DNA Banking: Current and Ideal Practices

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INTRODUCTION

A DNA bank stores human DNA so that it can be preserved for future analysis, for the purposes of research and diagnosis of human genetic disease.[1] It can contain extracted DNA, transformed cell lines, cryopreserved blood or other tissue, or biological samples preserved by some other method. A major goal of these banks is to facilitate the diagnosis of at-risk individuals among registered families. Potential beneficiaries include initial contributors, persons seeking counselling at a later date, and those entering the family through birth or marriage. Many academic and commercial labs have become increasingly involved in DNA banking. This phenomenon has not been extensively debated or publicized, when compared with other ethical issues in the field of genetics. Yet with the formal launch of the Human Genome Project (HGP) in 1990, human genetic material has gained new significance. As a result, the legal and ethical problems raised by DNA banking have begun to be addressed in the literature.[2]

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1 The study does not touch on the DNA forensic data banking issue.

2 See Ad Hoc Committee on DNA Technology, American Society of Human Genetics (ASHG), "DNA banking and DNA analysis: points to consider" (1988), *Am. J Hum. Genet.* 42; and G.J. Annas, "Privacy rules for DNA databanks. Protecting coded 'future diaries'" (1993), 19 *JAMA* 270; C.L. Earley and L.C. Strong, "Certificates of Confidentiality: A Valuable Tool for Protecting Genetic Data" (1995), *Am. J Hum. Genet.*, 57; B.M. Knoppers and C. Laberge, "DNA sampling and informed consent" (1989), *Can. Med. Assoc. J*, 140 and "Research and Stored Tissues: Persons as Sources, Samples as Persons?" (1995), 22 *JAMA* 274; J.E. McEwen and P.R. Reilly, "A survey of DNA diagnostic laboratories regarding DNA banking" (1995), 6 *Am. J Hum. Genet.* 56; and R.W. Yates, S. Malcolm, and A.P. Read, "Guidelines for DNA banking" (1989), *J Med. Genet.* 26.

In fact, comprehension of the molecular basis of genetic diseases has advanced considerably. The location of the genes for many common hereditary conditions is now known, and this knowledge is being applied to the screening of people at risk. In 1991, the Molecular Committee of the Canadian College of Medical Geneticists (CCMG) suggested that an accredited system of DNA banking and diagnostic testing be established in order to provide assistance in these areas.[3] A similar statement has been prepared by the ASHG.[4] However, little is understood about how DNA bankers actually conduct their storage activities.[5]

In 1995, the University of Calgary's Office of Medical Bioethics conducted three surveys to assess the current and ideal practices and policies with regard to the collection of and research with human genetic material in Canada. In this chapter, we will examine these issues based on a content analysis of respondents' comments. We will see that most DNA banks lack written internal policies, written depositor's agreements, or other relevant documentation regarding important aspects of this activity. National and internal guidelines already exist, but most of the respondents were not familiar with them. Those that did express preferences seemed to opt for general guidelines over a restrictive policy. We will also observe that commercial activities related to DNA banking seem to be rare in Canada, at least for individuals in the study sample. This would explain why they felt the whole issue pertaining to the misuse of genetic information wasn't relevant to them. At the same time, very few respondents thought that third parties, such as insurance companies, employers or family members, could misuse the genetic information contained in an individual's DNA sample. For the respondents, DNA banking was essential for families who wished to have DNA stored to ensure its preservation and availability as a source of information useful to themselves, their relatives, or their descendants. Often, members of a large family will be treated in several locations by diverse specialists and it is unreasonable to expect that the analysis be repeated in each centre. And yet, the misuse of genetic information is a widely recurring theme in the legal and ethical literature.[6]

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3 See J. Hall, J. Hamerton, D. Hoar, R. Korneluk, P. Ray, D. Rosenblatt, and S. Wood (CCMG), "Policy statement concerning DNA banking and molecular genetic diagnosis" (1991), 4 *Clin. and Inv. Med.* 14.

4 See Ad Hoc Committee on DNA Technology, supra note 2.

5 See McEwen and Reilly, supra note 2.

6 See P.R. Billings et al., "Discrimination as a consequence of genetic testing" (1992), *Am J Hum. Genet*, 50; E. Masood, "Whose right to genetic knowledge?" *Nature*, vol. 379, February 1, 1996; and M.A. Rothstein and B. M. Knoppers, "Legal Aspects of Genetics, Work, and Insurance in North America and Europe" (1996), *Eur. J of Health Law*.

