Survey of National Approaches to the Development of Population Biobanks – Background Paper

Prepared for

The Canadian Biotechnology Advisory Committee

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Introduction

In 2001, it was with great enthusiasm that researchers announced the completion of the human genome draft map. This research tool paved the way to new research avenues for diagnostics, treatment, drug development, and future health service needs.

In order to fulfil the expectations created by this novel chapter in human biology, researchers have expressed an increasing need for large-scale DNA banks. At the 3rd International Conference on DNA Sampling in Montreal, Eric Lander's opening address stressed the importance of using large databases to increase our knowledge of disease which can then be used to diagnose and treat patients.[1] As we turn to research on complex diseases and show a greater interest in human genetic variation and genetic epidemiology, we need to base our research not only on the DNA of an individual, but also on his social context, his genealogy, his environmental context and his geographic location and migration. The study of the genetic composition within a population offers the social and organizational context necessary to understand the complexity of the human genetic make-up.

Recently, proposals to create genetic biobanks of the population have drawn international attention. Praised by some and criticized by others, these innovative research initiatives raise complex issues which need to be identified and thoroughly discussed by all stakeholders. To participate in this debate, one needs a comprehensive overview of recent developments and policies related to population biobanks.

The *Canadian Biotechnology Advisory Committee* commissioned a background paper on approaches to the development of population biobanks. Our methodology was based on a comparison of different experiences of national biobanks. We examined national normative documents specifically regulating genetic research initiatives as well as selected literature on the subject. We also considered international normative documents on biomedical research and genetic research. Finally, we considered the Canadian normative and social context, in particular to orient future reflection on the possible elaboration of such research projects in the country. For the purpose of this paper, the term "biobank" is intended to refer to a collection of physical specimens from which DNA can be derived, as well as the data that has been derived from the DNA samples, and related data.

This review allowed us to identify nine themes which we think pose a number of major issues related to national population biobanks. We hope that a careful assessment and consideration of these issues will contribute to the development of a leading Canadian policy approach.

1- International approaches to the development of population genetic biobanks

National population genetic biobank initiatives are proliferating across the world. For the purpose of this report, we have chosen to focus on a few selected projects that offered interesting and innovative approaches to population research and conveyed sufficient public

material (in English or French) for a meaningful analysis. However, it should be noted that other projects are currently underway.[2] We have selected the following countries as representative of contemporary population research initiatives, providing a brief presentation of their projects and normative approaches.

a) Canada

Canada currently has a population research initiative in preparation. CARTaGENE, a project at an early stage of development in Quebec, aims to recruit 50,000 individuals between the ages of 25 and 74 to give a blood sample and to answer a general health and socio-demographic questionnaire.[3] The data collected will be anonymized. Participants will be randomly selected, according to their postal codes, to take part in the study and will be proportionally distributed throughout the province. Four major universities plan to be involved in the management of the project through the creation of a not-for-profit Institute. CARTaGENE is still in the phase of securing funding but has already collected material on legal, social and ethical questions relevant to the implementation of the project.[4]

b) Estonia

Estonia has recently joined the circle of population research initiatives. Estonia has a large enough European (Caucasian) population to provide sampling for common diseases prevalent elsewhere in western countries in similar proportions.[5] Moreover, the country has very competitive operating costs and a highly educated workforce.[6] In 2000, the Parliament passed (with a large majority: 42 yes, 3 no) an Act to "regulate the establishment and maintenance of a Gene Bank, to organize the genetic research necessary therefore, to ensure the voluntary nature of gene donation and the confidentiality of the identity of gene donors, and to protect persons from misuse of genetic data and from discrimination based on interpretation of the structure of their DNA and the genetic risks arising therefrom".[7] The legal owner (Chief Processor) of the bank is a non-profit foundation, the Estonian Genome Project Foundation, created by the Republic of Estonia in 2001.[8] Although the database will belong to this non-profit foundation, a for-profit company, eGeen (authorized processor), was set up and will have the right to sell access and information.[9]

In October 2002, the Foundation started a pilot project, which covers 3 counties. The main project should be in development from 2003 to 2007 and will recruit ~3/4 of the 1.4 million population of Estonia.[10] The Gene Bank will contain tissue samples, descriptions of DNA, health data, genealogies, and genetic data.[11]

c) Iceland

Iceland was a pioneer in the establishment of large-scale population genetic research with the coming of deCODE Genetics. DeCODE is a private company based in Reykjavik, largely funded by American interests and registered on NASDAQ.[12] DeCODE seeks volunteers to create a biobank for DNA analyses on more than 50 diseases. Almost 80,000 participants have given blood and medical information so far.[13] DeCODE claims that "this number represents one-third of the total adult population and includes more than 90% of

people over the age of 65."[14] DeCODE also collects medical information from participants. Biobanking is governed by a new set of rules adopted under The Biobank Act.[15]

DeCODE will have access to two other sets of data. First, deCODE can link participant data to the genealogical data widely available in the country (which is well known for its accuracy and its ability to reference 600,000 individuals, covering most of the people who ever lived in Iceland).[16]

Another important asset for deCODE's genetic research is the Health Sector Database. In 1998, the government approved legislation authorizing it to grant a licence for the creation of a health database for its entire population of 270,000 inhabitants.[17] Iceland granted deCODE genetics a 12-year licence to build and exploit Iceland's entire Health Sector Database.[18] Medical data will be collected from medical centres across the country and centralized in the database.[19] The HSDB project elicited debate, particularly in the field of consent, confidentiality and freedom of research.[20] Opposition is led by an organization called Mannvernd[21] and the Medical Association has also criticized the project. To date, 20,000 people (from a total of 270,000) have withdrawn from the Health Sector Database.[22]

d) Tonga

The project to establish a database of genetic information on the population of Tonga was abandoned by Autogen in mid-2002.[23] The proposal faced great opposition from church and pro-democracy groups.[24] In November 2000, Autogen Ltd., an Australian biotechnology company, announced "the signing of an agreement with Tonga's Ministry of Health to establish a major research initiative aimed at identifying genes that cause common diseases using the unique population resources in the Kingdom of Tonga."[25] This project specifically involved the collection of tissue samples (DNA and serum) and health data.[26] No specific law had been adopted for the project. However, Autogen had drafted an ethics policy for genetics research involving the use of biological materials collected from the people of Tonga,[27] albeit without enforcement mechanisms.

Tonga is composed of 170 islands with a population of 100,000. The population is attractive from a genetic point of view because it descends from a small number of people, is isolated and has a high prevalence of a variety of diseases.[28]

e) United Kingdom

An important national biobank project is about to be launched in the United Kingdom by the Medical Research Council, the Wellcome Trust (a private charitable organization) and the Department of Health. The project was funded in April 2002[29] and in March 2003 a joint venture between MRC and the Wellcome Trust will be created to run the project. The UK has a large heterogeneous population, scientific strengths, and a centralized National Health Service. These elements offer many advantages for the establishment of a population biobank in the country.[30]

The investigation will be based on a longitudinal prospective cohort, involving at least 500,000 adults aged 45-69 from the general population of the United Kingdom. The

inclusion of individuals in this age range will allow the accrual of appropriate numbers of events within a 10-year follow-up period. The database will include lifestyle data, environmental data, clinical data, DNA, and plasma.[31]

At this time, consultations both with the public and health professionals have been conducted, the draft protocol is completed, the initial funding has been allocated, and legal agreements are under negotiation.[32] However, the protocol could undergo further modifications as a result of recommendations from the Scientific Management Committee.[33] Pilot studies could begin in about a year.

The United Kingdom has historically left the regulation of medical research to the profession rather than to Parliament.[34] Currently, no legislation or guidelines relate specifically to population biobanks. The UK Biobank is covered by the Data Protection Act 1998 and by the Medical Research Council's guidelines on the use of biological samples and personal medical information.[35]

f) International Hap Map Consortium

In October 2002, an International Consortium launched the Genetic Variation Mapping Project or "HAPMAP."[36] Canada is part of this private/public initiative along with a few other countries such as Nigeria, Japan, USA, China, UK (Wellcome Trust) and the SNP Consortium which raised private funds for the project.[37] The National Institutes of Health pledged US $40 million for a total estimate of US $100 million for the 3-year project.[38] The research will examine 200 to 400 genetic samples from four populations in Africa, Asia and the United States.[39] In the United States, the samples will be stored at Corriell(?). An ELSI (ethical, legal and social issues) committee is currently working on the legal and ethical aspects of this project.[40]

2- Major themes and policy options for Canadians

A large body of norms has developed around genetic research. In fact, many countries have relevant provisions on the subject. However, for the most part, the framework was developed without bearing in mind research population representativity.

Throughout our studies, we observed that, as population research becomes an area of greater interest, we are confronted as never before with the question of the duality of human rights. In the past decade, focus has been almost entirely on individual rights. Population studies force us to re-examine the importance of collective rights in light of the population's contribution to research and the benefits and risks that may result for the group as a whole. We must strive to find a balance between individual rights and collective rights.

For these reasons, among others, we believe that the conception and execution of a genetic research project in a population has particular characteristics which would require the

development of a complementary set of norms addressing issues specific to population research.

a) Consultation

Communication with the population studied is particularly important before undertaking a population biobank project. Population consultation is a vehicle for communicating information about the research and its outcomes, listening to the interests and concerns of the population, and addressing ethical issues associated with the project.

The first issue is public trust. Transparency, public discussion and debate are vital to the success of population genetic research. Failure to conduct community consultation can erode trust in scientists and in research in general and compromise the conduct of genetic population research.[41] According to Frank Dukepoo, a Hopi Indian and geneticist, "when scientists don't show cultural sensitivity and respect for the beliefs of others --like our absolute opposition to gene patenting-- or won't take 'no' for an answer, there is no basis for discussion, and there can be no cooperation."[42] In Tonga, the proposal of Autogen to establish a population biobank has been jeopardized by opposition from church and pro-democracy groups. A major ground for opposition was the signature of an agreement to conduct national genetic research by the government, without prior appropriate public discussions.[43]

Also, by providing information to the population, population consultation is an intrinsic part of the informed consent process. Although the notion of consent will be discussed in another chapter, it is important to note that appropriate information is a fundamental prerequisite to consent in the field of research. Additionally, the more the public knows and understands about the project, the more comfortable they will feel in seeking further information and the better prepared they will be to correctly interpret the research results.[44]

Finally, population consultation may help prevent pitfalls in the design of a study. Establishing open dialogue with the population may uncover weaknesses in the research plan relating to such things as language barriers, beliefs, or concerns that would threaten the feasibility or the validity of the research if they were not considered.[45] Consultation with the public and groups with specific interests should be included as part of the process of developing guidelines to reflect a true partnership with the population.

Very few normative documents address the issue of public consultation. The American National Institutes of Health's (NIH) Points to Consider When Planning a Genetic Study that Involves Members of Named Populations focuses primarily on community consultation. While, the NIH does not require that researchers conduct consultations with targeted populations, they recognize the usefulness of consultation, encourage consultation, and believe that "investigators planning genetic research projects involving members of named populations should consider whether and how the community should be consulted."[46]

In Quebec, the position taken in the Statement of Principles on the Ethical Conduct of Human Genetic Research Involving Populations is unambiguous. It requires that all

research on a given population be based upon open dialogue between the population and the research team, insisting on the importance of prior and ongoing public consultation.[47]

Public consultation has been included~~foreseen~~ in many genetic population projects even if it is not a legal requirement. In the United Kingdom, a series of consultations have been conducted. In 2000, the Medical Research Council and the Wellcome Trust commissioned research consultants, Cragg Ross Dawson to conduct initial qualitative research "to explore public attitudes to the use of human biological samples and associated databases, and to inform policy-making about how they should be collected, stored and managed."[48] The public across the UK, religious and community leaders, and spokespeople for organizations with special interests in the issues relating to genetic research were consulted. During the same year, focus groups were held with primary health care professionals using themes that emerged from the previous consultation.[49] In 2002, the Medical Research Council and the Wellcome Trust commissioned People Science & Policy Ltd. to conduct a consultation with members of the public on the ethical and management issues relating to the proposed biobank project. The consultation involved three groups of 20 people aged 45-69, the proposed age for volunteers for BioBank UK.[50]

In Quebec, for the CARTaGENE Project, a quasi-public workshop gathering experts from the scientific, ethical and legal communities was held in 2001. The goal of the workshop was not only to present the state of the project and the scientific, ethical, and legal aspects involved, but also to collect comments and suggestions.[51]

For the HapMap project, a strategy for community engagement has also been developed.[52] The public consultation plans will vary from one place to another since each population involved in the project is culturally different.

Public consultation can also be part of the political process, as was the case for the discussions leading to the adoption of legislation in Estonia.[53] However, there was not an active public discussion about the project prior the to enactment of the Human Genes Research Act. ~~At least, t~~The media, however, was quite interested in the process and published articles provided everyone an opportunity to discuss the project. Media first covered the topic in spring 1999. By autumn 1999, the topic had reached most news channels and the first opinions were published. Since that time, approximately 300 articles, directly or indirectly connected to the project, have been published by the various media.[54] In Estonia, the fact that researchers presented their project to the government before initiating public debate was criticized.[55]

In Iceland, public discussions focused largely on the Health Sector Database (HSDB).[56] The questions related to the HSDB took centre stage and overshadowed ~~eluded~~ other discussions related to the genetic population biobank itself. People confused the two research projects and this blurred the ensuing debate.

There are numerous forms of population consultations[57]: dialogue with leaders of the population, small group meetings, focus groups, dissemination~~distribution~~ of written information (e.g., through newspapers), various media, contacting investigators with prior experience in conducting consultation, polls, etc. Information about the research should be

given to the general public and not only to eventual participants. At this level, transparency is important. Cultural, social, religious, and political aspects of the population, as well as its health status, should be taken into consideration throughout the project, especially in the elaboration of communication strategies, research protocols and the preparation of consent forms.[58] It may be necessary to consult multidisciplinary expertise in order to assess and understand the cultural values and characteristics of a population. The researcher must demonstrate respect for the population's culture, seek population input on protocol development, ensure that the research is useful and beneficial to the community, and respect the community's knowledge and experience.[59] Henry T. Greely stated that "a good deal of research must be done before a study group is even asked whether it wants to participate."[60] Among other comments, Greely emphasized the fact that the population should be asked to help set research goals because they have the most insight into their health background and needs, that the population should be kept informed of the progress of the research, be respected, and be viewed as research collaborators.

