

Iceland's Research Resources: The Health Sector Database, Genealogy Databases, and Biobanks

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Background

For several years, the National Institutes of Health (NIH), an agency within the U.S. Department of Health and Human Services (HHS), and the Icelandic Ministry of Health and Social Security explored the possibility that U.S. researchers could use Iceland's population-based data and tissue resources for research. Such discussions surrounded Iceland's efforts to facilitate epidemiology and the discovery of genes contributing to disease, including decisions by the Government of Iceland to allow the creation of the Iceland Health Sector Database, legislation on biobanks, and genealogical databases. These resources store family information, medical information, and/or biological tissues from Iceland's population. In addition, many Icelanders have consented, by their participation in medical research, to the use of their medical information and biological specimens that are stored in these, as well as other privately held, databases and repositories for research purposes. A Letter of Intent signed in September 2002 (Appendix A) between the HHS and Iceland formalizes these interests: "The [NIH] and the Icelandic Ministry of Health and Social Security intend to work to strengthen cooperation in the fields of biomedical and behavioral sciences, and related training, subject to the availability of resources."

Several laws, regulations, and policies, such as the HHS Protection of Human Subjects Regulations at 45 CFR part 46, govern research conducted or funded by the HHS. When research covered by 45 CFR part 46 takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in the HHS regulations. In these circumstances, if the Secretary of HHS determines that the procedures prescribed by the institution offer protections that are at least equivalent to those provided by 45 CFR part 46, the Secretary of HHS may approve the substitution of the foreign procedures in lieu of the HHS regulations. All foreign institutions engaged in HHS-conducted or supported research must follow the requirements of 45 CFR part 46, unless the procedures prescribed by the foreign institution have been found by the Secretary of HHS to provide protections that are at least equivalent to the HHS regulations. Thus, the NIH staff needed to better understand the relevant Icelandic laws and procedures for their access and use in order to assess whether HHS-funded scientists could collaborate with scientists in Iceland or conduct research involving Icelandic volunteers, the Icelandic biobanks, the genealogical databases, or, once completed, the Health Sector Database.

This report reflects discussions, visits, and correspondence between the NIH and the Icelandic Ministry of Health and Social Security that were initiated to inform the NIH staff about these resources, opportunities for research collaboration, and the applicability of Iceland's human subjects regulations pertaining to these resources. The report was developed to assist researchers within the NIH and those funded by the NIH in answering questions about Icelandic research resources, the status of these resources, their availability to researchers, opportunities for collaboration, and governance by Iceland's regulations.

NIH representatives have identified several opportunities for expanding collaboration between U.S. and Icelandic scientists. Even though the Health Sector Database is not yet complete, other opportunities for collaboration exist. These include opportunities to (1) use tissues and information in biobanks and other repositories for research, (2) use, for research, information in the genealogy databases and other databases, (3) conduct research with Icelandic volunteers, and (4) collaborate with research groups and private companies in Iceland.

Research Oversight and Iceland's Human Subjects Protections Regulations

Role of the Ministry of Health and Social Security

Iceland's Ministry of Health and Social Security, established in 1969, has the responsibility for administration and policymaking on health and social security issues in Iceland as prescribed by law, regulations, and other directives. The Ministry administers acts and regulations that pertain to the development and governance of the Health Sector Database, biobanks, and the rights of research participants, including:

- *Act on the Rights of Patients (No. 74/1997)*
- *Act on a Health Sector Database (No. 139/1998)*
- *Regulation on Scientific Research in the Health Sector (No. 552/1999)*
- *Regulation on a Health Sector Database (No. 32/2000)*
- *Act on Biobanks (No. 110/2000)*
- *Regulations on the Keeping and Utilization of Biological Samples in Biobanks (134/2001)*

These acts and regulations are located in Appendices B-G, respectively, and can also be found at the Ministry of Health and Social Security Web site <http://brunnur.stjr.is/interpro/htr/htr.nsf/pages/lawsandregs>. The Ministry of Health and Social Security also oversees contractual agreements between itself and the licensee of the Health Sector Database, deCODE Genetics, Inc., for the development and operation of the Health Sector Database. The Ministry also administers and oversees licenses to biobanks.