METHODOLOGY

The voluntary comments of survey respondents constitute our basic pool of data. Survey questions differed according to each target group. Deans and senior administrators (hereafter "senior administrators") of Canadian research institutions were asked about policy guidelines concerning banking and the commercialization of research outcomes. They received a single-page questionnaire with six yes/no choices that included a request to submit copies of policy guidelines where applicable. Comments were not solicited. The 69 respondents nonetheless offered a total of 15 comments, although these were not always very elaborate.

Chairpersons of Research Ethics Boards (REBs) were asked about their research protocol review practices, informed consent requirements, as well as current and desired policies for DNA banks. They received a single-page questionnaire, with 16 possible yes/no answers and a request to submit a copy of consent forms where applicable. Comments were solicited about their actual policies, their perceptions about the need for Canadian policies and, in an open question at the end, "If you wish, please append any comments you and/or your REB consider relevant to this topic." This produced 42 comments from a total of 106 respondents. Finally, researchers, contributors, and bankers (hereafter "DNA workers") received a four-page questionnaire in a folder format subdivided so that all respondents answered eight background questions and 14 others requesting their opinions on banking policies. In addition, two different sets of questions targeted two subgroups, with DNA researchers and contributors on the one hand, and DNA bankers or collectors on the other, answering respectively 15 and 28 additional questions specifically tailored to each category. This questionnaire had a full-page insert that was exclusively designed for comments and offered the following topics to help direct respondents' thoughts:

- The recruitment of participants
- The informed consent process
- Ownership and control options
- Sample sharing
- Sample storage
- Nominal linkage
- Other

This approach yielded by far the greatest number and variety of comments, with 230 respondents offering a total of 266 comments.[7] Since each comment was identified with a respondent number, a recurrence analysis shows that in

7 This is the main reason we tallied these comments by issues (table 1), while not doing so for senior administrators or REB chairpersons.

fact only 86 individuals were responsible for the totality of comments.[8] Finally, we suggest a higher frequency of comments per issue may indicate a greater level of respondents' concern, ranging from a high of 65 comments on consent (40 on the informed consent process, 25 on consent forms) to a low of five dealing with commercial activities (see table 1).

The comments themselves vary between brief clarifications (for example, "depends on lab"), personal testimony (for example, "I have just realized how little I know about all this"), rhetorical questions (for example, "Should Canada elaborate a better policy regarding such recruiting manners?"), and detailed technical paragraphs. The total number of comments can be slightly misleading in that sometimes they are repetitive expressions of unfamiliarity with an issue or at least the terminology. Five out of 14 comments regarding nominal linkage, for instance, were outright admissions of ignorance (for example, "What does this mean?").[9] As could be expected, the comments don't all fit neatly into the six suggested categories.

One objective sought in soliciting comments was to maximize survey validity by ensuring that respondents could clarify or expand on their answers and were not forced into answer choices that did not reflect their views or practices. Beyond that, comments constitute a privileged way of getting inside people's heads, of gaining an appreciation of the subjects' own interpretations of the events and circumstances they experience. These interpretations might include respondents' explanations of how things came about, how they change, what the consequences are, whether they perceive them as good or bad, desirable or undesirable, and whether they fit in or are at odds with their larger world views.[10]

In this context, our immediate goal was to recognize the relevance of and extract meaning from the respondents' comments. The three categories of respondents represented different perspectives on DNA banking. Comments that clarified, were related to, or expanded on the information obtained in the questionnaires were extracted. They were classified as they referred to the issues raised in the questionnaires. Those that could not be so categorized were looked at separately and were omitted when deemed sufficiently irrelevant to overall research objectives. Five issues emerged with the most clarity:

- The establishment of DNA banks
- The informed consent process
- Ownership and storage

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8 For the purposes of this chapter, therefore, n=86, for an average of three comments per respondent.