Canada

In the context of population genetic research, prior public consultation is now becoming a necessary preliminary step even in the absence of legal requirements. It is in the best interest of Canadians that fair and quality public consultation takes place for any population genetic research initiative. Canadian funding agencies need to take this trend into account and provide sufficient financial means to allow public consultation.

b) Recruitment

Recruitment for biomedical research can be conducted in different ways. Methods of recruitment should be founded on scientific, legal and ethical grounds. Very few normative texts specifically address the issue of recruitment. The principles that apply to the recruitment process are thus derived from general principles such as privacy, justice and the ratio of benefits torisks.

The privacy of potential participants must be respected at all times in a research project.[61] At the stage of recruitment, nominative data are necessary in order to contact eventual participants. Access to personal data is generally subject to consent or legislative authorization. For instance, privacy legislation foresees mechanisms by which such data could be used for research without consent. As demonstrated by the analysis of the countries' recruitment strategies, different approaches may be adopted to protect the privacy of individuals: involvement of the treating physicians and national bodies responsible for the protection of personal data, explanations on how and why people have been selected, mechanisms to avoid recontacting individuals if they do not want to be enrolled, and recruitment of relatives through the participants or with their appropriate consent.

In the UK, volunteers will be recruited via participating medical centers. These patients will be sent information on the study and an invitation to participate, signed by their general practitioner, along with the study questionnaire and consent form. General practitioners were generally viewed as an appropriate contact and collection point during public consultation.[62] Then, if interested in the study, the patients have to complete the

questionnaire and call a toll-free number or return a postage-paid reply slip to arrange an appointment with a research nurse at a local study recruitment centre. There will be a delay between the timethe questionnaire is sent back and the appointment with the nurse in order to allow sufficient time for the potential participant to consider his participation in the study and to discuss it with relatives and others. Further recommendations emanated from the public and health professionals' consultations.[63] People also recommended clarification in the initial recruitment material: how the study will add value to existing work, how and why that person has been selected as well as why he/she is important to the study, and why healthy people are important to the study.[64] This last recommendation can also be found in Beskow et al.'s consent form template for genetic population research where they suggest that explanations be provided to the participants on how they have been chosen.[65]

In Estonia, family physicians and general practitioners, designated as data collectors by the chief processor of the biobank, will inform their patients about the Estonian Genome Project and recruit potential participants.[66]

In Iceland, deCODE will first contact physicians to obtain a list of potential participants. The selection of potential participants will be made after genealogy analysis. In order to protect the privacy of individuals, the Data Protection Commission encrypts the list of selected individuals and transmits it to deCODE. This selection needs to go through a decryption process via the Data Protection Agency before returning to physicians. As in Estonia and the United Kingdom, recruitment is done through the physicians who have the task of contacting their patients, explaining the research, and obtaining their written consent.[67] For the recruitment of relatives, deCODE asks the participants through the consent form for permission for the researchers to contact their closest relatives to have them participate in the study.[68]

In Quebec, according to the current proposed recruitment strategy for CARTaGENE, the authorization of the Personal Information Access Commission will be sought to obtain home address and other personal information from the *Régie de l'assurance maladie du Québec*, a board established to administer and implement the programs of the health insurance plan in Québec. The recruitment office will establish the first contact with potential participants by mail. In this way, CARTaGENE will randomly recruit 50,000 adults representative of the population distribution~~density~~ of the province of Quebec. This recruitment will be unbiased with respect to disease or ethnic origin. Those individuals receiving the invitation to participate will be free to refuse, to not answer (if a second mailing is unanswered, it is presumed that the person refuses), or to accept by sending back a reply-coupon. For those accepting, an appointment will be set by phone to meet with a clinical team. The information letter sent to the individuals will explain the project and the possibility of recruiting relatives through them, the latter being required by the RMGA's *Statement of Principles*.[69] A 24-hour toll-free hotline and a website will be available to answer questions about the project.[70]

The fair distribution of risks and benefits implies that care must be taken to avoid over-recruitment of any given population. Attention should also be paid to the values and cultural perceptions of the population.[71] For example, in the HapMap Project, the researchers decided not to attempt to recruit individuals from indigenous groups that have

historically been disempowered in their own countries in order to avoid the appearance of biopiracy and exploitation.[72]

Finally, from a scientific and thus ethical point of view, adequate representativity of the population is important and needs to be considered in the recruitment methodology. During public and health professional consultations in the UK, people made recommendations, notably: to have a national information campaign, to develop localized strategies, to ensure that those in disadvantaged areas participate, to accommodate those who have low levels of literacy or whose first language is not English, and to identify other groups with specific needs.[73] Similarly, for CARTaGENE in Quebec, it was suggested that information be given in various formats and languages using vocabulary which is easily understood.[74]

Canada

The use of personal data in order to recruit participants is regulated by privacy legislation. If personal data is in the hands of a general practitioner, given the relationship of trust between the treating physician and his patient and the fact that the treating physician is bound by professional secrecy, the treating physician alone should approach his patients to propose participation in the research.[75] Legitimate access to information held by a private or a public institution could be assured through mechanisms anticipated~~foreseen~~ in legislation pertaining to personal data. For instance, research could be invoked as a reason for obtaining access without consent of participants in various jurisdictions.[76]

c) Consent

The individual and collective character of genetic information takes on an entirely new dimension in the context of population research. Even if the research does not require the participation of each member of the population, research on a particular population may bring about consequences for the entire population, particularly with respect to the interpretation of results. This raises the issue of obtaining support at an individual level as well as at a group level. We will address these two issues below.

i) Individual consent

Individual consent is a well-established principle of biomedical research.[77] Participants (or the legal representatives of incompetent persons) need not only consent, but must do so after being informed of the nature of the research, its context, the procedures, and of the specific benefits and risks related to the research. Information provided to eventual participants has to be clear and easily understandable.[78] Documents intended for participants should take into account ethnic diversity and level of education.

In most of the national and international biobank projects, such as in Tonga,[79] Estonia,[80] United Kingdom,[81] Quebec,[82] and for the international HapMap Project,[83] individual written informed consent is required for participation. In Estonia, there is even a criminal offence for inducing persons to become gene donors or for conducting scientific research on a person who has not granted his or her valid consent.[84]

For the collection of DNA in Iceland, the Act on Biobanks allows the use of clinical medical samples for research as long as general information on this was provided by a health care professional or health institution and the patient did not object.[85] However, notwithstanding this legislative exception, we should point out that deCODE has decided to obtain consent from the participants for the collection of DNA.[86]

Population genetic research usually requires the collection of health data. These data can be obtained by questionnaires or through the medical records of participants. In Iceland, health data will be obtained by deCODE, through both questionnaires and medical records. The Data Protection Commission is authorized, pursuant to the Act on the Recording and Presentation of Personal Information, to give access to information contained in clinical records for the purpose of scientific research.[87] Nevertheless, deCODE has decided to obtain the consent of participants to have access to the health record.[88] In Quebec, it is possible to obtain data from medical records for research purposes (and consequently for population research) without consent through a legislative exception.[89] For the moment, researchers from CARTaGENE rather chose to obtain health information by questionnaires.[90] In the United Kingdom, section 60 of the Health and Social Care Act (2001) follows a similar disposition with the approval of a committee.[91] Notwithstanding, the UK Biobank will be based on an opt-in approach. Participants will have "to provide written consent for follow-up through NHS registers, their general practice and other medical records, for permission to use their data and blood samples for various analyses and specified and unspecified biochemical and genetic tests and for permission to contact them again at a latter date."[92] It would appear that consent has become the norm in population genetic research, reflecting a more transparent partnership approach.

Unlike traditional genetic research projects, obtaining truly informed consent is difficult in the context of national large-scale biobanks when the future research uses are unknown. As underlined by Caulfield et al., "[g]iven the speed of scientific development in the area of genetics and the vast spectrum of potential research hypotheses that may arise and can legitimately be addressed by such databanks, there is no way to predict future uses of donated samples."[93] Cambon-Thomsen also raises the same consideration.[94] National biobanks may require the reassessment of the current normative framework. Should the current rules apply to research involving population biobanks? The question of broad or blanket consent has always been controversial. Some argue that blanket consent cannot amount to informed consent. Others argue that, according to the right of self-determination, a person has the right to grant broad or blanket consent to the use of his material or information. Finally, some proponents propose legislative changes in order to adopt an authorization model.[95]

In Tonga, a choice was offered to the participants to consent to the use of their samples and data for multiple research projects or for a defined few.[96] In the UK, according to the protocol, consent will be asked for various analyses, for specified and unspecified biochemical and genetic tests, and for permission to contact participants again at a later date.[97] For the international HapMap Project, consent will be obtained not just for the HapMap itself but also for many types of future genetic variation studies, gene-related diseases and pharmacogenomics studies that cannot be specifically detailed at the time the consent form is signed.[98] In Estonia, the consent form states that "By signing this

document, I give my free and informed consent to : (…) Enter the tissue sample, description of my state of health and my genealogy in the Gene Bank in coded form; The use thereof for genetic research, public health research and statistical purposes in conformity with the law."[99] In this case, broad consent is given by the participant. In Iceland, it is interesting to note that the Act on Biobanks requires that biological samples be acquired for clearly defined purposes but gives the board of the biobank the power to authorize the use of biological samples for other purposes than those for which samples were originally collected, provided that important interests are at stake, that the potential benefit outweighs any potential inconvenience to the donor or other parties, and that the approval of the Data Protection Authority and the National Bioethics Committee has been secured.[100] It is also relevant to note that in Canada, the use of the Nuu-chah-nulth First Nations~~tribe~~ DNA database for research projects related to diseases other than that for which consent was obtained has offended the Amerindian tribe and opened a debate on the secondary uses of DNA samples.[101]

Consent is a continuing process.[102] It must be reaffirmed every time a significant change to the protocol or to the banking conditions occurs. Such modification could include, in the case of a population biobank, adding a new partner, changing the bank's purpose, etc.

A corollary to consent is the right of withdrawal.[103] Countries have opted for various approaches to abide by this principle. Withdrawal of consent may entail the destruction of the samples and information,[104] or their complete anonymization. The Estonian participants can ask for the destruction of all of their data that can be decoded.[105] Actually, a gene donor has the right to withdraw his or her consent until the coding of the sample and data takes place. In such case, the sample and the data will not reach the Gene Bank. After encryption, the gene donor may require, at any time, the destruction of the data enabling decoding. Thus, it will become impossible to associate a blood sample and a gene donor, but the sample and data will not be destroyed. In Iceland, a donor may ask for the destruction of his biological sample.[106] As stated in the consent form, "any results already obtained and derived with the inclusion of this data would not be destroyed since considerable time and effort has been spent in achieving such results. The destruction of these results could also make it impossible to evaluate data derived from other individual participants and/or the participant group as a whole."[107] For the CARTaGENE Project, the provisions ~~dispositions~~ of the Civil Code of Quebec contain a right of withdrawal.[108] In the United Kingdom, participants are free to withdraw at any time.[109]

Finally, instead of collecting DNA from individuals, one could have recourse to stored samples. Consent rules must nevertheless be respected. HapMap has considered using such stored samples. The ELSI group has established three criteria that must be met before samples could be used in small-scale projects without recontacting participants. "The consent form had to indicate that the samples would be used to study genetic variation. Samples that were collected using consent forms that were disease-specific, such as heart disease, were disqualified. The consent form had to include an agreement to share samples with investigators in other countries. The consent form had to give permission for the creation of permanent cell lines at the time of collection or at some point in the future."[110] As Clayton et al. observed, '[v]ery few of the forms, and hence very few of the already existing collections, met these criteria."[111] Thus, in some cases, the recruitment of new

participants may become unnecessary or limited. But in most cases, a recruitment process will need to be put in place or at least consent reaffirmed.

ii) Population support

Genetic information has both an individual and a collective character. UNESCO as well as the Human Genome Organization recognize that the human genome is the common heritage of humanity.[112] HUGO also adds "[t]hat informed decisions to consent to participate can be individual, familial, or at the level of communities and populations."[113] The risks and benefits of population genetic studies may fall upon the whole population. Thus, group interests need to be considered. Should some form of consent or at least consultation be required from the group as a whole, in addition to individual consent? Different positions and mechanisms have been put forward.

First, the notion of population consent has been considered by academics. The rationale is that the population itself is a research subject and should be treated as such. The North American Regional Committee of the Human Genome DiversityProject supports this idea. According to their Model Ethical Protocol for Collecting DNA Samples, which was elaborated for the HGDP, "consent must be sought by culturally appropriate authorities within the community, where such exist, or through a consensus of the entire community, where there are no relevant authorities or where a consensus is the culturally appropriate authority."[114] This suggestion encountered many difficulties.[115] Who can consent on behalf of the population? What defines a population? Facing these obstacles, many researchers and scientists concluded that group consent is too difficult to implement.

An intermediate position has been widely adopted whereby researchers have an obligation to inform and consult the population.[116] Support of the population or at least absence of objection before or during the project should be morally required. Public opinion would then be taken into account.[117] Population support should be obtained before the beginning of the project. Otherwise, the population is faced with a *fait accompli* and discussion becomes irrelevant~~insignificant~~.

Finally, some academics questioned the population consultation approach. According to Juengst, it tacitly and erroneously endorses the view that our social groups correspond to discrete human demes and as long as the social group is nested within a larger population or has expatriate components, group consent or group consultation will be impossible to implement. He also sees public consultation as a population-specific inducement. Though public consultation may lead to the participation of more people, this should~~was~~ not be the goal of the consultation.[118] Juengst also points out that group approval for genetic research suggests that the group's real identity is at the genetic level, a scientific inaccuracy leading to racism. Thus, he proposes that ~~the~~ potential DNA donors be informed of the risks that their participation could impose on all others who share their broadest social identities.[119]

In current population genetic projects, even in the absence of specific legislative dispositions on population support, taking into account group considerations was an important factor. As previously discussed, different consultation strategies have been conducted in the various countries. The Public opinion can influence the development of a project and could even call into question its social relevance.

