

Biosamples, Genomics, and Human Rights: Context and Content of Iceland's Biobanks Act

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ABSTRACT

In recent years, human DNA sampling and collection has accelerated without the development of enforceable rules protecting the human rights of donors. The need for regulation of biobanking is especially acute in Iceland, whose parliament has granted a for-profit corporation, deCODE Genetics, an exclusive license to create a centralized database of health records for studies on human genetic variation. Until recently, how deCODE Genetics would get genetic material for its genotypic-phenotypic database remained unclear. However, in May 2000, the Icelandic Parliament passed the Icelandic Biobanks Act, the world's earliest attempt to construct binding rules for the use of biobanks in scientific research. Unfortunately, Iceland has

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lost an opportunity for bringing clear and ethically sound standards to the use of human biological samples in deCODE's database and in other projects: the Biobanks Act has extended a notion of "presumed consent" from the use of medical records to the use of patients' biological samples; worse, the act has made it possible—perhaps likely—that a donor's wish to withdrawal his/her sample will be ignored. Inadequacies in the Act's legislative process help account for these deficiencies in the protection of donor autonomy.

INTRODUCTION

Around the world, laws have been enacted on organ and tissue banks in connection with grafting and transplantation of organs between individuals. However, legislation on tissue banking for scientific research is in its infancy. The Icelandic Biobanks Act, passed in May 2000, is the world's earliest attempt to construct specific and binding rules for the use of biobanks in scientific research. Analysis of the Icelandic Biobanks Act is important because of the impending construction of deCODE Genetics' genotypic-phenotypic database and the increasing international interest in similar projects: from Estonia to Framingham, Massachusetts, genomics projects similar to deCODE's are being planned without the benefit of clear guidelines for biobanking.¹ First, the political and legislative context of the Biobanks Act will be presented, and then a preliminary assessment of the Act itself.

CONTEXT OF THE BIOBANKS ACT

Any discussion of Iceland's new rules on biobanking must begin with a brief history of the controversy surrounding deCODE Genetics and the Icelandic Act on a Health Sector Database. In December 1998, the Icelandic Parliament, the *Althingi*, passed a law called the Act on a Health Sector Database (HSD Act).² The law made it legal for the Minister of Health in Iceland to grant a license to a private company to construct an electronic database containing health records. The government granted the license to deCODE Genetics in January 2000, and the for-profit Delaware corporation plans to use the license to construct one piece of a centralized database linking medical records with genealogical and genetic information.³ Both the law and the license have generated strong criticism in Iceland and abroad.⁴ A good history of the Act's opposition can be found on the website of MANNVERND, the Association of Icelanders for Ethics in Science and Medicine.⁵

MANNVERND has announced its plans to challenge the HSD Act in court on the basis of Icelandic and

History of the deCODE Genetics Controversy

Aug. 1996	deCODE becomes a Delaware corporation: receives \$12 Million in venture capital from seven U.S. venture capital companies
Dec. 1996	deCODE labs open in Reykjavik, 45 employees
Feb. 1998	Agreement with Roche Pharmaceuticals announced and signed with the assistance of Iceland's Prime Minister. Issue of 2 million shares of stock in Iceland, added to 22 million outstanding shares
April 1998	First version of Health Sector Database Bill introduced in the Icelandic Parliament (<i>Althingi</i>), criticized, and then withdrawn
Sept. 1998	Second version of Health Sector Database Bill introduced in <i>Althingi</i>
Dec. 1998	Health Sector Database (HSD) Act passed by a vote of 38 to 23
May 1999	Majority government re-elected in Iceland
June 1999	Venture capital backers sell 5 million founder shares to consortium of Icelandic banks for between \$16-17/share. Banks sell 40% to Icelandic investors
July 1999	Original National Bioethics Committee dissolved. New committee and new committee rules established by the majority government
Jan. 2000	HSD license awarded to deCODE
Apr. 2000	Second version of Biobanks Bill introduced in <i>Althingi</i>
May 2000	Biobanks Act passed by <i>Althingi</i>
July 2000	DeCODE begins "roadshow" for I.P.O. on NASDAQ