9 One reason why we don't refer to this issue in our chapter.

10 See L.I. Pearlin, "Structure and Meaning in Medical Sociology" (1992), *J Health Soc. Behavior* 33.

Table 1 DNA Workers' Comments by Decreasing Frequency of Issues Addressed

Issues	Number of comments
Informed consent process	40
Collection of samples and recruitment of participants	39
Sample sharing	34
Storage conditions	26
Consent forms	25
Comments on survey and respondent eligibility	22
Ownership and control options	21
CCMG policy statement	15
Institutional policy	12
General comments regarding policy	12
Maintaining DNA banks	8
Third parties	7
Commercial activities	5
Total	266

- DNA sample sharing
- DNA banking policies

Numbers of comments provided by the different respondent groups per issue are noted to give an idea of relative frequency with which various issues are addressed. While a qualitative analysis, by definition, does not provide a statistically representative picture, it can provide an adequate representation of the variety of perspectives on a given subject. We are not in a position to put numbers on these perspectives—that is, to estimate how prevalent they are in the field. But this research procedure will allow us to outline the dimensions and the dynamics of the debates concerning DNA banking in the milieu. Apart from being valuable results in and of themselves, the insights they provide can point the way toward future research efforts.

RESULTS

The Establishment of Human DNA Banks

Five senior administrators dealt with the presence of research requiring human DNA banking at their institutions. One respondent remarked that it was "difficult to be aware of all research activities," while three others noted that their institution did not sequence human DNA. Among REB chairpersons, one mentioned that "the review of research protocols requiring DNA banking occurs only in the setting of specific malignancies or specific diseases in restricted, high-risk populations." Another indicated that "DNA banking has never been a prime object." Three REBs did *not* review protocols for research comprising a

DNA banking component, although one chairperson expressed mild surprise at this state of affairs, answering to "Do you currently review research protocols ..." with "not as yet, although we have a large genetics department." In another case the genetic analysis study reviewed had "no storage component."

DNA workers offered a total of 69 comments regarding DNA banking.[11] Eight did not actually collect DNA themselves, nine worked with non-human DNA, and 10 worked with human DNA derived from patients' tumours. Twenty-six respondents mentioned different forms of work with human DNA, variously specifying that they didn't deal with patients, that they worked only as collaborators, "only when an informed consent is possible," with "DNA fragments only" or, still, "non-nominative samples."

Some researchers did not consider DNA banking to be an important issue. These researchers did not feel the issue to be one over which, say, they felt they could lose control or one that "could easily get away from them unless given careful forethought." One researcher reported that "given the enormous potential of molecular biology with respect to human health, it is not clear that DNA banking is the most relevant area to concentrate one's attention on." But no one conducting DNA research considered that DNA banks should *not* be established. On the contrary, "DNA samples should be kept as long as space permits it." It would seem that the term "bank" is somewhat confusing, however. Many saw themselves as having a collection rather than a bank—whence, the conclusion that their DNA banking activities didn't require the approval of their REBs.

Commentary

The confusion over the meaning of DNA banking can be better appreciated by going through a short list of different approaches to banking. In fact, DNA banking can be systematic, as for specific diseases (for example, Huntington disease), serendipitous, as for rare, interesting cases arising from clinical experiments (for example, mitochondrial diseases), random, as for genetic diversity surveys or mapping (for example, CEPH), interested, as for special needs (for example, congenital myotonic dystrophy), coordinated, as for reference (for example, brain banks for Alzheimer research), or specific, as for surveillance needs (for example, HIV types).[12] The conditions of such collection are also diverse with regard to consent, to choice (for example, present and future), to terms of deposit and withdrawal, to duration of storage, to anonymous versus nominative use, to followup obligations, to the renunciation of potential commercial value,

11 By way of example, this is how the total breaks down: sample collection and participant recruitment (39); the survey itself and respondent eligibility (22); and maintenance of DNA banks (8).

12 See B.M. Knoppers, project director, *Genetic Testing*, Ontario Law Reform Commission (forthcoming).

to the availability of the listing, and to collaboration. Hence, the question "To whom does it belong?" can be raised at various stages. More important, what do the choices offered mean in terms of respect for the donors, the scientific freedom of researchers, and the legal and ethical obligations of REBs?

The Informed Consent Process

Among REB chairpersons who expressed opinions on the informed consent process (10), all required consent forms, but these were not standardized: forms were "study specific," or "project specific" or, still, "produced by the investigator," while another noted "no separate form for just [DNA banks]." This REB insistence on investigator responsibility for consent was somewhat at odds with some DNA researchers' positions, a number of whom thought that in fact it was their REBs that took care of all the ethical and legal issues raised by their consent forms. For another, the survey itself was a learning experience:

> I have just realized how little I know about all this. Since I get my samples from clinicians, I assume everything is covered in their consent form (naiveté on my part!)