In Estonia, ~~the~~ public opinion has been taken into account. Emor, the largest marketing research and consulting company has carried out four surveys ~~in order to find out the~~ on awareness of and ~~the~~ opinions ~~of~~ the population about the project. The first survey was carried out in June 2001, the second in September 2001, and the third in February 2002. Each survey included 500 citizens of the Republic of Estonia, aged 15-74. The fourth investigation was carried out in August 2002 and included 400 citizens of the three counties involved in the pilot studies, Saarema, Tartumaa, and Lääne-Virumaa. In February 2002, 60 % of the population of Estonia was aware of the Estonian Genome Project. Only 5 % of them said that they were against the project. In August 2002, 76% of the population of the counties was informed about the project and only 2% of them said that they were against it.

In the UK, recommendations ~~issued~~ from members of the public and health care professionals brought some modifications to the scheme of the Biobank Project. For instance, the public consultation has resulted in ~~will lead to~~ the establishment of the oversight body. [120]

The cultural heritage, customs and beliefs of a population need to be taken into account to foster an approach that will protect the population's interests. For example, families may need to be involved in order to achieve a successful population consultation. Autogen's ethics policy focuses on prior informed consent of individuals but remains silent on the traditional Tongan role of the extended family in decision making. This became a point of discord. The Tonga Human Rights and Democracy Movement wants recognition of the prior informed consent of the extended family because of the familial nature of the genetic material. [121]

Canada

International experiences strongly suggest that individual consent should be obtained to collect and store DNA samples and personal data in a population biobank. Consent forms should be adapted to reflect issues specific to population genetics, for example, the benefits and risks for the population as well as the question of benefit-sharing.

Since we have a democratic political structure, the points of view of Canadians need to be taken into account in the elaboration of a population biobank. Although population consent is difficult to implement, we believe that it is possible to inform and consult the population and to consider public opinion. We ought to ask Canadians if they want to be part of a national biobank initiative with appropriate forums of discussion.

d) Governance

In a report prepared for the Law Reform Commission on governance of research involving ~~with~~ human subjects ~~beings~~, McDonald suggests this simple definition of governance: "… about the processes by which human organization whether private or public or civic steer themselves."[122]

The governance of a population genetic research project can be the result of a complex intertwining of rules (laws, protocols, contracts), general ethical principles, and

organizational structures (oftentimes including partnership with public and private sector). Establishing a proper and effective governance scheme requires coherent and concerted efforts as well as a global vision of the whole entire~~research~~ activity~~ies~~ within a population.

We have tried to identify the organizational structures of these research initiatives as well as the major documents regulating their research activity. The structures have already been described in the introduction. We will now focus on the rules and principles governing research and more particularly on the mechanisms put in place to assure proper adherence to these rules and principles.

i) Normative framework

General ethical principles applicable to research with human beings apply equally to any research on population genetics. These general ethical principles may be echoed in the legislation creating or regulating biobanking[123] and must reflect more directly in the research protocol. In Iceland, all biobanking initiatives (whether involving a population or a cohort) must comply with the Act on Biobanks.[124] Estonia chose the path of drafting specific and comprehensive legislation to structure the whole population research initiative (covering not just the biobank *per se*).

Self-~~Auto~~regulation is also another avenue. Thus, deCODE[125] and Autogen[126] both adopted a code of ethics offering more specific guideposts to the way research should be conducted. RMGA also adopted two sets of guidelines: one on genetic research in general[127] and the other on population genetics.[128]

Finally, the biobank itself can be subject to specific banking policy micro-managing its activities. Such a recommendation was made by the RMGA in its Statement on population genetics.[129] For instance in Estonia, the Chief Processor must enter into a contractual agreement with any authorized processor or gene researcher by which they setconditions~~modalities~~ such as place and term of storage, method of storage, security measures in place, the procedure for copying, distributing or destructing samples.[130] In Iceland, the licence granted by the Minister is contingent upon a governing board being appointed with one individual nominated to be answerable for the bank[131] and the objective of the operation of the biobank, the operational basis and the conditions of storage being described.[132] Furthermore, protocols for the biobank must be drawn up, including ~~regulations of the~~ governing~~biobank~~ arrangements for collaboration with foreign parties.[133] All these specific rules for biobanking apply along with more general regulations, for instance, on research involving human subjects~~with human beings~~, privacy, human rights, or financial accountability.

The development of an appropriate legal and ethical framework for a project requires careful consideration. In theUK, an Interim Advisory Group has just been announced. This group will meet regularly and will advise the funding agency on approaches to the project.[134] CARTaGENE also commissioned the preparation of a legal and ethical framework paper by scholars.[135]

In order to ensure compliance with the legal and ethical framework erected for the establishment and use of a population genetic biobank and their related databases, some form of surveillance and oversight must be exercised over the varied activities that comprise such a project. The next sections will address two areas: the accountability and oversight of the project and ethical review and monitoring. It should be noted that mechanisms specific to privacy and confidentiality were dealt with in an earlier section.

ii) Oversight of the project and surveillance activities

The entity responsible for the research project must be accountable, at the very least, to the collaborating population by granting them access to health resources and DNA samples. This is a question of respect, justice and recognition of a true partnership. It is also important to build and maintain trust between the researchers and the population. Accountability can be achieved in two ways. The research entity can be asked to report on its activities, but it can also be subject to some form of oversight or surveillance.

In the UK, the public voiced, during public consultations, the need for some form of body to oversee and thus exercise control over the management and use of biobanks.[136] The same recommendation was issued by the Select Committee on Science and Technology report: "We recommend that the Government should establish an independent body, including lay membership, to oversee the workings of the National DNA Database, to put beyond doubt that individual's data are being properly used and protected."[137] This led to the creation of an oversight body, independent from the research group, which will have the responsibility to monitor research activities and conduct audits.[138] Also, the World Medical Association suggests that research involving a health database should establish procedures for addressing enquiries and complaints.[139]

The establishment of a system of surveillance will be dependent upon the way the research project was set up. In Iceland and Estonia, the legislation regulating biobanking activities foresees multiple mechanisms to ensure some form of surveillance and even immediate control over the research activities. For instance, surveillance can focus on the biobank, the database, or the financial well-being of the organization.

In Iceland, under the Act on Biobanks, the establishment and operation of a biobank is permissible only for those who hold a licence from the Minister of Health following receipt of recommendations from the Director General of Public Health and the National Bioethics Committee.[140] The Act sets conditions under which such a licence may be issued.[141] The licence can only be granted once a framework is set up for the management of the bank including: stating the objective of the biobank, stating the conditions of storage, drawing up a protocol for the biobank, nominating a governing board, respecting security measures as laid down by the Data Protection Authority, etc.[142] The governing board must monitor the operations of the biobank[143] and the licencee is responsible for the implementation of ongoing internal monitoring and security assessment protecting the security of the data.[144] By merely granting deCODE a licence to operate a biobank, the Government of Iceland maintains a certain amount of control over it. It may be revoked upon violation of the Act or the conditions of the licence.[145] The Director General of Public Health must keep~~shall issue~~ a registry of all biobanks within Iceland including their purposes, activities and

protocols.[146] The Director General of Public Health ensures surveillance of biobanks in so far as this monitoring does not fall within the ambit of the Data Protection Authority or the National Bioethics Committee.[147]

When deCODE has recourse to the Health Sector Database to validate research hypotheses, it will have to do so under the surveillance of the Monitoring Committee. The *Monitoring Committee* was created by law and is mandated to ensure that the creation and operation of the database is in keeping with the legal framework of the terms set by the Minister of Health and to advise the Ministry of Health regarding the use of the database.[148]

In Estonia, the Genome Project Foundation is a non-profit foundation founded by the government and responsible for the activities of the bank.[149] The Chief Processor (i.e., the Genome Project Foundation) may grant processing rights by contract. This contract is governing the activities of the authorized processor.[150] The legislation enabling the population genetics research project entrusts a *Supervisory Board* to oversee the activities of the Chief Processor,[151] and to be held accountable for the establishment and management of the Gene Bank.[152] The *Supervisory Board* is composed of 9 members, each nominated by 3 different levels of government.[153] All databases are regulated by a specific law~~legislation~~ in Estonia.[154] A registry of all databases in Estonia is mandated by legislation.[155]

For countries where the biobank is not regulated by specific legislation, the designation of an appropriate independent oversight body requires careful thought and planning from the outset of the project and specific mention of the scheme in the protocol. The oversight body could be seen merely as a public whistle blower or could also be granted some form of executive power over the project. In the UK, in keeping with public consultation recommendations, the protocol for the biobank foresees the establishment of an oversight body.[156] They envision "a separate body or committee, independent of both the users of the information and the scientists involved in developing it, that would be responsible to the public, the research participants and other stakeholders for ensuring that the samples and the data collected are used responsibly and within the terms of the consent obtained from the volunteers."[157] For the HapMap project, a Community Advisory Group is set up for each community taking part in the project. The committee will ensureoversee that future uses of the DNA samples are within the activities authorized by the participant in the consent form.[158]

iii) Ethical approval and ethical monitoring

In general, population genetics research with a blood sampling component implies research with human subjects and thus requires Research Ethics Board (REB) approval as does any other biomedical research project.[159] Finding an appropriate REB is quite a challenge. Many dilemmas must be solved: should ~~they set up~~ a dedicated REB be set up or should ~~or designate~~ an already existing one be dedicated? Should the REB be~~Do they recourse to a~~ multi-cent~~e~~red REB ~~or~~ local ~~REB~~? Should the REB have advisory or decision-making~~consultative or executive power~~? What should be the appropriate composition of such an REB? In the following section, we will examine how the countries surveyed have dealt with these questions.

There are two elements to review: (1) the establishment of the population bank, and (2) the research protocols which will use the data or biobank. In smaller-scale research projects, REBs will usually focus on the research protocol and will examine the banking process through the evaluation of the protocol. However, the management and organization of the database or biobank cannot be severed from the protocol itself: it is an essential component of the research protocol. As so many ethical issues might arise from the establishment of the biobank (and the whole research structure) itself, it would be wise to involve the REB or ethicists from the outset of the project. However, it is not clear what kind of involvement occured~~they had~~ in the preparation of research initiatives. E~~Evidence of e~~thics committee~~s~~ activities usually only start~~s~~ just before the sampling takes place as they are generally called upon to assess the research proposals involving the use of data or banked DNA samples rather than the whole biobank project. To fill the potential gap between the time the REB is called upon to review the project and its actual conception, UK Biobank created the Ethics and Governance Advisory Group to advise the project managers on ethical issues.[160]

Designating one or multiple appropriate REBs is also a difficulty. Some countries have appointed special committees for population research projects, while others have relied on existing committees. Allowing the REB sufficient executive power to properly exercise its mandate is equally important.

In Iceland, it is mandatory to receive the approval of an ethics committee prior to the performance of scientific research with human subjects of a collaborative or multinational nature.[161] The creation and use of deCODE's biobank is therefore subject to this general rule: all research protocols must be submitted to the National Bioethics Committee.[162] The National Bioethics Committee must monitor the progress of a study and may revoke its permit should the committee believe that the research is no longer conducted in accordance with the protocol or with ethical rules.[163] Furthermore, the legislation on the Health Sector Database foresees the creation of the Interdisciplinary Ethics Committee[164] specifically for the HSDB to "assess the studies carried out within the licencee's company and questions which are received … evaluation must reveal that there is no scientific or ethical reason to prevent the study in question being carried out …".[165] The regulation confirms that the collecting, transferring and processing of data require compliance with the international "rules on science ethics."[166] The Interdisciplinary Ethics Committee has power to monitor the research they approve and to stop research that is not conducted in an appropriate manner.[167] If deCODE uses~~recourses~~ to the Health Sector Database, there will be a double ethics review of these activities.

In Estonia, an Ethics Committee oversees the processing procedures of the Gene Bank. A caveat must however qualify this affirmation since its decisions are not binding.[168] The REB's role is purely consultative. Also, the Estonian Genome Project Foundation created a Science Committee to advise~~counsel~~ on the scientific validity of research carried out with the gene bank.[169]

Where the legislators do not designate a REB for the population research project, finding an appropriate one can be challenging. In Tonga, Autogen resolved to rely on two ethics committees for the review of the project: one already in existence and based in Australia, the International Diabetes Institute Human Ethics Committee, and another to be established

in Tonga.[170] For the HapMap project, all studies using the biobank will require REB review of the country where the DNA is banked.[171] For example, in the United States, the REB of Corriel (Cornell?)(the repository for the United States) will review the research projects. In Quebec, however, the CARTaGENE project faces a complex situation when it comes to finding a proper ethics review scheme.[172] There is no "national REB" and the Tri-Council policy statement requires that research taking place in an institution funded by the agency be reviewed by local ethics committees (all major hospitals might be involved in drawing blood samples). Since the sampling would be done across the province, this means that dozens of REBs would be involved in the review and evaluation of the project. In contrast, in the UK, where studies using the biobanks are also subject to peer review and ethics approval,[173] protocols will be examined by the Multi-Center Research Ethics Committee (MREC) created / established~~instituted~~ with/for the purpose of overseeing these types of projects.[174] A MREC must be consulted about any multi-site research involving human subjects taking place within five or more Local Research Ethics Committee geographical boundaries anywhere in the UK ~~involving human subjects~~.