international law. There remains some doubt as to whether the HSD Act in its present form will sustain such a legal challenge. The act allows the licensee to collect medical records from every Icelander into a centralized database without any affirmative "informed" consent of individuals. The government justifies the act's treatment of informed consent by claiming that the information will be non-identifiable and by providing a possibility, albeit a time-limited one, for opting out.⁶ Challenge to the act will likely be brought under a combination of art. 71 of the Icelandic Constitution, which deals with privacy,⁷ European Directive 95/46/EC dealing with Data Protection,⁸ art. 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms, and Chapter II of the Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine.⁹ Analysis of the merits of such a case lies outside the purview of this article. Published and unpublished legal commentary on the dispute has been divided as to whether the HSD Act is legal under domestic and international law.¹⁰

The ethics embodied by the project have also been hotly contested. On 14 June 2000 the *New England Journal of Medicine* featured an exchange of articles between executives of deCODE Genetics and George Annas, professor of health law at Boston University, concerning the ethics of Iceland's Health Sector Database.¹¹ Gulcher and Stefansson argue that presumed consent is

the standard used for research on health care data that is produced in the process of delivering medical services. Annas argues that informed consent should have been required because of the commercial nature of the medical records databank and its for-profit research agenda.

According to its stated business plan, DeCODE will link the medical record database with genealogical and genetic databases to create an "unprecedented" tool for discovering pathogens. This planned linkage raises questions about DNA procurement and linkage to the other databases: What will be the rules of access and construction of biobanks? For example, will researchers and for-profit companies have access and use existing biosamples without informed consent? And how will such rules be established? Both Annas and Gulcher/Stefansson point out that the HSD Act provides no information on how a DNA database should be constructed, how it should run, who should have access to it, or what control individuals should have over their biological samples once stored in it. Perhaps most importantly, the HSD Act gives no guidance on rules for linking DNA information to the centralized database of health records.

The novelty of connecting electronic medical to biobanks, DNA databases, and genealogical information creates new possibilities; but it implicates the privacy of research participants and their families in new ways.¹² The need for new rules is pressing, as researchers seek to use existing collections of biosamples, and continue to

collect new samples. In Iceland, deCode Genetics has already begun collecting samples for its linked database.

On 13 May 2000, the Icelandic Parliament responded to the need for biobanking guidelines in Iceland by passing a new Biobanks Act, no.110/2000. The Act has recently been published in an English translation.¹³

LEGISLATIVE HISTORY OF THE ICELANDIC BIOBANKS LAW

The Althingi does not publish committee reports similar to those used in the United States as a source of legislative history. However, the Biobanks Bill was accompanied by "Notes to the Bill," prepared by the Icelandic Ministry of Health and Social Security.¹⁴ The other source of legislative history lies in the log of parliamentary discussions.¹⁵ These sources, along with personal interviews in Reykjavik, reveal that the passage of the Icelandic Biobanks Act was rushed and that the legislative process was marked by a surprising lack of community consultation and public debate.

The Notes to the Bill explain that the Biobanks Act is based upon a draft written by the Ethics Committee of the Directorate General of Public Health in 1996–1997 and upon a bill that was submitted to parliament, and later withdrawn, at its 123rd session in 1998. The Bill was produced by a Ministry of Health "working party" that included members of the biobanking community and which allegedly called in "various specialists" in medicine, ethics, research and data protection for consultation. The Notes to the Bill examined a series of international guidelines governing human subjects research and tissue banking including conventions and recommendations of the Council of Europe, a paper on tissue banking by the European Commission's Group on Ethics in Science and New Technologies, the 1964 Helsinki Declaration of the World Medical Association, and declarations of the HUGO Human Genome Project. In fact, the Act contains inconsistencies with these documents.

The Ministry Staff made one round of revisions between the withdrawal of the first bill in 1998 and the introduction of the second version in March 2000. These revisions redefined "temporary storage" and "tissue sample," heightened qualification requirements for the operators of biobanks, included a withdrawal provision, and explicated the idea of "assumed consent." No bioethics committee helped revise the bill; however, the Data Protection Commission, a government body in the Icelandic Ministry of Justice, criticized the bill in a written statement. The criticism focused on the lack of informed consent, provisions concerning the use of samples that seemed to conflict with existing laws, and the

vagueness of the Bill's relationship to the Health Sector Database Act, especially regarding how deCODE may or may not acquire existing blood samples for its database.¹⁶ The Ministry of Health ignored these criticisms. The bill was passed soon after, but not before the Ministry of Health staff at the last minute added ¶12, article 7 on a donor's withdrawal of a sample. This last incident reflects a process seen by many to be rushed, exclusive, and opaque.