When projects require a DNA bank, what do DNA geneticists and researchers inform the sample-donors about? Examining the comments regarding the consent process, we noted that out of 65 comments:

- 8 respondents affirmed *not* asking consent at all.
- 10 researchers insisted on the *essential* character of informed consent.
- 3 mentioned that the consent was obtained by clinicians, one by the principal investigator, and another one by a collaborator.
- 6 used a consent form specifying ownership or control options for banked samples.
- 5 specified the storage conditions.
- 8 indicated that they asked consent to share samples.
- 3 allowed withdrawal of samples.
- 1 disclosed the linkage of clinical data.
- 1 specified a statement about the discovery of non-paternity.

In other respects, nine DNA workers shared the following general position expressed by one of them: "consent for DNA banking should not necessarily be requested for retrospective access to residual tissues routinely collected with consent during medical care, as for anonymous studies, or for clinical diagnostic purposes, since, by analogy, patients do not consent for medical laboratory tests." Some attitudes seemed slightly at variance.

Compare:

> Participants must be fully informed of the purposes and objectives of the studies and the DNA should be used only for the purposes granted.

with

DNA samples are stored at the request of researchers rather than for an immediate benefit to donors.

Respondents suggested that at the least, informed consent was to be obtained in accordance with the Medical Research Council of Canada (MRCC) guidelines, although, as one put it, the latter "may not be reaching the actual users of DNA-based technology." Ideally, informed consent should:

- Specify ownership options: "these need to be much more extensive and stringent because it is not clear in current guidelines who decides what tests will be done with the DNA samples." It seems "this is too wide open, outside the control of DNA donors, and without attention given to the autonomy and privacy of these persons."
- Include "storage options for specified purposes, or else the remaining sample should be discarded, even if this may limit future options for patients or family members." Sample sharing should require the same consent.
- Include "the ability for participants to withdraw their sample at any time of the project."
- Guarantee "the protection of children, who are unlikely at present to have participated in any consent process."
- Include "statements about the discovery of non-paternity, about the anonymous use of banked DNA for research, about its use by family members for their clinical purposes, about the ban on divulging results of any testing to employers or insurance companies."

Commentary

The preceding comments enlighten us about the lack of uniformity in the informed consent process. Do researchers simply inform donors that their privacy will be maintained without further describing how this will be done, or what will be done with their DNA sample? While recognizing that limitation or waiver of consent may be appropriate in some circumstances or in emergency public health situations, these positions are a significant shift away from a broad public health rationale and from the traditional collection of basic scientific data.[13] Informed consent involves choices and possible control by the participants over time and even after death. There are ongoing obligations for researchers in this continuum, from the time of obtaining samples and testing through to identifying markers and genes with other researchers and industrial partners. In the absence of explicit guidelines or specific case law on genetic research and DNA banking in Canada, the protection of individuals (and their anonymity) remains uncertain.[14] Only Quebec's new Civil Code has characterized the use of any

13 See Knoppers and Laberge, supra note 2.

14 See Knoppers, supra note 12.

tissues, substances, and cells for research purposes under the law of persons (art. 22).

Ownership and Storage, or To Whom Do DNA Samples Belong?

Not much consensus existed on issues of sample ownership: out of 21 DNA workers, six indicated that DNA samples belonged strictly to the public domain, with no applicable property rights: "Donors make a donation and, as with other donations to say, charity, the donation belongs to the research worker, provided it is used for the purpose originally described to the donor." For eight others, DNA remained the donor's property. As one noted, "any individual should be informed as to the purposes of the DNA banking and should be able to withdraw their sample or know that the whole sample will be destroyed as, for instance, cell lines, extracted DNA, and whole blood." One respondent considered that ownership should be shared between the institution involved in the original study and the donors, another that it should be limited to the institution, while five saw DNA samples as actually belonging to researchers.

Consensus on sample storage was just as elusive. Out of 26 DNA workers, three reported that their consent forms did not specify storage conditions. An equal number thought a uniform policy regarding this practice was desirable. Another three considered that storage should be done only for a specific study or, as one put it, only "when specific mutations or abnormalities are known." Furthermore, one respondent noted that "any individual should be able to withdraw their sample, and know that all of the sample will be destroyed." Finally, three admitted keeping the samples in their institution while six claimed to keep DNA samples as long as possible.

