical. In this regard, public engagement is a critical requirement before major technological ventures are decided on. If a national biobank is being contemplated, meaningful public involvement requires posing the question of whether this is an appropriate direction for research and an appropriate use of public funds. This is not to say that public opinion is the only determinant of decisions such as these, but it ought to be regarded as a necessary one.

Public Consultations on Biobanks

What are the modes by which publics can be engaged in consultation? Given the diversity of different publics, the diversity of research uses, and the complexities of issues implicated, a variety of public engagement approaches are clearly called for. Table 3 provides some examples of consultation approaches on DNA banking, each of which carries its own set of strengths and weaknesses.

Should the initiative be carried out, it is imperative that the groundwork be laid for a governance framework, which should also include public representation. The conditions for collection, storage, access and use requires consideration by a multidisciplinary group that spans specialists from a variety of scientific and technical disciplines as well as legal scholars, ethicists, advocacy organizations, and public representation. Considerations of this technology are too far-reaching to be left to scientists or to professional ethicists alone.

From the public's point of view, providing for the conditions that make informed consent and the protection of privacy and confidentiality meaningful is paramount. By the time members of the public are invited to participate, an important component of information provision should include (a) the purpose(s) for obtaining the sample and health information; (b) the conditions for maintaining privacy and confidentiality, (c) consent conditions for future access or secondary uses of the data; (d) conditions for storage, maintenance; (e) oversight mechanisms; (f) commercialization possibilities.

Table 3. Public Consultation Mechanisms Employed on DNA Banking

Approach	Strengths	Inadequacies
Public Opinion survey	Representative	Superficial coverage of issues
Focus Groups	In-depth exploration of reasoning, bases for preferences	Not generalizable
Deliberative consultation models	-Learning opportunities for lay and expert panels -Interactions with experts, more extensive deliberation	Time, resource intensive; Fewer individuals involved
Stakeholder consultations	-Stakeholders' familiarity with issues -Involvement of those with direct benefits or risks	Exclusion of general public
Community consultations	-Critical where collectivity is highly valued	-Challenges of who provides consent
Web-based consultations	-Larger numbers participating -Quick and on-going information sharing	-Selected by technology access
Lay representation on expert committees	-Broadens base for considering issues beyond technical considerations.	-May be marginalized by experts

The HUGO Ethics Committee's Statement on DNA Sampling--Control and Access (1998) has recommended that there be no disclosure to third parties of an individual's participation in a research project and that security measures should ensure that desired levels of confidentiality be respected. Rules regarding anonymity in relation to data linkages have differed among biobanks. In Canada, these have to be negotiated and spelled out. Again, these have to be made clear and made transparent to the public. The HUGO Ethics committee also regarded as essential the international standardization of ethical requirements for control of and access to DNA samples and information (fr. Webster et al, 2001). Adherence to international standards will likely be a point of consideration for Canadian publics.

The oversight mechanisms for biobanks will similarly be critical to the public. How reviews and are audits carried out, by whom, and how frequently will be some of the issues of interest. If we look to the gene therapy experience for lessons, the instances of scientists and drug companies in the U.S. not complying with federal reporting requirements by failing to notify the National Institute of Health of deaths that occurred in these experiments are indicative of the need for stringent oversight over research in such highly sensitive areas. It may be necessary, for instance, to establish a standing oversight panel for biobank research at the national level. This does not preclude the use of local research ethics boards, but these local institutional review boards also have their limitations, including "being shot through with conflicts of interest," according to privacy specialist George Annas (Uehling, 2002). A federal oversight committee might review protocols and monitor biobank-related research, providing assurance that standards and guidelines were being adhered to. This oversight committee might also keep track of the history and use of the biobank, develop periodic reports, serve as a resource for guidance regarding socio-ethical issues, and provide a forum for ongoing national discussion (Martin, 2001). This committee could also act in a foresight capacity, encouraging discussion of prospective issues of public concern (see Kaye and Martin, 2000; Martin, 2001; Cohen, 2001).

Further research. It is obvious that any effort to develop a gene bank and its associated legal and institutional framework will need to be set within the specificities of the regional or national setting it is to be located in. We have provided snapshots of public and professional views from an international landscape but the importance of understanding and accounting for local particularities – social, legal, political and economic – cannot be overemphasized.

For example, one of the central questions on which debate on activities related to use of genetic information should focus is the extent to which social values and inequalities determine which conditions are regarded as serious and important (see Chadwick, 1988). What is viewed as a "serious" or "significant" health problem, and what type of therapies are available are determined by a complex of social, cultural, economic and political considerations. The extent of individualism versus communitarian

traditions will also have some impact on how consent procedures are designed and carried out.

Canada is a very large geographic landmass with a current population that is multi-ethnic and multicultural. It also has significant numbers of different aboriginal communities and geographic pockets of homogeneous subpopulations (e.g., Newfoundlanders, French Canadians). Many of the issues we have raised in this paper will require sensitivity to international standards as well as to local needs and interests.

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