The composition of an ethics committee responsible for reviewing population genetics research projects requires special attention. The candidates must be independent evaluators and possess relevant expertise in the field. Although it goes without saying that members should collectively possess the knowledge required to discuss population genetic research, we found that the countries studied fell short of identifying what kind of expertise is required. ~~to examine population genetics research.~~ In Estonia, the legislation merely states that: " Each member shall be an Estonian citizen with active legal capacity shall be a recognized specialist in his or her field with the necessary expertise to perform the duties of a member of the Ethics Committee and shall have an impeccable reputation."[175] Members are nominated by the Supervisory Board for a period of five years.[176] In Iceland, the National Bioethics Committee is comprised of five people appointed for a period of four years. One member is appointed by nomination of the Minister of Education and Culture, one by nomination of the Minister of Justice, one by nomination of the Director-General of Health and two by the Minister of Health and Social Security.[177] The legislation makes special attention to: "ensure that the committee is manned by people with specialist knowledge in the fields of health sciences, scientific ethics and human rights."[178] We are concerned about the fact there are no requirement to include a representative from the public in Estonia or in Iceland.[179] In Tonga, there would have been at least six lay members of the public on the Diabetes committee.[180] Finding appropriate representation from the public may pose a particular challenge for research projects with a non-homogeneous population such as the UK or Canada.[181]

Financial and decisional independence of the REB itself is important. For example, to ensure independent decision-making, the budget for the operations of the ethics committee in Estonia is allocated directly from the state budget.[182] Also, nomination and withdrawal of members of the REB is made by the Supervisory Board (the highest body of the Estonian Genome Project Foundation).[183]

Canada

Oversight of the project and surveillance activities

In Canada, some important gaps with respect to research with human beings were highlighted in the report on governance prepared by McDonald.[184] The application of international and national principles that govern ethical research in a population genetics research project requires a fair bit of reflection. Designing a proper scheme that is transparent and accountable to the population and that will inspire trust by all stakeholders is a challenge. We foresee that accountability to a public organization or another independent body and the creation of an appropriate oversight body would be essential. Also, there is currently no organization where citizens can file a complaint regarding the conduct of a research project.[185] Although a specific research initiative may provide for the designation of such an ombudsman, we might want to reflect on the need for such surveillance on a permanent and independent basis.

Despite tighter privacy legislation regarding the oversight of databases and the use of medical or private information, it should be noted that we do not currently have research biobank legislation and there is no public registry that would enable identification of such research initiatives. Perhaps we ought to consider the need for a coherent management and oversight structure to monitor these activities.

Ethical Approval and Ethical Monitoring

In Canada, approval by an REB is now mandatory in any pharmaceutical research.[186] However, genetic research could fall outside the scope of this legislation. The Tri-Council Policy Statement requires approval by an REB but private initiatives would not~~also~~ be covered~~excluded~~. It is therefore uncertain, albeit strongly encouraged by international and national guidelines, whether a population genetics research project would be subject to REB review.

The Tri-Council Policy Statement addresses all of the above-mentioned concerns, but its application in a population research project context requires some adjustments. Firstly, it is not clear at what point in time the REB should be consulted. Clearly their approval is required before beginning recruitment of participants. However, perhaps an earlier collaboration would help to appropriately grasp ethical questions raised by such a project. Secondly, the question of multi-centred research is difficult to resolve. Even outside of the context of population research, REBs and the research community are struggling to organize proper review of large-scale projects. Finally, identifying the appropriate composition of a research ethics board to review a population biobank initiative requires careful reflection. What kind of expertise is required to insure proper evaluation of research projects? Who may serve as a community representative or lay participant on an REB reviewing a population research project?

Finally, long-term monitoring of population biobanks by REBs must be implemented and well organized. In general, observers have reported that REB's monitoring activities are deficient.[187] As a population biobank is a long-term enterprise, the need for monitoring is essential.

e) Commercialization

There are different theoretical conceptions about the right of ownership of biological samples. In Iceland, the *Act on Biobanks* clearly sets out that: "The licensee shall not be counted as the owner of the biological samples, but has rights over them, with the limitations laid down by law, and is responsible for their handling".[188] In Quebec, the RMGA has adopted a similar approach.[189] Estonia, however, adopts another point of view. The gene donor consent form contains a disposition according to which "[t]he right of ownership of the tissue sample, of the description of my state of health and of other personal data and genealogy shall be transferred to the Estonian Genome Project Foundation."[190] In all cases, even though they are not the owners of the genetic material, researchers may eventually acquire intellectual property rights or commercialized products.

It is incumbent upon researchers to explain to the population and to the research participants the commercial arrangements~~settlements~~ regarding the development of products with commercial application derived from the research as well as the commercialization of the bank itself. The questions of benefit-sharing, freedom of research, and conflicts of interest need to be addressed before research may start.

i) Benefit-sharing

Traditionally in genetic research, participants did not take part in any profit-sharing from the commercialization of research results. The Moore case and certain normative documents have established the need to inform the participants that the research may result in commercial products, patents, and profits.[191] However, in the case of population studies, benefit-sharing with a population in return for research participation has already been discussed.[192]

The Human Genome Organization in its *Statement on Benefit-Sharing* has suggested an innovative approach to population research: "…even in the absence of profits, immediate health benefits as determined by community needs could be provided and suggests that "profit-making entities dedicate a percentage (e.g. 1% - 3%) of their annual net profit to health care infrastructure and/or humanitarian efforts."[193] In Quebec, the RMGA has adopted the idea in a recent *Statement*: "[f]or the sake of equity, population research should promote the attribution of benefits to the population."[194] In the same perspective, Chadwick and Berg suggest

> …that it is the duty of those who are well off to share with the poor that is the central element in the moral duty of the pharmaceutical industry to share benefits. It could be argued that the pharmaceutical industry has an added moral duty to help promote health and healthcare systems because they are making their income from patients and these systems, and because they have first-hand knowledge of medical and social needs."[195]

Recently, the Canavan Foundation, a disease organization, sued a hospital that obtained a patent on a gene linked to the disease, claiming that the participation of the families in the research gave them commercialization rights.[196]

The notion of benefit-sharing has also been extensively discussed in Newfoundland. In August 2001, the province of Newfoundland and Labrador commissioned a study to examine different options and to make recommendations on an appropriate policy for governing commercial genetic research. A public forum and consultations were conducted, gathering together representatives from the government, the industry, health sector, research sector and experts in health law and related aspects of genetic research. The main recommendation coming out of these consultations is that the province should establish an approval process for benefit-sharing as an adjunct to research ethics review. The process would require all human genetic studies to submit a proposal for how financial or in-kind benefits will be shared with appropriate stakeholders.[197]

Benefit-sharing can take different forms: prompt diffusion of research results, collaboration with members of the scientific community, attribution of licences when the invention resulting from the research is patented, etc. If the research yields profits, the distribution of benefits could include access to future treatments resulting from the research or donation of a part of the profits to a local humanitarian organization or financial support for research or contribution to health technology infrastructures, etc. Knoppers proposes that, in addition to this, agreement could be reached that sees a return of information from the private sector to the population banks.[198]

Our survey shows how diverse the benefit-sharing models can be. The most well known example of benefit-sharing is in Iceland. Roche made a public commitment that, if it developed any products as a result of the research, it would provide these products free of charge to Icelanders during the period of patent protection.[199] The value of this commitment is at most a public promise made by Roche.[200] Iceland offers another interesting example of benefit-sharing worth mentioning even if it is not entirely connected to genetic research. The Operating Licence for the Creation and Operation of a Health Sector Database foresees that ~~the Icelandic state will receive from deCODE~~decode will provide a share of annual profits obtained from the running of the database to the Icelandic State be used to promote health services, research and development.[201] The government will also have full access to the database. The country's medical records facilities would be standardized, modernized, and computerized at deCODE's expense.[202]

In the United Kingdom, contracts foresee the return of research results to the biobank in exchange for the use of the samples.[203] For the HapMap Project, the goal of the research, creating a haplotype map, could be seen as a form of benefit-sharing, since it will offer a new tool to speed the discovery of genetic contributions to diseases. The haplotype map "will be placed in the public domain for the express purpose of promoting health research."[204]

It is of interest to underline the fact that one of the reasons why the people of Tonga objected to the creation of the biobank was the conversion of their DNA into corporate property through patent monopolies.[205] Although Tonga had obtained promises of free drugs and benefits from any royalties or profits, the director of the Tonga Human Rights and Democracy Movement, Lopeti Senituli, insisted that the benefits that could result from the research were insufficient: "What they are offering us is little, a drop in the ocean in comparison to what Autogen is bound to get if there is any success."[206]

Benefit-sharing implies a discussion with the population on the potential benefits and how they can be fairly shared. The form of benefit-sharing cannot be drawn in the abstract. It will vary from one project to another. An appropriate benefit-sharing plan would be tailored to the population's needs and cultural values and would not be coercive. In consideration of the principle of equity, distribution of benefits should profit the whole population and not only the participants. Prior consultation with individuals and communities and their involvement in the research design sets a foundation for the future distribution of benefits and may be considered a benefit in itself.[207]

ii) Freedom of research

Genetic research has a tremendous commercial potential. While commercialization may stimulate research it may also hinder the development of knowledge. Greely argues that:

> The exclusive control over the use of the database granted to deCODE by the Act illuminates a tension in modern biological science. The traditions of the science call for sharing data, materials, and tools. The reality of both commercial and academic competition have undercut that tradition. Without a preferential right, deCODE and its investors would have no incentive to spend millions of dollars constructing the Heath Sector Database. On the other hand, researchers other than those who contract with deCODE might have been able to use the database more effectively, and general availability of the resource could speed research by increasing the competition among researchers to find particular genetic disease links."[208]

In the field of population genetic research, monopoly on population biobanks could be perceived as going against the interests of the population. Freedom of research is beneficial to the population as it enables the exploration of various avenues of research by different research teams. The exclusive appropriation by an entity of a population's DNA is thus a point of contention.

As a public corporation, deCODE has decided to granted exclusive licences for the use of genetic information produced from its research. Under a new three-year alliance, deCODE has provided Roche with exclusive access to the results emerging from the conduct of research on four hereditary diseases for commercial application.[209] deCODE has other agreements with other partners.[210]

In other countries, the situation is different. According to the law, researchers who are legal persons in public law or state agencies of the Republic of Estonia are granted the right to use descriptions of DNA or parts thereof without charge. Foreign researchers may also obtain a right to use the descriptions of DNA or parts thereof. Whether the tissue samples will be accessible to the scientists in the future or not will depend on several aspects. In all cases, commercial entities~~modalities~~ will have to ~~be~~ negotiate with Egeen as the exclusive commercial licencee for all data emerging from the Estonian Genome Project.[211]

In the UK, no single company will(?)~~should~~ be granted exclusive access.[212] In fact, access by commercial entities was a controversial issue raised by a number of people during one of the public consultations. Worries tended to dissipate when it was explained that these commercial entities would do much of the research work and that none of them would get

exclusive access to the bank. Moreover, general practitioners and nurses encouraged strict control of the commercial entities' involvement.[213] The approach of the UK Biobank is indubitably influenced by the fact that the project is funded by two public entities and by a charity organization bound to act for the public good and for a non-profit goal by virtue of the law.

Finally, in Quebec, the CARTaGENE project is also considering the idea of giving access to all biotechnology companies and academic researchers if their protocols have scientific value and adhere to the pertinent ethical norms.[214]

iii) Conflict of interest

Commercialization may raise issues of conflicts of interest. Commercial interests should be disclosed to research ethics committees and to participants via consent forms.[215] However, mere disclosure of commercial interests does not solve the problem entirely. Since conflicts of interest need to be managed properly, there may be a need for other mechanisms. For instance, the separation of commercial interests from the interests of the population could be considered. As stated in the RMGA's Statement of Principles on the Ethical Conduct of Human Genetic Research Involving Populations, "[m]echanisms should be foreseen to take into account the interests of the population in any commercialization. For example, an independent body could be created for its management."[216]

In light of the available information, it seems that this is the approach chosen by the Estonian Genome Project Foundation (EGPF). The EGPF is the legal owner of the database and performs data collection and storage. It grants exclusive licences for all commercial activity via EGeen Ltd. to EGeen, Inc. EGeen Ltd. (EG) is a for-profit limited company founded by the EGPF on April 2001 to carry out the financial-economic objectives of the Genome Project. Currenly, Egeen belongs entirely to the Estonian Genome Project Foundation. Egeen will analyze DNA in order to prepare electronic gene cards for each participant. Egeen International Corporation (EGI) is a for-profit private entity established in May 2001. It is located in Silicon Valley in the United States. EGI is responsible for finding investments that will be forwarded to EGPF through EG for the preparation and development of the Estonian Genome Project. The activities of EGPF, EG, and EGI are regulated by agreements.[217]

Alternatively, an independent body or person could be mandated to determine and manage conflicts of interest arising from the commercialization of products derived from the research. This could be directed by REBs, provided that they are properly informed of all commercial agreements and that they have sufficient expertise.

Canada

Technological innovations have intensified the commodification of nature, particularly of the human body. There is no question about the development of population biobanks around the world. The pressing question is rather: how should this resource be exploited? The creation of population biobanks in Canada requires a collective reflection on the commercial aspects of such a resource. How should commercialization be managed in order to keep it aligned with population interests? Who will look after the interests of Canadians in any commercial agreements? Should a population biobank remain the

property of public entities? How can the principle of benefit-sharing be fully implemented in a Canadian context? Finally, commercialization may give rise to conflict of interest problems. If need be, a proper scheme to manage such a situation should be proposed.

f) Privacy

Privacy is a fundamental right recognized in many international documents, including the *Universal Declaration of Human Rights.*[218] "The right to privacy entitles people to exercise control over the use and disclosure of information about them as individuals."[219] We will examine both confidentiality mechanisms and the issue of control over the use of the data and tissue samples.

i) Confidentiality

Population genetic research usually requires collection and linkage of a number of sources of information, including medical information, general personal information (residence, age, etc.), genetic information, and genealogy. The particular nature of genetic information (both unique and familial) makes it very sensitive medical data. The concentration of a critical mass of personal information for research or commercial exploitation in such large-scale undertakings calls for very strict safeguards to protect the confidentiality of the information entrusted by the participants to the researchers[220] and experts.[221] The *Universal Declaration on the Human Genome and Human Rights* makes it clear that the use of genetic material in research should be held confidential.[222] Health databases are currently attracting attention and there is concern about possible misappropriation or misuse of such information[223] and what protections exist or should exist.[224] The worry is such that the World Medical Association adopted, a few months ago, a *Declaration on Ethical Considerations Regarding Health Databases.*[225]

Since in genetic research total anonymization is rarely an option, measures to protect the identity of participants and their personal information are required. Researchers must design a scheme by which personal information may be linked for research purposes and yet ensure protection of the identity of the participants. This is a complex task. The issue of data confidentiality is usually at the forefront of discussions when we consider genetic research and biobanking.