Presented with cases where DNA samples were said to generate revenues or profits, five DNA workers held similar positions, best expressed by one who insisted that "any income from personal DNA should go to the government and not to institutions or private practitioners." Moreover, if DNA samples were to be used for profit, the agreement with the donors had to be renegotiated: "an analogy would be to give money to a charity which, after the donation has been made, diverts some of the money by investing it for private profit." One respondent emphasized that "the science of genetics is more important than ownership, and the freer the distribution is, the better the science and progress are; credit assignment is important and necessary, not ownership!"

Commentary

In law, property is defined as a collection of rights, enforceable against third parties, over tangible or intangible things. These rights may include concepts such as the right to exclusive use, the right to destroy, and the right to exploit for profit.[15] We might underscore the fact that in Canada blood and blood

15 Ibid.

constituents are the only human tissues that are not prohibited from sale and purchase.[16] In Quebec, art. 25 of the Civil Code states that the alienation of any body part or tissue must be done free of charge.

However, property rights are not absolute: they may be restricted or modified in order to accommodate social policy and moral concerns. In *Moore v. Regents of the University of California*, the right to control one's DNA through the application of property principles was rejected by the State of California Supreme Court, which held that the doctrines of informed consent and fiduciary duty were sufficient to protect the patient's interests.[17] In another US case regarding the abandonment of human material, it was noted that an individual may have property rights to his or her waste material.[18] Is there anything inherently wrong or ethically reprehensible with viewing human genetic material as property? Does it ultimately offer better control and thus protection for all interested parties? Some authors consider the recognition of a right of property to the human body to be morally abhorrent.[19] It would lead to the commodification and commercialization of human material, which has unique characteristics and qualities that warrant special consideration and protection. There is a substantial capital investment associated with research involving human genetic material. So, is financial gain to play a decisive role in research with human genetic material, with the original patients and families to be considered as shareholders?[20]

DNA Sample Sharing

Under which circumstances and with whom should DNA samples be shared? In order of generally decreasing frequency of opinions expressed, the 34 responses can be summarized as follows:

1. DNA sharing requires only the donors' permission (4). Donors should be allowed options as "to whom the sample will be given and for what reason."

2. DNA workers considered that "DNA sharing should be mandatory if cooperative research requires it, as long as consent is obtained" (4).

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16 See Law Reform Commission of Canada, *Procurement and Transfer of Human Tissues and Organs*, Working Paper no. 66 (1992).

17 See *Moore v. Regents of University of California*, 252 Cal. Rptr. 816 (Sup. Ct. 1988).

18 See *Venner v. State of Maryland*, 354 A2d 483 (Maryland, 1976).

19 See R. Marusky and M. Swain, "A Question of Property Rights in the Human Body" (1989), *Ottawa LJ* 21; T. Murray, "Gifts of the Body and the Needs of Strangers" (1987), 17 *Hastings Centre Report* 30; and Royal Commission on Reproductive Technologies, *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies* (Ottawa, 1993).

20 See Royal Commission on New Reproductive Technologies, supra note 19.

3. Opinions were divided on whether "DNA sharing should include financial compensation that realistically covered all the costs of sample collection and processing " (4), or whether samples should be shared freely, "especially if taxpayer money was used to create the collection" (4).

4. DNA sharing should be anonymous (3).

5. Finally, respondents felt that either a bank or information about available DNA samples would be useful to them. "Sample sharing could be done through a central storage and catalogue system to free up time," or, still, "The 'World Wide Web' would probably be the best media to inform the scientific community of existing banks and how to obtain samples."

For eight respondents, "DNA sharing should be part of a mutual courtesy of investigators," while two considered sharing DNA "only with collaborators who are part of the project": "samples should be available to all reputable researchers; clinicians should not 'own' patient material, nor regulate access to them." Three respondents mentioned sharing DNA with clinicians. At the least, one thought, there should be a "uniform policy on disposal, storage, or continued use of DNA, once a diagnostic service has been performed."

DNA Banking Policies

Only three senior administrators mentioned that their institutions followed the Medical Research Council of Canada (MRCC) guidelines, the Canadian Council of Medical Geneticists (CCMG) guidelines,[21] or the NCBHR research ethics policy. Five affirmed having no commercial guidelines specifically for DNA/genetics.