HUMAN RIGHTS PROTECTIONS IN THE BIOBANKS LAW

Two vital human rights issues plague the use of biobanks in scientific research: whether previously collected human biological materials may be used for newly conceived research without free and affirmative informed consent; and, how such materials ought to be collected in the future (for example, what type of permission mechanism ought to be used to balance the interests of the donors and the research?).

Unfortunately, Iceland seems to have lost an opportunity for bringing clear and ethical standards to the use of human biological samples in scientific research: the Biobanks Act's provisions regarding consent are ambiguous; it seems that the Biobanks Act has extended the notion of presumed consent from the use of medical records to the use of patients' biological samples; and further, the Act has made it possible, perhaps likely, that a subject's wish to withdrawal his or her sample will be ignored.

Iceland's Biobanks Act consists of 16 articles, broken into six sections: 1) general provisions; 2) establishment and operation of biobanks; 3) collection, handling and access to biological samples; 4) monitoring and obligation to supply information; 5) penalties; 6) miscellaneous provisions. In its English translation, the entire Act fits onto nine sides of A4 paper. At the onset, it is important to note that the legislature has provided that the Ministry of Health shall promulgate regulations providing more detailed rules regarding the use of samples.¹⁷ These regulations have not yet been created.

Previously Collected Biosamples

How to regulate previously collected materials remains one of the most controversial issues in research ethics, and no clear consensus has emerged.¹⁸ For example, can blood collected with informed consent for a study on heart disease be used for a new study on Alzheimer's disease—or for general genomics research such as deCODE's proposed "data-mining"—without new informed consent? Debate has centered around whether and how the degree of identifiability of the

samples—*i.e.* whether they anonymous, anonymized, identifiable, or identified—ought to dictate the type of consent required by research ethics.¹⁹

Curiously, the new Biobanks Act leaves these questions unsettled. It seems unlikely that existing collections of biological materials fall under the Act. Article 2 states that “this Act applies to the collection of biological samples, and their keeping, handling, utilization and storage in biobanks.” The wording implies that only future collections fall under the regulation. Article 4 states that “the establishment and operation of a biobank, *i.e.* collection, keeping, handling and storage of biological samples, is permissible only for those who have been granted a license from the Minister.” Does this mean that hospitals and blood banks with preexisting collections can “operate” without a license because the collection has already been established? What about researchers who have collected a group of samples for specific research? Nothing in the Act whatsoever bears on these previously collected materials. And so the most vexing question regarding the use of biobanks in scientific research has been completely ignored. The entire issue is absent.

Future Collections of Biosamples

The Biobank Act’s rules regarding how such materials ought to be collected in the future fall below the minimum ethical standards of other national and international bodies. Here the major problem is not one of oversight. Rather, the Act establishes consent mechanisms that provide inadequate protections for the rights of patients and research subjects.

In article 7, the Biobanks Act stipulates two different consent mechanisms, one for donation of biological material collected for the purpose of biobanking, and a second for the collection of biosamples resulting from clinical tests or treatment. Each of these mechanism must be analyzed in turn.

Biosamples Expressly Collected for Research

For human biological samples collected for research, the Biobanks Act mandates the use of informed consent; however, this provision is qualified by a later provision that permits its use for unforeseen research projects without mandating a renewal of informed consent. Article 7, I states:

In connection with collection of a biological sample for preservation in a biobank, the free, informed consent of the person giving the biological sample shall be sought. This consent shall be given freely and in writing after the donor of a biological sample has been informed of the objective of the sample collection, the benefits, the risks associated with it’s [sic] collection, and that the biological

sample will be permanently stored at a biobank for use as provided in art. 9. (Art. 7, ¶1).