The countries reviewed in this paper have privacy legislation in place that regulates how personal data should be dealt with.[226] Some have instituted guidelines regarding research and health information[227] or more specifically on research databases.[228] The handling of genetic information and health databases are primarily regulated by these general privacy laws. In population genetic research projects, either the protocol or the enabling legislation also include built-in mechanisms designed to protect the confidentiality of the information gathered in the database. We will now focus on these specific mechanisms.

Physical and logistic measures to ensure confidentiality

Data collections should be physically protected. The usual safeguards used for any database containing important information should be employed.[229] Similar protection applies to tissue samples, as they are also bearers of personal information. In Iceland, DNA samples must be kept safe and secure~~: and must ensure that~~ "Biological samples shall be stored in such a way that they are not lost or damaged."[230] In Estonia, the Chief Processor must also enter into a contractual agreement with anyone who might have stored DNA that sets out such elements as the security measures, the method of storage, the place and term of the storage, etc.[231] In the UK, the protocol specifies all the measures related to storage of the tissue samples.[232]

Another means of protecting the data or DNA samples is to make sure that it does not directly reveal the identity of the person from whom it was collected. Some groups have chosen to completely anonymize data and samples. The HapMap project will not collect personally identifiable information and will collect more samples than necessary to ensure the complete anonymity of the donors.[233] CARTaGENE project is also leaning towards a similar strategy.[234] Anonymization offers participants total protection against misuse provided that it is truly anonymized.[235] Caution should be exercised with the use of the word "anonymization" because it is subject to great confusion.[236]

While anonymization might seem a safe solution, there is an important downside -- since the samples may lose their scientific potential because it is impossible to update clinical data or to re-contact participants. If not anonymized, genetic material and information should at least be codedwhen entered into a bank.[237]

If linkage with personal identifiers is necessary, a UK report efficiently sums up a common approach:

> For research involving human genetic databases, complete de-linkage between personal identifying information and medical, genetic and other data is not possible, since it is vital to be able to follow-up that person over time. When they are distributed and used, however, this should be at the highest level of anonymisation possible consistent with the aims of the research. It follows that data could be made available to different people with different degrees of anonymisation.[238]

In the United Kingdom, all identifiable information will be stored separately from the other data of each participant but some form of linkage is necessary to allow for the follow-up of participants.[239] Linkage can occur only when it is strictly necessary and performed in accordance with the eventual Scientific Management Committee guidelines to be developed prior to commencement of the study.[240] In Estonia, the chief processor gives each sample or piece of information a unique code consisting of at least sixteen random characters.[241] The chief processor is allowed to decode data only in cases specified in the enabling legislation.[242] In Iceland, deCODE receives only encrypted health data and biological samples prepared by the Data Protection Commission Encryption Agency. "Researchers that have access to healthcare and genetic data can only see encrypted ID numbers and those in charge of the genealogical information see the names of the individuals but never have access to any healthcare or genetic data."[243] Storage of biological samples must be done without identifiers.[244] Also, as the licencee of the HSDB, deCODE may only process

data from the Health Sector Database that cannot be connected to an identifiable individual and cannot grant direct access to the database.[245]

Measures to restrict access

Access should also be restrained within specific parameters. Access should only be granted on a need-to-know basis and in accordance with the authorization granted by the participant for usage of personal data.[246]

Access for research purposes may be controlled by an entity which does not conduct research and serves as a guardian and ensures that the information meets the appropriate level of confidentiality before releasing it for research. Such guardian may also be held accountable for the protection of the identity of participants. For instance, in Estonia, the Chief Processor controls access for research and prepares the data samples for the researchers.[247] In Estonia, the persons designated by the Chief processor of the Gene Bank are exclusively entrusted with coding and decoding the personal data[248] and have the technical ability to do so. Researchers and other users handle only de-identified data.[249] In Iceland, the tissue and medical information are encrypted by the Data Protection Commission Encryption Agency before being sent to deCODE. deCODE must always pass through the agency in order to reidentify samples or data. [250]

Access to the database for purposes other than research should be clearly restricted. For instance, use for criminal investigations or surveillance is prohibited by legislation in Estonia.[251] Access by insurers is restricted in the UK protocol.[252] However, access for the direct benefit of participants may be considered as an exception. For instance, access by a doctor is permitted in Estonia to treat participants.[253]

Special Cautionary Measures for Data Processing and Linkage Between Databases

Security and confidentiality of the information must be ensured in any handling or data linkage. In transferring data, only coded or anonymized information or material should be used. One must carefully link and organize the information in such a way that its specific character or linkage to different types of information does not render the data retraceable to a specific individual.

In Estonia, tissue samples or information may be issued only in coded form and for only five individuals at a time.[254] Moreover, the data can only be transmitted and linked to genealogical data within specific parameters prescribed by the law.[255]

In Iceland, deCODE will link genealogical information along with health information and tissue from volunteers. However, such linkage is under the supervision of the Data Protection Commission. Otherwise, deCODE can also couple research results with the HSDB. However, information is retrievable from the database only for groups of ten or more.[256] The Data Protection Commission may prohibit the processing of information in the database if the security is deemed inadequate.[257] Procedural rules for cross-referencing of data between databases (genetic and genealogy databases) must be submitted by deCODE for approval by the Commission. The Commission must be satisfied, amongst other things, that the results of cross-referencing are not personally identifiable.[258]

Other measures to ensure confidentiality

It might be wise to require that every person who can access the material or information sign a confidentiality agreement unless they are already bound by confidentiality via legislation.[259] In Iceland, the staff of a biobank must keep information confidential and this obligation of confidentiality remains in force even after an employee ceases employment.[260] Furthermore, deCODE's Code of Ethics sets strict rules of confidentiality for its employees and employees must sign a confidentiality agreement.[261] The ethical framework proposed for CARTaGENE also suggests that researchers and any persons who will be granted access to data and results should sign a confidentiality agreement.[262]

ii) Surveillance/Accountability

An independent authority may also be called upon to supervise the protection of privacy in all aspects of the management and exploitation of the database. Often times, the privacy commissioner will play a key role in data protection supervision to ensure compliance with the general rules on privacy in force in the country. It is also possible to create a separate private entity for the same purpose. Ethics committees can also play a role in that respect, but we will discuss their role in another section. In Estonia, the Data Protection Supervision Authority supervises the collection, coding, decoding and processing of data or tissue samples.[263] In Iceland, the Data Protection Authority monitors the security of personal data in biobanks.[264] Also, the legislation requires the party responsible for a biobank to implement an internal monitoring system to carry out security assessment.[265] In the UK, the Data Protection Commissioner ensures compliance with the Data Protection Act 1998.

iii) Sanctions and Remedies

Estonia amended its legislation to make disclosure of confidential data a criminal offence punishable by fine or imprisonment.[266] In Iceland, if deCODE violates the terms of the licence, penalties entail revocation of the licence as well as the possibility of fines and imprisonment.[267]

In Estonia, a unique remedy is proposed if the identity of participants is unlawfully disclosed. Generally, participants can only ask for the destruction of the codes linking their identity to the samples and other data in the bank. However, if the information is unlawfully disclosed, a participant may ask for the complete destruction of their information and tissue samples.[268]

Canada

Protection of privacy is a fundamental value in Canada. It is protected under the Canadian Charter of Rights and Freedoms.[269] As a general background, Canada has a mosaic of privacy legislation. The Canadian legislative framework is currently in a state of flux with some jurisdictions reviewing or adopting new legislation designed to afford better protection for the information of individuals.[270] Protection of personal health information is generally seen as a matter of provincial jurisdiction.[271] However, exchange of data for commercial or inter-provincial purposes may be subject to the new federal legislation. It is,

therefore, not always easy to identify the regulatory scheme ~~which should be~~ applicable for a given database. For instance, is access to a research database by third parties for purposes such as criminal procedures, insurance, surveillance or other governmental purposes restricted? We ought to be very clear about the extent of current protection for personal information as uncertainty may discourage participation in research.

Events on the Canadian federal scene have shown that Canadians are very sensitive about the establishment of huge databases.[272] Any such endeavour must be transparent and be coupled with important safeguards.

g) Communication of Research Results

In exchange for participation, participants can legitimately expect that the general research results be communicated.[273] In fact, the broad dissemination of results maximizes the benefits from research. However, caution must be exercised in communicating such critical information. A research project may also yield personal results. They can be communicated to participants, provided we can retrace them in the bank, such is the case in Estonia.[274] In most population research projects we surveyed, participants will not receive any personal results. Such is the case for the HapMap project, deCODE genetics and the UK research project.[275] In this next section, we will focus mainly on the management of the former, since the management of personal results in the context of population research does not differ from any other genetic research project.

One can reasonably expect that a population involved in a large-scale undertaking should be informed regularly of the general results of the research.[276] Regular feedback regarding such results fulfills at least two objectives. The first one is the diligent translation of the information obtained from research into the public and scientific domain for the better management of health, thus maximizing the benefits resulting therefrom. The public interest and ethical principles ~~recommend~~(require/demand?) that all results from the research be communicated, even if they are negative.[277] The second is to provide feedback to the population about how their contribution is used and what can be achieved from their participation, thus strengthening a true partnership.

We assume that all the population research projects we studied are committed to providing general results to the population.[278] For example, the protocol for the UK Biobank provides that information about the progress of the research will be available to all participants. The protocol even suggests ways by which general results will be disseminated, including peer-review journals and newsletters (to reach participants).[279] We can also mention deCODE's website which gives updates on the genetic research by providing a table of their research findings.[280]

In the context of population research, researchers might be encouraged to communicate general statistical data and research results to governmental authorities when they relate to public health.[281] This would likely enable a proper follow-up by the health care system as well as a better management of public health.

Research results may be used to serve population health. However, it is also feared that research results may be used to the detriment of the population or individual, for instance by discriminating against members of a group (on the basis of their personal results or by

their association with the studied population) or the group itself on the basis of common genetic characteristics.[282] Genetic information about individuals may pose collective risks for all who share a social identity.[283] One may anticipate that genetic information resulting from research could also be of interest in matters of employment, health insurance and immigration.

> "Some genetic variants will be identified that promote wellness and protect against disease, while other variants will be identified that increase the risk for particular diseases. When researchers will use the HapMap and find that a disease is associated with a genetic variant that is common in a particular population, some people may mistakenly generalize that all individuals in that population have increased risk for the disease or that the population as a whole is somehow genetically inferior."[284] Such risks could occur in any population research.

A well-known example of group discrimination concerns the community of Ashkenazi Jews and their predisposition to breast, ovarian and colon cancer. Although the discovery of these mutations will have an important impact on cancer prevention and treatment, this group nonetheless experiences fear of discrimination.[285]

Populations involved in research initiatives have expressed concerns. For instance, in Iceland, it is feared that, since the government of Iceland has free access to the health database, it could used to stratify individuals according to risk. Fusion of genetic data with the Health Sector Database can enable extrapolation to the genetic results on the whole population. It is also feared that the use of such information by the private sector could be detrimental to its citizens. At present, Iceland has no law preventing ~~genetic~~ discrimination on the basis of genetic make-up.[286] Another cause of concern is the HapMap project where genetic information could be stratified according to the ethnic or geographic groups the samples came from.[287]

Different approaches have been adopted to minimize the risks of ~~genetic discrimination~~. One ~~A~~ first approach is to limit access to personal research results for purposes other than research. Hence, insurers, employers and certain governmental authorities should generally not have access to individual data. Privacy rules will usually prevent such unauthorized access.[288] Also, specific dispositions or banking rules may help reinforce this position. For instance, Estonia clearly restricts use of the gene bank in the Human Gene Research Act.[289] It prevents employers and insurers from collecting genetic data.[290]

A second possible approach is to simply ban discrimination by legislative dispositions or guidelines. The UNESCO Declaration states that: "No one shall be subject to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity."[291] Estonia opted to include specific dispositions within the Human Genes Research Act prohibiting discrimination.[292] The first clause prohibits discrimination in a general fashion. Two subsequent dispositions prohibit discrimination by employers or insurers on the basis of genetics. In fact, it prevents them from requiring individuals to provide a DNA sample. Estonia went as far as modifying the criminal code to couple this ban on discrimination with criminal sanctions: "Unlawful restriction of the rights of a person or conferral of

unlawful preferences on a person based on the genetic risks of the person is punishable by a fine, detention or up to one year imprisonment."[293]

A third approach stresses the importance of communicating results in such a way as to encourage a correct interpretation and understanding by everyone. Knoppers and Laberge state that: "Caution should be taken against involuntary consequences of public disclosure of results without complete explanations. The absence of explanatory comments and opportunity for questions and discussion can results in erroneous perceptions, leading to stigmatization or ostracism."[294]

Thus, the scientific community has a duty to take part in the discussion and to make sure that their results are correctly interpreted. There is also a duty to reflect upon the use of research results in society as whole. Aware of the potential consequences for the population of the diffusion of their research results on hereditary disease, *L'Institut Interuniversitaire de recherche sur les Populations (Quebec)* suggested guidelines to its researchers and collaborators on how to release results to the public. In making their results public, researchers should strive to present a complete account including all required nuances, avoid making affirmations susceptible of triggering frustration or anxiety within the population, and negotiate a reasonable compromise between the duty of informing the population with the duty of respecting the reputation of the population in question.[295] Caution in the communication of results and education of the population are the main strategies proposed by the HapMap project to minimize the risk of population discrimination.[296] HapMap will set up Community Advisory Groups which will play an active role in the proper interpretation of research results.[297] The deCODE code of ethics states that: "deCODE employees are conscious not to promote unwarranted hopes among patients, by publishing unconfirmed research results. DeCODE is, along with its collaborators, responsible for providing information and education about genetics to all participants in genetic research ."[298]

It is not sufficient that the communication be scientifically accurate; results must also be expressed in a manner that the populations, families and individuals can easily understand. Mailing a reprint of a scientific article does not constitute effective communication, even where the population's first language is English.[299] It has been noticed in the field of research on Indian tribes that some tribal leaders complain that their people never receive significant and accessible information related to the research. Some tribes are now asking for return visits to discuss results or for translations of articles resulting from the research.[300]

Some communities ask for prior review and approval of all publications.[301] An interesting question has appeared while discussing the issue of disclosure of information: what if the community wants to suppress adverse or undesirable research findings? There might be conflict between the need for a community to protect itself and the obligation to publish results for the common good, whether they are positive or negative. It has been suggested that researchers and the Kahnawake community negotiate a mechanism by which consensus between the researcher and the community on data interpretation can be sought.[302]

Canada

Communication of results is intimately linked to the maximization of benefits and the minimization of risks of a research project.