Of 13 REB chairpersons commenting on DNA banking policies, eight indicated not having specific policies, arguing that they "routinely require recruitment by methods which would be acceptable in any research study" or that "our general policies address most of the issues relative to DNA banking." One chairperson said their REB followed "NCBHR or MRCC or CCMG guidelines." Another reported that "our guidelines are generally consistent with international practice. ... No need has been identified to distinguish Canada from other countries." However, five did mention that Canadian policies needed to be developed: "Assuring informed consent is the central issue and control, ownership aspects of these issues need clear guidelines." Moreover, guidelines were deemed to be more appropriate than policies: "policies should be left to the individual institutions involved. Canadian 'policies' would not be enforceable, [and] likely could not ever be monitored adequately." In the same way, "guidelines should be formulated openly, with broad input, and without involving persons with vested interests."

Among DNA workers mentioning involvement in DNA banking, 12 commented on institutional policies, seven to admit that they did not know if their

21 See Hall et al., supra note 3.

institutions had one; only one seemed to be familiar with it. Out of 15 DNA workers commenting on the CCMG policy statement on DNA banking, seven admitted their unfamiliarity with it:

> To be honest, although I read the document when it arrived, I don't recall the details since the issues are not directly relevant to my current practice. Obviously, nothing in it raised my concern.
>
> I am aware that there is a policy, but I am not intimately familiar with it.
>
> I was familiar four years ago. ... the CCMG policy statement should be more widely available.

Eight researchers made comments indicating that they were not satisfied with the CCMG statement:

> Areas of recruitment of participants, ownership and control options ... do not seem to be specifically addressed in the statement.
>
> CCMG guidelines are not really practical.
>
> CCMG guidelines may be not reaching the actual users of DNA-based technology.

Finally, seven out of 12 DNA workers expressed a need for guidelines on DNA banking:

> Some guidelines should probably be distributed to all clinicians.
>
> The whole issue of research vs. licensed testing should be dealt with. If someone has "deposited DNA" in a bank for polycystic kidney disease testing, what happens if a relative wants BRCA1 gene information?
>
> There is a need for tighter limits on how much testing a sample can undergo. Alternatively, it should be explicitly stated that there are no limits on testing. Either way, explicit statements need to be made.
>
> The rules for DNA should not be different from the rules for other biological specimens. The process must make research possible and relatively easy to accomplish while protecting real risks rather than "angels-on-the-heads-of-pins" risks.

Commentary

These comments raise questions about the multiple ethical and legal issues of DNA banking. The nature of information given to patients, confidentiality as it relates to human genetic research, and the issue of autonomy (the right of refusal of information or result at any step of the project) rarely seem to be brought up. The preceding results suggest that either institutional policies do not exist or that when they do, they are little known or rarely followed. Institutions and laboratories have little or no written documentation to govern important aspects of their DNA storage activities. Are researchers involved in DNA work in one way or another not aware of DNA banking policies? Or are there communication gaps between different levels of institutional decision makers?

DISCUSSION: WOULD GUIDELINES OR POLICIES BE DESIRABLE FOR DNA BANKING?

The lack of clear written protocols for banking in a number of institutions may heighten the potential for future misunderstandings with depositors or for unforeseen legal liability. As Knoppers and Laberge (1995) have written, all human materials, whenever, wherever, however, and for whatever purposes they may have been sampled or will be kept, are potentially of clinical or research interest.[22] Who consents, chooses, contacts, and controls are the issues surrounding the current and future uses of human genetic material. But many researchers have given little thought to the dangers of DNA banking as opposed to its advantages. Yet, the dangers of the misuse of DNA samples are real and likely to increase as more disease genes are isolated.[23] For example, ones thinks of molecular tests for specific gene mutations that may result in the detection of a genetic defect in a healthy relative who had neither expected this possibility nor given specific consent to such testing. Because consent was not given, problems suddenly appear or are aggravated. The implications of finding an unexpected abnormality in a healthy relative are too serious to make it wise to use samples except in a carefully controlled way. If such an abnormal result might be obtained, investigators should attempt to ensure the anonymity of sample donors to protect both the person at risk and themselves.[24] Furthermore, principles of autonomy and informed consent imply that no donor should be pressured into providing a DNA sample for banking. Donors should also retain some measure of control over what happens to their samples (for example, length of storage, storage failure contingencies, sample withdrawal or destruction, and commercial interests). Donors must be assured that strict procedures are in place to prevent any breakdown of confidentiality.