The problem with this provision is that it deals ambiguously with the question of unforeseen research uses of the samples. The use of “informed consent” here is misleading and incorrect. If the Act means to make it possible for a subject to grant permission for undefined future uses of the sample, then it misuses the term “informed consent” and inadequately addresses the key ethical issues involved in new genetics research.

Informed consent helps protect the autonomy interests, privacy interests, and self-interest of the research subject. There is consensus that, by definition, “informed consent” can only apply to specific research projects; otherwise, it would be impossible to “inform” the research subject in a meaningful way about the particular potential risks and benefits of the project.²⁰ The National Bioethics Advisory Commission recommends that signed consent to unforeseen research uses of biological samples may be an acceptable alternative to requiring informed consent for each specific use of the sample.²¹ Some well-respected bioethicists disagree.²² Henry T. Greely stakes out a compromise position that would allow signed consent to unforeseen research uses, but only within a well-defined regulatory framework. His prospective regulatory framework would mandate signed “permission” for unforeseen research, provisions stipulating the conditions of recontact, an absolute right of withdrawal at any time, time limits, limitations on availability of information to third parties, group permission requirements on top of individual permission, disclosure of commercial interests, confidentiality stipulations, and community benefits.²³ If the Icelandic parliament truly means to allow signed permission for unforeseen research uses, then it would do well to address the vexing ethical issues in a more responsible way.

If the language of article 7, ¶1 is intended to limit the creation of biobanks to those involved in specific research projects, then a different problem arises from the provision about “use as provided in art. 9.” Article 9 makes it possible for the sample to be used for future research without the donor’s informed consent: the board overseeing a new biobank “shall negotiate with scientists on access to biological samples,”(¶13) although approval of access must be granted by two oversight committees. Further,

The board of the biobank may, if approved by the Data Protection Authority and the National Bioethics Committee, authorize the use of biological samples for other purposes than those for which the samples were originally collected, provided that important interests are at stake, and that the potential benefit outweighs any po-

tential inconvenience to the donor of a biological sample or other parties (Art.9, ¶4).

Read in conjunction with article 7 on the consent of donors, this provision undermines the very idea of informed consent therein. Biosamples are to be banked only with informed consent for a specific project, but a future research project may be allowed to use the samples without the donor's informed consent. This means that samples can legally be banked for future research uses without any consultation with the subject. Further, there are no provisions mandating levels coding and anonymization, and no distinctions between commercial and non-commercial research.

Further problems arise with the withdrawal mechanism. Article 7, ¶2 states that "a donor of a biological sample can at any time withdraw his/her consent under the terms of para. 1, and the biological sample shall then be destroyed." However, the provision goes on to say that "material that has been produced from a biological sample by performance of a study or the results of studies already carried out shall, however, not be destroyed" (Art.7, ¶2). This is the provision that was inserted at the eleventh hour, and it provides an unfortunate loophole. Curiously, the rule seems to suggest that a sample may be destroyed, but sensitive information—including all information or data derived from the sample, and also biological derivatives, blood cells, proteins, cloned DNA, tissue culture, etc.—would not be destroyed. The rule creates an easy way for researchers to avoid giving up their samples, despite a subject's revocation of consent.

Biosamples Collected for Clinical Testing and Treatment

The Biobanks Act creates a second donor consent mechanism for biosamples collected for clinical tests and treatment. It covers anything from simple blood tests, to urinalyses, to surgical tissue removal. It states:

If biological samples have been collected for the purpose of clinical tests or treatment, the consent of the patient may be assumed for the storage of the biological sample in a biobank for use as provided in art. 9., provided that general information on this is provided by a health care professional or health institution (Art.7, ¶3).

Consent for entry of one's biosample is simply "assumed" for entry into the biobank, just as consent for entry of medical data is "presumed" under the Health Sector Database Act.

This means that there is less autonomy and privacy protection for a patient who walks into his doctor's office needing health care than for a person who knowingly donates his sample for research. This provision expressly

contradicts the guidelines of the Human Genome Organization (HUGO), which draw a sharp distinction between samples collected for research and those collected in the process of clinical care.²⁴

Despite the inclusion of an "opt-out" provision for clinical biosamples, the current rules make it possible that the sample will still be used for research *even after opt-out*. The relevant provision states:

A donor of a biological sample may at any time withdraw his/her assumed consent for his/her biological sample to be stored in a biobank for use as provided in art. 9, in which case it shall thereafter only be used in the interests of the donor of a biological sample or by his/her specific permission, *but see also para. 4 art. 9* (Art.7, ¶4, emphasis added).