In order to optimize the benefits derived from genetic research, one might encourage a partnership with public health authorities, particularly in the context of a universal health care system. The research community will need to be strongly involved in the adequate dissemination of research results and their proper interpretation. We also need to assess the level of preparedness of the primary health care providers and health infrastructure to efficiently capitalize on these results and to guide Canadians in their correct interpretation.

The use of research results arouses concerns, due to the fear of discrimination. The Canadian Charter of Human Rights can be interpreted as seeking the prevention of genetic discrimination.[303] In Ontario, the *Ontario Human Right Code* could also be interpreted the same way based on its juridically broad definition of "handicap."[304] In Quebec, the *Charter of Rights and Freedoms* prohibits discrimination based on the "perception of discrimination" and this could include genetic characteristics.[305] However, section 20.1 legitimates discrimination by insurers based on health characteristics. Therefore, there is some uncertainty about the use of genetic information and possible discrimination.

The three approaches mentioned above must be considered in order to ensure an environment in which Canadians will feel confident to participate in population genetic research and where the risks will be truly minimized.

h) Contribution to the Welfare of the Population

In any research project, a benefit (proportional to or even greater than the risks) should reasonably be expected.[306] Such a balance is reviewed by REBs to evaluate if human participants should be subject to the proposedresearch. In population genetics research, since the whole population runs a risk, there should also be a population benefit.[307] This is a question of beneficence that influences public support for genetic research and trust. Genetic research using large biological sample collections is potentially highly controversial. It is therefore important that the social benefits of research outweigh the risks to society and that the research objectives are socially and ethically acceptable."[308]

What is a "benefit" in the context of a population? Certainly, health and financial outcomes can be beneficial. But should we consider other elements such as the prestige, the development of expertise or even the strategic or commercial interests of the country?[309] We have already dealt with financial benefits in the section on commercialization. In this section, we will identify other kinds of benefits that have been put forward for the population with respect to the current research initiatives.

First, the objective of a population genetics research project should, at the very least, aim to increase knowledge of health and prevent disease,[310] especially for the participant population. This is what differentiates "exploitation" of a population for research purposes from "working with" a population. Such objectives are usually clearly stated, as it also serves as a safeguard for any future use of a biobank or related database. For example, in

Estonia, one of the objectives of the Chief Processor is to use the results of the genetic research to improve public health.[311] The mission statement of the Estonian Genome Project clearly focuses on improving health.[312] In Iceland, the code of ethics of deCODE states that: "The mission of deCODE Genetics is the following: -To conduct research in the area of human genetics in order to increase understanding of the origins of the disease. –To use the knowledge obtained in this research to improve the diagnoses and treatment of diseases."[313] The UK biobank protocol extensively explains the anticipated health benefits.[314]

Access by health authorities to the data and the results is also a way to maximize the benefit for the population. For instance, in Estonia, the law provides that gene researchers which are state agencies of the Republic of Estonia shall be granted the right to use descriptions of DNA or parts thereof without charge.[315] In the UK research protocol, researchers undertake to inform the Department of Health and the appropriate regulatory bodies at the "earliest possible stage" of any relevant findings.[316] Also, the development of a research tool, such as the haplotype map, which will be in the public domain, can also be seen as a benefit for the population.[317]

Contribution to the welfare of the population can also take other forms. In Quebec, RMGA's Statement of Principles requires that aliquots of the genetic material collected be kept in their jurisdiction of origin. This enables the population to exploit its own genetic material.[318] Some countries go as far as requiring that the biobank be kept entirely within the country, thus maintaining full control over the usage of those samples. In Iceland, all biobanks need a licence from the state; an important condition for obtaining such a licence is that the biobank be located in Iceland.[319] In Estonia, DNA samples must be stored in the Republic except with the express authorization of the government, provided that the tissue samples not be used in a manner prohibited by Estonian legislation and that the Chief Processor has effective control over the samples.[320]

The fact that the material is to~~shall remain~~ in the location of its origin encourages partnership with local research teams or the development of a new scientific infrastructure and expertise. This enables expertise and information resulting from the research to stay within the population and to flourish within the community.[321] In Iceland, many elements of the project have been identified which benefit Icelanders directly, including repatriation of a large number of scientists, financial support for research done in Iceland, opportunities for Icelandic scientists to do cutting-edge genetic research and creation of new industrial ventures within the country that will create many jobs for highly educated people.[322]

Relying on or contributing to local expertise avoids the possibility of a situation such as the one that occurred in Newfoundland and Labrador.[323] Local researchers were not involved in a research project on a rare cardiac disease that was conducted by Texas doctors originally from Newfoundland. Since local researchers were not involved in the research from the beginning, they could give the participants neither the results of the research nor proper follow-up. In fact, this amounted to a total loss of control over their genetic heritage.[324] Today, new research initiatives have adopted a very different approach in Newfoundland and Labrador.

Finally, one of the biggest challenges is to clearly state in the project itself and communicate to the potential participants the anticipated benefits. Population research projects may create great expectations in the population, but the benefits may only accrue

in the longterm. The research community needs to articulate, in a simple, clear and coherent manner, its research needs and identify the expected benefits of these biobank projects. Public education about genetics is essential and is another potential benefit, as it will empower the population.

Research should not be conducted on a population unless the benefit to the population is likely to outweigh the risk.[325] In addition to possible discrimination related to the research results (which ha already been discussed in a previous section), other risks ~~are mentioned~~ rang~~e~~ing from breach~~es~~ of confidentiality, creation of ~~a~~ centralized databases which contain~~s~~ very sensitive DNA or other health information,[326] the appropriateness of spending large sums of money on such projects before improving the health care system,[327] concern for future use, etc. Many concerns voiced by observers or the population itself were identified in the literature.

It goes without saying that the biobank should not be used to the detriment of the population or to serve an immoral purpose. The use of a biobank for cloning or genetic engineering was one of the concerns voiced by the population during the UK consultations.[328] Research should be used for peaceful purposes and measures should be undertaken to preclude the use of results for bioterrorism.[329] Less dramatic uses can also arouse concerns. For example, in Estonia, ~~it is stated that~~ the Gene Bank may only be used for scientific research. Use for other purposes, especially to collect evidence on civil or criminal proceedings or for surveillance, is prohibited by legislation in Estonia[330] and in UK by the protocol.[331] In Tonga, Autogen was committed to "using any samples and information collected in these projects for the sole purpose of improving the diagnosis, prevention and treatment of human disease."[332] A thorough reflection must be initiated to consider all the pros and cons of such an endeavour and to ensure that the risks are minimized and benefits optimized.

Canada

The massive investment of research resources and expertise, such as that required to establish a population research biobank, as well as the commitment to a collaborative effort by the population, should clearly benefit Canadians. Canadians are used to sharing the risks and benefits in the field of health care through the universal health care system. Reflection is necessary to ensure that Canadians get all the benefits they are entitled to from the use of their common genetic background. Among other things, access by health authorities to general statistics about the health of the population for public health purposes should certainly be encouraged.

One of the challenges for the scientific community is to clearly enunciate, from the outset of such a project, the anticipated benefits and risks for Canadians, in lay and simple terms and to disseminate this information efficiently and appropriately. The context in which one must convince the Canadian population is not easy: financial resources are scarce and the eventual benefits of genetic research are in the long run. In this context, there certainly is a need for educating Canadians about genetic research and potential outcomes.

Another challenge is to make sure that an acceptable balance of risks/benefits will remain for the duration of the project, taking into account future scientific development and evolution of society as a whole. To this end, periodic reassessment of the entire project

must occur. A population genetics research project should be well managed and governed to make sure that the anticipated benefits for the population will materialize and be maximized. It is all the more important since the tangible benefits may only accrue over the longterm. Public accountability to the population about the benefits and risks might thus be required.

The necessity to keep, at least, a small aliquot of the material in Canada and to support local scientific expertise is vital. Canada has already been the victim of questionable research practices in the past. We should make sure that this does not occur again.

Finally, the awaited federal legislation on reproductive technology will prohibit certain activities and thus send a clear signal about what is considered immoral and unethical for Canadians. Perhaps we need to consider the application of legal boundaries for the immoral use of biobanks.

i) Contribution to the Welfare of Humanity

The scientific community claims that population genetic projects will uncover the genes related to some of the common diseases that plague not only this particular population but also the populations of other countries. The Human Genome Organization recommends that all humanity share in, and have access to, the benefits of genetic research.[333] Universality of the human genome, the principle of beneficence and the principle of justice mandate sharing of knowledge at an international level. Besides the dissemination of research results, the distribution of knowledge can be achieved through different means. Part of the mission of the bank could be to sign up international partners. The population biobanks could also be seen as an international tool for the research.

Canada

Canada has a long tradition of international cooperation. In the area of biotechnology, Canada has an internationally renowned expertise that could be shared with other countries. We could exchange knowledge in genetic research at all levels whether scientific, ethical, legal, and social (e.g., information pertaining to the establishment and management of the bank). We should strive to make certain that scientific discoveries are channeled towards the development of improved methods to diagnose, prevent, and cure disease throughout the world.

Conclusion

Canadians need to participate in the international reflection on population biobanks. The issue is not purely an academic one. Canadian citizens may soon have to deal with the reality of population biobanks. Certain Canadian populations have already attracted the attention of researchers who wish to explore this innovative research strategy. We have world-renowned expertise in genetic research. We also benefit from a universal health system (with centralized health data on the whole population) and have a communitarian approach to health. These elements are good reasons for doing population research in Canada.

Population genetic research embraces complex social, legal, and ethical issues. First and foremost, we ought to identify ~~the~~ health priorities for Canadians. We also ought to consider in what form such research could unfold with optimal benefits. For instance, what kind of involvement should the government have in such undertakings? What kind of partnership with the private sector would best serve the common good? What governance scheme could be established so as to ensure public accountability? Finally, as this report shows, issues related to human rights such as privacy need careful attention.

To ensure the success of population genetic research, we deem it necessary to review the current normative framework based on new scientific developments, social consensus and ~~taking into account~~ international developments relevant to genetic research. This is an absolutely essential element to maintain public confidence in research activities. The future of genetic research depends on a close partnership between researchers, populations, public authorities and industry.

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[229] Insuring the data is kept in lock facilities, with passwords, safeguard copies and firewalls against outside access. See e.g. MEDICAL RESEARCH COUNCIL, THE WELLCOME TRUST and THE DEPARTMENT OF HEALTH, Protocol for the UK BioBank: A study of genes, environment and health, 14 February 2002, http://www.ukbiobank.ac.uk/protocol.htm, s. 2.3.10.

[230] Act on Biobanks, No. 110/2000, (2000), http://www.stjr.is/interpro/htr/htr.nsf/pages/Act-biobanks, (date accessed: 16 April 2002), s. 8.

[231] Human Genes Research Act, RT I 2000, 104, 685, Dec. 29, 2000, entered into force January 8, 2001, <http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed : 23 April 2002), p.18 (3).

[232] MEDICAL RESEARCH COUNCIL, THE WELLCOME TRUST and THE DEPARTMENT OF HEALTH, Protocol for the UK BioBank: A study of genes, environment and health, 14 February 2002, http://www.ukbiobank.ac.uk/protocol.htm, p. 19-20.

[233] NATIONAL INSTITUTES OF HEALTH, Background on Ethical and Sampling Issues Raised by the International HapMap Project, (29 October 2002), <www.genome.gov/page.cfm?pageID=10005337> (Date accessed: December 2002).

[234] Claude LABERGE, "CARTaGENE? What is it?," (15 August 2001) 1:2 Newsletter – Map of Genetic Variation in the Quebec Population, pp. 1-2, p. 2.

[235] For instance if a lot of information is linked with the sample in such this could reveal the identity of the participants.

[236] Eg.: MEDICAL RESEARCH COUNCIL, THE WELLCOME TRUST and THE DEPARTMENT OF HEALTH, Protocol for the UK BioBank: A study of genes, environment and health, 14 February 2002, http://www.ukbiobank.ac.uk/protocol.htm, s. 5.2: "All data… will be stored in an anonymized linked format." In Iceland, the literature on the HSDB often use the word Anonymized, when in fact, the data are 'one-way coded' which means that health information can be added on the same file but cannot return to the individual.

[237] E.g. CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects, (2002), <http://www.cioms.ch/frame_guidelines_nov_2002.htm> (date accessed: January 2003), p. 77; MEDICAL RESEARCH COUNCIL OF CANADA, NATURAL SCIENCES AND ENGINEERING RESEARCH COUNCIL OF CANADA & SOCIAL SCIENCES AND HUMANITIES RESEARCH COUNCIL OF CANADA, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (Ottawa: Public Works and Government Services Canada, 1998) s. 10.1 a), National Council on Ethics in Human Research (NCEHR) <http://www.nserc.ca/programs/ethics/english/index.htm> (date accessed: 1 August , 2000), s. 8.2: "Family information in databanks shall be coded;"; RÉSEAU DE MÉDECINE GÉNÉTIQUE APPLIQUÉE DU FRSQ, Statement of Principles : Human Genomic Research, (2000), http://www.rmga.qc.ca/doc/principes_en_2000.html (date accessed : 10 February 2003), princ. III (1): "genetic material and information should be coded or anonymized;" Iceland Act on Biobanks, No. 110/2000, (2000), http://www.stjr.is/interpro/htr/htr.nsf/pages/Act-biobanks, (date accessed: 16 April 2002), s. 8 "Biological samples shall be kept securely and labeled, but stored without personal identification."

[238] U.K., H.L., Select Committee on Science and Technology, Human Genetic Databases: Challenges and Opportunities, Fourth Report, (2001), <http://www.publications.parliament.uk/pa/ld200001/ldselect/ldsctech/57/5701.htm> (date accessed: 24 January 2002), ss 7.63 and 7.64.