Relatively few respondents addressed issues of commercial activities related to DNA banking (5) and the use of genetic information by third parties (7), yet such practices can nevertheless lead to the misuse of DNA samples. A change in the type of research funding or in the regulatory framework governing genetic testing could modify the attitudes and practices of DNA bankers. Private companies standing to benefit from these changes would increase the pressure for the greater commercialization of genetic testing.

As the banks grow, issues of ownership, storage, and sharing may become more pressing. Furthermore, one may question whether human genetic material can even be owned since it is arguably part of the common heritage of

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22 See Knoppers and Laberge (1995), supra note 2.

23 See P.S. Harper, "Research samples from families with genetic diseases: a proposed code of conduct" (1993), *BMJ*, 306.

24 Ibid.

humankind and a birthright of human beings.[25] It has been suggested that to recognize a right of property over human genetic material might be contrary to the concept of human dignity.[26] Conversely, property considerations are appropriate in the recognition of scientific discovery and inventiveness. As one respondent put it, "One hopes that scientific considerations will prevail, while patient anonymity is preserved." If anonymity is guaranteed, DNA banking should not present any problems. With that in mind, shouldn't a policy regarding recruitment methods be formulated? To date, no country has adopted legislation on the collection of human genetic material, yet, according to certain authors, "samples, even more than the human sources, will take on a life, if not a legal personality, of their own."[27]

DNA banking is still a rare clinical activity, conducted mostly in relation to research, but it seems there is a reasonable enough expectation of its growth to justify setting up mechanisms to ensure that the practice develops in a manner that protects the individuals who use it. The recognition of the banks' existence and an understanding of the need for DNA banking by such diverse stakeholders as granting agencies, institutions, interest groups, and mappers are challenging the social perception of human genetic research. Might guidelines used by research groups involved in DNA banking carry over to clinicians and medical institutions, the primary and most important collectors of human genetic material? Is it necessary to define their collections as being in the public domain, or should all questions of ownership and control be limited to bona fide banks, thus leaving most collections unregulated? Once again, analysis of the respondents' comments reveals no consensus on the subject.

Although guidelines would be valuable, fears were expressed of practical impediments to research: such guidelines "must not make patients' recruitment more difficult than it is." Since DNA usage is quite varied, overall policies are difficult to devise—general codes of conduct seem more appropriate. It also appears that any policy would need to be formulated in the best interests of patients and their relatives, since the implications of DNA banking can be very different from one genetic disease to the next. In fact, the field of genetic diagnosis is expanding from the domain of classical single-gene conditions to encompass various forms of adult illnesses. The molecular diagnosis of diseases with extensive clinical variation and complex modes of inheritance will be correspondingly complex. The need for further guidelines and regulations on

25 See B.M. Knoppers, *Human Dignity and Genetic Heritage* (Law Reform Commission of Canada, 1991).

26 See UNESCO, *Revised Outline of a Declaration on the Protection of the Human Genome* (Paris: International Bioethics Committee, March 7, 1995).

27 See Knoppers and Laberge, supra note 2.

DNA banking practices remains. This is why it was suggested, as early as 1991, that certified DNA banks and diagnostic laboratories be established.[28]

What does the future hold? It is difficult to tell from the present state of scientific knowledge, lab techniques, and regulatory trends. There is no doubt that DNA banking is here to stay. Fortunately, it would appear that while the comments reveal varying degrees of awareness about the underlying issues, overall, Canadian scientists seem to have adopted a rather prudent approach (which seems to be an expression of their personal values). Leaning toward caution helps ensure that confidentiality and security are maintained at DNA banks. As general awareness levels slowly rise, policy makers have an opportunity to better respond to the oft-expressed need for guidance. Otherwise, if DNA banking eventually does become widespread, will the risk of misusing genetic information not rise as well? Eventually, do we risk seeing eugenics come to the fore, with its attendant, stigmatizing attitudes? In spite of its limitations, this study seems to indicate that for now there is little cause for concern. This does not preclude the need to remain alert to the evolution of DNA banking, all the while working to investigate and evaluate the phenomenon as rigorously as possible.

28 See S. Narod, D. Rosenblatt, and E. Lamothe, "The banking of DNA for the prevention of genetic disease" (1991), 4 *Clin. and Inv. Med.* 14.