Recall that article 9, ¶4 allows biobanked samples to be used for research without informed consent, subject to approval by two committees. Does this mean that provided that the committees use their discretion to approve the use of samples for research, the patient's express wishes not to be a research subject will be ignored? The notes on article 7 seem to confirm this interpretation, for the right to opt out is again qualified by article 9.²⁵

The notes to article 9 reiterate that the consent-over-ride provision in ¶4 applies only when the stated conditions are met. But recall that these conditions are vague and discretionary: what constitutes a situation where "important interests are at stake, and the potential benefit outweighs any potential inconvenience to the donor of a biological sample or other party"? The notes state, "such an example might relate to inheritance or other legal necessity" (p.19). Again, these examples are vague. What constitutes "legal necessity"? Broad interpretation is possible. For example, this provision could easily be used to create a DNA databank for criminal prosecution.

In the context of the Health Sector Database, a much more immediate concern to many people in Iceland, it seems perfectly possible that the oversight committees could use their discretion to allow blood from people who have opted out to go to deCODE's genotypic-phenotypic database. The HSD Act expressly states that the aim of the legislation is to improve health care, which seems to satisfy the "important interests" condition. And in terms of the balancing test between potential benefit and donor inconvenience, the Icelandic government has already shown by its use of presumed consent in the HSD Act that it is satisfied that patient autonomy and privacy rights may be replaced by assurances of confidentiality. The current chairman of the Data Protection Committee has expressed his firm position that he would not let such blood go to deCODE or any other genomics firm without

express and informed consent.²⁶ However, it is clear that control of one's blood should not depend exclusively on politically appointed committees, in Iceland or anywhere else. The majority government in Iceland has already been criticized harshly for dissolving the existing National Bioethics Committee at a key moment in the deCODE Genetics database debate,²⁷ and Data Protection Committee is due to be reconstituted in August 2000.

The next blood test, urinalysis, or biopsy in the course of clinical care could thus become a source of genetic information for deCODE without the patient's consent, or even knowledge. Legal counsel and research executives at deCODE have indicated that written permission will be required before a donor's blood will be entered into its database; further, the company has recently published a code of ethics stating that "research on DNA samples from people are only conducted with an informed consent of the participating donor."²⁸ If deCODE holds to this policy, it should be commended. However, such a minimal requirement for the protection of autonomy must not depend on corporate goodwill, but have a firm basis in domestic law.

IMPLICATIONS

In recent years, the world has witnessed an important expansion of human DNA sampling and data collecting. The status of existing collections is not well known and most DNA banks have no written rules or policies. It is admirable that Iceland felt the need to establish legal rules for this activity; however, its Biobanks Act suffers from ambiguity, and may have created more problems

of than it solves. The Act provides for the Minister of Health to promulgate further regulations regarding the use of biological samples, and one hopes that some of the existing ambiguities will be clarified, and infringements on human rights rectified.

The Act creates no rules for existing collections of biological samples. Further, the Act contravenes developing consensus about the minimal ethical and human rights requirements for future collections of biological material: the necessity to gain affirmative permission for future unforeseen research uses of biological samples, and the unqualified right of withdrawing the sample and the genetic information contained therein from the research project. In an era of commercialized genomics research, as the pace of data accumulation accelerates, traditional ethical principles must not be sacrificed in order to make data more complete, projects more profitable.

In order that scientific research may proceed, implementation of legal rules requires expediency, but not speed. The history of scientific research in this century exhibits both the desirability and the fragility of trust between the public and researchers, and its maintenance requires careful consideration and community involvement. This is especially true for research on populations where the dangers of discrimination and prejudice loom larger, and for "Big Science" where mistakes reverberate more harmfully. For these reasons, the deficiencies both in process and content of the Icelandic Biobanks Act are compounded. The law should be amended, lest it remain challengeable under domestic and international law. ■

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