[239] MEDICAL RESEARCH COUNCIL, THE WELLCOME TRUST and THE DEPARTMENT OF HEALTH, Protocol for the UK BioBank: A study of genes, environment and health, 14 February 2002, http://www.ukbiobank.ac.uk/protocol.htm, s. 2.3.10.3.

[240] MEDICAL RESEARCH COUNCIL, THE WELLCOME TRUST and THE DEPARTMENT OF HEALTH, Protocol for the UK BioBank: A study of genes, environment and health, 14 February 2002, http://www.ukbiobank.ac.uk/protocol.htm, p. 23.

[241] Human Genes Research Act, RT I 2000, 104, 685, 29 Dec. 2000, entered into force 8 January 2001, <http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed : 23 April 2002), s. 23.

[242] Human Genes Research Act, RT I 2000, 104, 685, Dec. 29, 2000, entered into force 8 January 2001, <http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed : 23 April 2002), s. 24 (2).

[243] DECODE GENETICS, Code of ethics (DeCODE's inhouse website), s. 2.2.

[244] Act on Biobanks, No. 110/2000, (2000), http://www.stjr.is/interpro/htr/htr.nsf/pages/Act-biobanks, (date accessed: 16 April 2002), s. 8.

[245] Act on Health Sector Database, No. 139/1998", (1998-99), http://www.stjr.is/interpro/htr/htr.nsf/pages/gagngr-log-ensk, (date accessed: 3 May 2000), s. 10.

[246] DECODE GENETICS, Code of ethics (DeCODE's inhouse website), s. 2.2: 'Access to information on electronic form is limited and at each stage of the research only granted to those individual who need it.'

[247] Human Genes Research Act, RT I 2000, 104, 685, 29 Dec. 2000, entered into force 8 January 2001, <http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed : 23 April 2002), s. 14, 20(1) .

[248] Human Genes Research Act, RT I 2000, 104, 685, 29 Dec. 2000, entered into force 8 January 2001, <http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed : 23 April 2002), s. 3 (3) and 14. s. 22 (3), the Chief processor may appoint 'Specific persons' to perform the coding and decoding and have access to consent of gene donors.

[249] ESTONIAN GENOME FOUNDATION, Estonian Genome Project, <http://www.genomics.ee/genome/index.htm> (date accessed: 13 October 2000), p. 4.

[250] Conversation with Dr. Edward Farmer, DeCODE Genetics, February 2003.

[251] Human Genes Research Act, RT I 2000, 104, 685, Dec. 29, 2000, entered into force 8 January 2001, <http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed : 23 April 2002), s. 16(1).

[252] MEDICAL RESEARCH COUNCIL, THE WELLCOME TRUST and THE DEPARTMENT OF HEALTH, Protocol for the UK BioBank: A study of genes, environment and health, 14 February 2002, http://www.ukbiobank.ac.uk/protocol.htm, s. 5.2.
[253] Human Genes Research Act, RT I 2000, 104, 685, 29 Dec. 2000, entered into force 8 January 2001, <http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed: 23 April 2002), s. 16(2).
[254] ESTONIAN GENOME FOUNDATION, Gene Donor Consent Form, < http://www.geenivaramu.ee/index.php?lang=eng&sub=74 > (date accessed : 27 January 2003), ss 20 and 22 (4).
[255] Human Genes Research Act, RT I 2000, 104, 685, Dec. 29, 2000, entered into force 8 January 2001, <http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed : 23 April 2002), ss 16 (1) et 17.
[256] JR. GULCHER, K. STEFANSSON, "An Icelandic saga on a centralized healthcare database and democratic decision making," (1999) 17 Nature Biotechnology 620, 620.
[257] MINISTRY OF HEALTH AND SOCIAL SECURITY, Operating Licence for the Creation and Operation of a Health Sector Database, (January 2000), http://www.raduneyti.is/interpro/htr/htr.nsf/pages/operat-lic, (date accessed: 2 October 2000), ss 6.4; Regulation on a Health Sector Database, no. 32/2000, (2000), http://www.stjr.is/interpro/htr/htr.nsf/pages/Govreg32-2000, (date accessed: 16 April 2002), s. 30.
[258] MINISTRY OF HEALTH AND SOCIAL SECURITY, Operating Licence for the Creation and Operation of a Health Sector Database, (January 2000), http://www.raduneyti.is/interpro/htr/htr.nsf/pages/operat-lic, (date accessed: 2 October 2000), s. 6.6., 6.7 ; Regulation on a Health Sector Database, no. 32/2000, (2000), http://www.stjr.is/interpro/htr/htr.nsf/pages/Govreg32-2000, (date accessed: 16 April 2002), s. 32.
[259] WORLD MEDICAL ASSOCIATION, Declaration on Ethical Considerations Regarding Health Databases, WMA General Assembly, Washington, (2002), s. 23: "People who collect, use, disclose or access health information must be subject to an enforceable duty to keep the information secure." RESEAU DE MEDECINE GENETIQUE APPLIQUEE DU FRSQ, Statement of Principles: Human Genome Research, version 2000, Princ. III (1): "Every person having access to the participant's medical, family and research records is subject to professional confidentiality;" In Iceland: Act on Biobanks, No. 110/2000, (2000), http://www.stjr.is/interpro/htr/htr.nsf/pages/Act-biobanks, (date accessed: 16 April 2002), s. 8 "Biological samples shall be kept securely and labeled, but stored without personal identification."
[260] Act on Biobanks, No. 110/2000, (2000), http://www.stjr.is/interpro/htr/htr.nsf/pages/Act-biobanks, (date accessed: April 16, 2002), s. 11.
[261] DECODE GENETICS, Code of ethics, (DeCODE's inhouse website), s. 2.6.
[262] CARDINAL, G., DESCHENES, M., OBADIA, A., AND B.M. KNOPPERS, Le projet Cartagène, l'encadrement juridique et éthique, Document de discussion, Centre de recherche en droit public, Université de Montréal, 20 juin 2001, p. 34.
[263] Human Genes Research Act, RT I 2000, 104, 685, Dec. 29, 2000, entered into force January 8, 2001,<http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed : 23 April 2002), s. 23 (1) and 28.
[264] Act on Biobanks, No. 110/2000, (2000), http://www.stjr.is/interpro/htr/htr.nsf/pages/Act-biobanks, (date accessed: 16 April 2002), s. 12.
[265] Act on Biobanks, No. 110/2000, (2000), http://www.stjr.is/interpro/htr/htr.nsf/pages/Act-biobanks, (date accessed: 16 April 2002), s. 12.
[266] Human Genes Research Act, RT I 2000, 104, 685, Dec. 29, 2000, entered into force January 8, 2001, <http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed: 23 April 2002), s. 31(modifying s. 128 of C. Cr.).
[267] Act on Health Sector Database, No. 139/1998, (1998-99), http://www.stjr.is/interpro/htr/htr.nsf/pages/gagngr-log-ensk, (date accessed: 3 May 2000), s. 13 and 14.
[268] Human Genes Research Act, RT I 2000, 104, 685, 29 Dec., 2000, entered into force 8 January 2001, <http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed : 23 April 2002), s. 10.
[269] Canada Act 1982, Schedule B, 1982 (UK), c. 11, s. 7. Although it is not expressly mentioned, courts have found it was nevertheless protected by the Constitution. J. DOWNIE, T. CAULFIELD, C. FLOOD, Canadian Health Law and Policy (2002) Butterworths, p. 160.
[270] E.g. the awaited Ontario Privacy legislation or the Health Information Protection Act of Saskatchewan S.S. 1999, c. H-0021.
[271] The Constitution Act 1867, 30 & 31 Vict., R.-U., c.3, 30 & 31 Vict., R.-U., c.3, s. 91 et 92.
[272] In spring 2000, the Federal Privacy Commissioner Bruce Phillips reported that the Human Resource Department held a huge database on almost 30 million individuals containing a lot of personal information that "tantamount to citizen profile." This story sparked national concern. John E. Dougherty, Big Brother Snoops Canadian, (2000) worldnetdaily.com (http://www.worldnetdaily.com/news/article.asp?ARTICLE_ID=15362).
[273] THE WELLCOME TRUST and MEDICAL RESEARCH COUNCIL, Public Perceptions of the Collection of Human Biological Samples, London, 2000, <http://ftp.cc.ic.ac.uk/pub/depts/neuropat/HS/humtis4b.pdf> (date accessed: 27 March 2002), p. 8.
[274] Participants have a right to ask for their personal results and get genetic counseling. Human Genes Research Act, RT I 2000, 104, 685, Dec. 29, 2000, entered into force 8 January 2001, <http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed : 23 April 2002), s. 11(2) (3).
[275] HapMap project participants are totally anonymous. Therefore it is impossible to retrace them in the bank to communicate personal results. See HAPMAP PROJECT, Consent form, The Haplotype Map Project (HapMap) and Other Research on Genetic Variations, website of the National Human Genome Research Institute, p. 4. DeCODE project

participants will not receive any personal results. This information was confirmed by conversation with Dr. Edward Farmer from deCODE Genetic. United Kingdom participants can have access to result of their physical exam but will not receive their results from the blood samples. See MEDICAL RESEARCH COUNCIL, THE WELLCOME TRUST and THE DEPARTMENT OF HEALTH, Protocol for the UK BioBank: A study of genes, environment and health, 14 February 2002, http://www.ukbiobank.ac.uk/protocol.htm, p. 30.

[276] Bartha M. KNOPPERS, "Of populations, Genetics and Banks," (2001) 1:5 Genetics Law Monitor 3-6, 5.

[277] WORLD MEDICAL ASSOCIATION, Declaration of Helsinki, (2000) Edinburgh, s. 27.

[278] However, we could not find much evidence of it in the legislative documents.

[279] MEDICAL RESEARCH COUNCIL, THE WELLCOME TRUST and THE DEPARTMENT OF HEALTH, Protocol for the UK BioBank: A study of genes, environment and health, 14 February 2002, http://www.ukbiobank.ac.uk/protocol.htm, p. 32.

[280] DECODE GENETICS, Disease Projects, http://www.decode.com/main/view.jsp?branch=3621.

[281] RÉSEAU DE MÉDECINE GÉNÉTIQUE APPLIQUÉE DU FRSQ, Statement of Principles on the Ethical Conduct of Human Genetic Research Involving Populations, (2003) (to be published) <http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed : 27 February 2003), s. 8.

[282] Ruth CHADWICK, K. BERG, "Solidarity and Equity : new ethical farmeworks for genetic databases", (2001) 2 Nature 318-321, p. 319-320.

[283] M.W. FOSTER, R.R SHARP, W.L. FREEMAN, M. CHINO, D. BERNSTEN, T.H. CARTER, "The Role of Community Review in Evaluating the Risks of Human Genetic Variation Research", (1999) 64 Am. J. Hum. Genet. 1719-1727, p. 1719

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[285] C. WEIJER, E.J. EMANUEL, "Protecting Communities in Biomedical Research," (2000) 289 Science 1142-1144, p. 1142.

[286] Bogi ANDERSEN and Tomas ZOEGA, "The Icelandic Health Sector Database: DeCode and the "new" ethics for genetic research," (1999), http://www.mannverd.is/english/articles/tz_database.html, (date accessed: 16 April 2002), s. 2.1.4.

[287] This risk is mentioned in the consent form, HAPMAP PROJECT, Consent form, The Haplotype Map Project (HapMap) and Other Research on Genetic Variations, website of the National Human Genome Research Institute,. 2 This brought high discussion at the 3rd International conference on DNA sampling.

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[289] Human Genes Research Act, RT I 2000, 104, 685, 29 Dec., 2000, entered into force 8 January 2001, <http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed : 23 April 2002), s. 16.

[290] Human Genes Research Act, RT I 2000, 104, 685, 29 Dec. 2000, entered into force 8 January 2001, <http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed : 23 April 2002), s. 26-27.

[291] UNESCO, Universal Declaration on the Human Genome and Human Rights, (1997) <http://www.unesco.org/human_rights/hrbc.htm> (date accessed : 25 July 2002), s. 6

[292] Human Genes Research Act, RT I 2000, 104, 685, Dec. 29, 2000, entered into force 8 January 2001, <http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed : 23 April 2002), ss. 25-27.

[293] Human Genes Research Act, RT I 2000, 104, 685, Dec. 29, 2000, entered into force 8 January 2001, <http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed : 23 April 2002), s. 31 (Amending the Criminal Code, s. 134).

[294] Bartha M. KNOPPERS, CLAUDE M. LABERGE, "Ethical Guideposts for Allelic Variation Databases," (2000) 15 Human Mutation 30-35, 34.

[295] INSTITUT INTERUNIVERSITAIRE DE RECHERCHES SUR LES POPULATIONS, Ligne de conduite suggérée par l'IREP en matière de diffusion de résultats de recherche sur les maladies héréditaires, (1993).

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[299] Henri T. GREELY, "Informed Consent and Other Ethical Issues in Human Population Genetics," (2001) 35:785-800 Annual Review of Genetics, http://genet.annualreviews.org/cgi/content/full/35/1/785, p. 798

[300] H.T. GREELY, "Informed Consent and Other Ethical Issues in Human Population Genetics," (2001) 35:785-800 Annual Review of Genetics, http://genet.annualreviews.org/cgi/content/full/35/1/785.

[301] H.T. GREELY, "Informed Consent and Other Ethical Issues in Human Population Genetics," (2001) 35 Annu. Rev. Genet. 785-800 , p. 797; C. WEIJER, G. GOLDSAND, E.J. EMANUEL, "Protecting Communities in Research: Current Guidelines and Limits of Extrapolation," (1999) 23 Nature genetics 275, p. 278.

[302] C. WEIJER, E.J. EMANUEL, "Protecting Communities in Biomedical Research," (2000) 289 Science 1142-1144, p.1144. If consensus cannot be attained within a reasonable amount of time, the competing interpretation of the study will both be published.

[303] Jocelyn DOWNIE, Timothy CAULFIELD, Colleen FLOOD, Canadian Health Law and Policy, (2002) Butterworths, p. 438.

[304] Ontario Human Right Code R.S.O. 1990, c. H-19, s. 22. C.f. Ouimette v. Lilly Cups (1990), 12 C.H.R.R. D/19 (Ont. Bd. Of Inquiry) at D/33.
[305] Charter of Rights and Freedoms R.S.Q., c. C-12, ss. 10 and 16. Quebec (Commission des droits de la personne et des droits de la jeunessse) v. Boisbriand (City), (2000) 1 S.C.R. 665, at 700.
[306] WORLD MEDICAL ASSOCIATION, Declaration of Helsinki, WMA General Assembly, Edinburgh, (2000), s. 16; CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects, (2002), <http://www.cioms.ch/frame_guidelines_nov_2002.htm> (date accessed: January 2003), guidelines 8.
[307] WORLD MEDICAL ASSOCIATION, Declaration of Helsinki, WMA General Assembly, Edinburgh, (2000), s. 19.
[308] PAUL MARTIN, JANE KAYE, The Use of Biological Sample Collections and Personal Medical Information in Human Genetics Research, (1999) Background paper for Wellcome Trust Workshop.
[309] Ruth CHADWICK, "The Icelandic Database – Do Modern Times Need Modern Sagas?", (1999) 319 BMJ 441-444. See also, G. WILLIAMS, "Banques D'ADN : quelques questions éthiques", (2000) 206 Biofutur 104-106, 105.
[310] Ruth CHADWICK, K. BERG, "Solidarity and equity: new ethical frameworks for genetic databases," (2001) 2 Nature Review Genetics 318, 319.
[311] Human Genes Research Act, RT I 2000, 104, 685, Dec. 29, 2000, entered into force 8 January 2001, <http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed : 23 April 2002), s. 3 (2) 3). See also FRANK, L., "Storms Brews Over Gene Bank of Estonian Population," (1999) 286:5443 Science Magazine 1262-1263, < http://www.sciencemag.org/cgi/content/full/286/5443/1262 > (date accessed: 23 April 2002).
[312] ESTONIAN GENOME FOUNDATION, Estonian Genome Project. 1: "The underlying idea of the EGP is the establishment of databases including phenotype and genotype data of the Estonian population, with the objective carrying out genetic and health studies, in order to find the genes that cause and influence common diseases, and to prepare for the development directions of the new millennium medicine."
[313] DECODE GENETICS, Code of ethics (DeCODE's inhouse website).
[314] MEDICAL RESEARCH COUNCIL, THE WELLCOME TRUST and THE DEPARTMENT OF HEALTH, Protocol for the UK BioBank: A study of genes, environment and health, 14 February 2002, http://www.ukbiobank.ac.uk/protocol.htm, pp. 29, 32.
[315] Human Genes Research Act, RT I 2000, 104, 685, Dec. 29, 2000, entered into force January 8, 2001, <http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed : 23 April 2002), s. 19 (1).
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[317] HAPMAP PROJECT, Consent form, The Haplotype Map Project (HapMap) and Other Research on Genetic Variations, website of the National Human Genome Research Institute, p. 2.
[318] RÉSEAU DE MÉDECINE GÉNÉTIQUE APPLIQUÉE DU FRSQ, Statement of Principles : Human Genomic Research, (2000), http://www.rmga.qc.ca/doc/principes_en_2000.html (date accessed : 10 February 2003) principle V.
[319] Act on Biobanks, No. 110/2000, (2000), <http://www.stjr.is/interpro/htr/htr.nsf/pages/Act-biobanks>, (date accessed: 16 April 2002), s. 5 (2).
[320] Human Genes Research Act, RT I 2000, 104, 685, Dec. 29, 2000, entered into force 8 January 2001, <http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed : 23 April 2002), s. 18 (4).
[321] G. KEYEUX, "La génétique des populations et l'étude du polymorpnisme génétique humain", Rapport pour l'UNESCO _'.
[322] Conversation with Dr. Edward Farmer of deCODE Genetics, February 2003. See also, J.R. GULCHER, K. STEFANSSON, "The Icelandic Healthcare Database: A Tool to Create Knowledge, A Social Debate, and a Bioethical and Privacy Challenge," (1999) Medscape, Medscape http://www.medscape.com/medscape/MolecularMedicine/journal/1999/v01.n08/mmm6872.stef/mmm601.html, (date accessed: 26 April 2000).
[323] Transfer of research skills and expertise in the community is viewed as a potential way to protect community. See C. WEIJER, E.J. EMANUEL, "Protecting Communities in Biomedical Research," (2000) 289 Science 1142-1144, p.1142-1143.
[324] W. DAVIDSON, "Testing the Waters," (1999) Biotechnology Focus 13, 14.
[325] GEORGES ANNAS, "Rules for Research on Human Genetic Variation- Lessons from Iceland," (2000) 342 NEJM 1830, "Community consultation and benefits."
[326] T. ZOEGA, B. ANDERSEN, "The Icelandic Health Sector Database: DeCODE and the "new" ethics for genetic research", October 1999, <http://www.mannverd.is/english/articles/tz_database.html>, (date accessed: April 16, 2002), p.16, s. creation of a centralized database.
[327] Karin PALMQUIST, "Mapping Estonia", (15 May 2001) International Reports.Net - The Washington Times, International Reports.Net <http://www.internationalspecialreports.com/europe/01/estonia/education/index.htm> (date accessed : 15 April 2002).
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[329] RÉSEAU DE MÉDECINE GÉNÉTIQUE APPLIQUÉE DU FRSQ, Statement of Principles on the Ethical Conduct of Human Genetic Research Involving Populations, (2003) (to be published) <http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed : 27 February 2003), s. 8.

[330] Human Genes Research Act, RT I 2000, 104, 685, Dec. 29, 2000, entered into force January 8, 2001, <http://www.genomics.ee/index.php?lang=eng&show=20&sub=57> (date accessed : 23 April 2002), s. 16 (1).
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[333] Human Genome Organization, Statement on Benefit-Sharing, Vancouver, BC, 9 April 2000, http://www.gene.ucl.ac.uk/hugo/benefit.html (accessed: February 8, 2001), rec. 1.

Appendix 1
Challenges for Canadians

Consultation

In the context of population genetic research, prior public consultation is now becoming a necessary preliminary step even in the absence of legal requirements. It is in the best interest of Canadians that fair and quality public consultation takes place for any population genetic research initiative. Canadian funding agencies need to take this trend into account and provide sufficient financial means to allow public consultation.

Recruitment

The use of personal data in order to recruit participants is regulated by privacy legislation. If personal data is in the hands of a general practitioner, given the relationship of trust between the treating physician and his patient and the fact that the treating physician is bound by professional secrecy, the treating physician alone should approach his patients to propose participation in the research. Legitimate access to information held by a private or a public institution could be assured through mechanisms anticipated ~~foreseen~~ in legislation pertaining to personal data. For instance, research could be invoked as a reason for obtaining access without consent of participants in various jurisdictions.

Consent

International experiences strongly suggest that individual consent should be obtained to collect and store DNA samples and personal data in a population biobank. Consent forms should be adapted to reflect issues specific to population genetics, for example, the benefits and risks for the population as well as the question of benefit-sharing.

Since we have a democratic political structure, the points of view of Canadians need to be taken into account in the elaboration of a population biobank. Although population consent is difficult to implement, we believe that it is possible to inform and consult the population and to consider public opinion. We ought to ask Canadians if they want to be part of national biobank initiative with appropriate forums of discussion.

Governance

Oversight of the project and surveillance activities

In Canada, some important gaps with respect to research with human beings were highlighted in the report on governance prepared by McDonald.[333] The application of international and national principles that govern ethical research in a population genetics research project requires a fair bit of reflection. Designing a proper scheme that is transparent and accountable to the population and that will inspire trust by all stakeholders is a challenge. We foresee that accountability to a public organization or another independent body and the creation of an appropriate oversight body would be essential. Also, there is currently no organization where citizens can file a complaint regarding the conduct of a research project.[333] Although a specific research initiative may provide for the

designation of such an ombudsman, we might want to reflect on the need for such surveillance on a permanent and independent basis.

Despite tighter privacy legislation regarding the oversight of databases and the use of medical or private information, it should be noted that we do not currently have research biobank legislation and there is no public registry that would enable identification of such research initiatives. Perhaps we ought to consider the need for a coherent management and oversight structure to monitor these activities.

Ethical Approval and Ethical Monitoring

In Canada, approval by an REB is now mandatory in any pharmaceutical research.[333] However, genetic research could fall outside the scope of this legislation. The Tri-Council Policy Statement requires approval by an REB but private initiatives would not be covered. It is therefore uncertain, albeit strongly encouraged by international and national guidelines, whether a population genetics research project would be subject to REB review.

The Tri-Council Policy Statement addresses all of the above-mentioned concerns, but its application in a population research project context requires some adjustments. Firstly, it is not clear at what point in time the REB should be consulted. Clearly their approval is required before beginning recruitment of participants. However, perhaps an earlier collaboration would help to appropriately grasp ethical questions raised by such a project. Secondly, the question of multi-centred research is difficult to resolve. Even outside of the context of population research, REBs and the research community are struggling to organize proper review of large-scale projects. Finally, identifying the appropriate composition of a research ethics board to review a population biobank initiative requires careful reflection. What kind of expertise is required to insure proper evaluation of research projects? Who may serve as a community representative or lay participant on an REB reviewing a population research project?

Finally, long-term monitoring of population biobanks by REBs must be implemented and well organized. In general, observers have reported that REB's monitoring activities are deficient. As a population biobank is a long-term enterprise, the need for monitoring is essential.

Commercialization

Technological innovations have intensified the commodification of nature, particularly of the human body. There is no question about the development of population biobanks around the world. The pressing question is rather: how should this resource be exploited? The creation of population biobanks in Canada requires a collective reflection on the commercial aspects of such a resource. How should commercialization be managed in order to keep it aligned with population interests? Who will look after the interests of Canadians in any commercial agreements? Should a population biobank remain the property of public entities? How can the principle of benefit-sharing be fully implemented in a Canadian context? Finally, commercialization may give rise to conflict of interest problems. If need be, a proper scheme to manage such a situation should be proposed.

Privacy

Protection of privacy is a fundamental value in Canada. It is protected under the Canadian Charter of Rights and Freedoms. As a general background, Canada has a mosaic of privacy legislation. The Canadian legislative framework is currently in a state of flux with some jurisdictions reviewing or adopting new legislation designed to afford better protection for the information of individuals. Protection of personal health information is generally seen as a matter of provincial jurisdiction. However, exchange of data for commercial or inter-provincial purposes may be subject to the new federal legislation. It is therefore, not always easy to identify the regulatory scheme applicable for a given database. For instance, is access to a research database by third parties for purposes such as criminal procedures, insurance, surveillance or other governmental purposes restricted? We ought to be very clear about the extent of current protection for personal information as uncertainty may discourage participation in research.

Events on the Canadian federal scene have shown that Canadians are very sensitive about the establishment of huge databases. Any such endeavour must be transparent and be coupled with important safeguards.

Communication of Research Results

Communication of results is intimately linked to the maximization of benefits and the minimization of risks of a research project.

In order to optimize the benefits derived from genetic research, one might encourage a partnership with public health authorities, particularly in the context of a universal health care system. The research community will need to be strongly involved in the adequate dissemination of research results and their proper interpretation. We also need to assess the level of preparedness of the primary health care providers and health infrastructure to efficiently capitalize on these results and to guide Canadians in their correct interpretation.

The use of research results arouses concerns, due to the fear of discrimination. The Canadian Charter of Human Rights can be interpreted as seeking the prevention of genetic discrimination. In Ontario, the *Ontario Human Right Code* could also be interpreted the same way based on its juridically broad definition of 'handicap'. In Quebec, the *Charter of Rights and Freedoms* prohibits discrimination based on the 'perception of discrimination' and this could include genetic characteristics. However, section 20.1 legitimates discrimination by insurers based on health characteristics. Therefore, there is some uncertainty about the use of genetic information and possible discrimination.

The three approaches mentioned above must be considered in order to ensure an environment in which Canadians will feel confident to participate in population genetic research and where the risks will be truly minimized.

Contribution to the welfare of the population

The massive investment of research resources and expertise, such as that required to establish a population research biobank, as well as the commitment to a collaborative effort

by the population, ~~Canadians~~ should clearly benefit Canadians. Canadians are used to sharing the risks and benefits in the field of health care through the universal health care system. Reflection is necessary to ensure that Canadians get all the benefits they are entitled to from the use of their common genetic background. Among other things, access by health authorities to general statistics about the health of the population for public health purposes should certainly be encouraged.

One of the challenges for the scientific community is to clearly enunciate, from the outset of such a project, the anticipated benefits and risks for Canadians, in lay and simple terms and to disseminate this information efficiently and appropriately. The context in which one must convince the Canadian population is not easy: financial resources are scarce and the eventual benefits of genetic research are in the long run. In this context, there certainly is a need for educating Canadians about genetic research and potential outcomes.

Another challenge is to make sure that an acceptable balance of risks/benefits will remain for the duration of the project, taking into account future scientific development and evolution of society as a whole. To this end, periodic reassessment of the entire project must occur. A population genetics research project should be well managed and governed to make sure that the anticipated benefits for the population will materialize and be maximized. It is all the more important since the tangible benefits may only accrue over the longterm. Public accountability to the population about the benefits and risks might thus be required.

The necessity to keep, at least, a small aliquot of the material in Canada and to support local scientific expertise is vital. Canada has already been the victim of questionable research practices in the past. We should make sure that this does not occur again.

Finally, the awaited federal legislation on reproductive technology will prohibit certain activities and thus send a clear signal about what is considered immoral and unethical for Canadians. Perhaps we need to consider the application of legal boundaries for the immoral use of biobanks.

Contribution to the Welfare of Humanity

Canada has a long tradition of international cooperation. In the area of biotechnology, Canada has an internationally renowned expertise that could be shared with other countries. We could exchange knowledge in genetic research at all levels whether scientific, ethical, legal, and social (e.g., information pertaining to the establishment and management of the bank). We should strive to make certain that scientific discoveries are channeled towards the development of improved methods to diagnose, prevent, and cure disease throughout the world.

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