Human Subjects Regulations

Authorizing Legislation

Iceland issued three regulations that offer comprehensive protections for research participants. The *Act on the Rights of Patients* (1997) specifies when a researcher must obtain (1) informed consent from research participants and (2) research project approval from a scientific ethics committee review. This Act empowered the Ministry of Health and Social Security to issue requirements for the National Bioethics Committee through the *Regulation on Scientific Research in the Health Sector* (1999). The National Bioethics Committee, which is similar, in principle, to a U.S. Institutional Review Board (IRB), is composed of individuals appointed by elected officials to review collaborative projects, multinational studies, and other scientific studies that are not eligible for review by a local board. The National Bioethics Committee conducts ethical reviews of scientific projects while a second board appointed by elected officials, the Data Protection Authority, reviews projects that require access to clinical data for data protection and privacy under the *Act on Protection of Individuals with Regard to the Processing of Personal Data* (2000)¹ (see Appendix H). Many projects will require approval from an Icelandic ethics committee and from the Data Protection Authority, all of which are currently in place. These regulations are summarized in Appendix I.

¹ The *Act on Protection of Individuals with Regard to the Processing of Personal Data* (2000) is administered by the Ministry of Justice and Ecclesiastical Affairs.

Informed Consent for Research

Informed consent for research is part of the human subjects protections in Iceland. In general, a participant must give his or her formal consent prior to participation in scientific research (e.g., all genotyping research requires informed consent). Consent, if given, is obtained after the participant has reviewed the possible risks and benefits that participation entails. Generally, informed consent is given for a specific study, but consent to participate in scientific research may be broader. For some public health activities, however, such as research on health records for epidemiology or public health, the National Bioethics Committee does not usually require informed consent, provided the information is not identifiable. For children up to the age of 16 years, parents would give such consent and, where possible, the assent of the child is also sought.

National Bioethics Committee

The National Bioethics Committee was created under the *Regulation on Scientific Research in the Health Sector* (1999) to review research projects that involve more than one institution in Iceland or that involve foreign collaborators. This Committee is funded by the Icelandic Government and comprises five regular and five substitute members who were nominated in 1999 for a term of 4 years, with no restriction on consecutive terms. The five-member Committee consists of one member appointed by each of the following: the Minister of Education and Culture, the Minister of Justice, and the Medical Director of Health. The Minister of Health and Social Security appoints two members. The National Bioethics Committee meets every 2 weeks to review protocols; it reviewed 169 protocols in 2002, an increase from 69 in 1998. Generally, final decisions are reached in 4 to 6 weeks after the National Bioethics Committee receives the proposal. Abstracts from approved research protocols and the National Bioethics Committee's guidelines are posted on the National Bioethics Committee Web site <http://www.visindasidanefnd.is/>.

The main role of the National Bioethics Committee is to perform a scientific and ethical evaluation of health-focused research proposals involving humans as subjects. It follows the procedures set forth by the *Regulation on Scientific Research in the Health Sector* (1999),² which also includes project monitoring. Projects requiring access to clinical records must receive approval from the National Bioethics Committee and the Data Protection Authority before beginning.

Where research projects do not involve multiple Icelandic sites or international collaborators, a local ethics board reviews the research. Currently, there are three active, local ethics review boards in Iceland at the Landspítali – University Hospital, the FSA University Hospital, and the National Health Service. These boards are similar to local U.S. institutional review boards (IRBs). The intrainstitutional ethics review boards operate independently of their affiliated institution, but their decisions are forwarded to the National Bioethics Committee, with appeals to decisions made to the National Bioethics Committee. The National Bioethics Committee will work with the recently appointed Health Sector Database Ethics Review Board once the database is complete.

² Prior to 1997, when the first regulation on scientific research in the health sector was established with the *Act on the Rights of Patients* (1997), local ethics review boards operated within health institutions and under the auspices of the Director General of Public Health and the Icelandic Medical Association.

Data Protection Authority

The Data Protection Authority was established by the *Act on Protection of Individuals with Regard to the Processing of Personal Data* (2000) to control the implementation of the Act. The Data Protection Authority is an independent authority with its own board, administratively subject to the Minister of Justice. The Minister of Justice appoints the five-member board and five alternates for a term of 4 years. The Minister of Justice appoints the chair and the vice chair, both lawyers, without nomination. The Supreme Court of Iceland nominates one board member, and the Icelandic Society for Information Processing nominates another board member with expertise in electronic data processing and technology. Alternate members have the same qualifications as principal members. The Minister of Justice also appoints a managing director for the Data Protection Authority for a term of 5 years. The Data Protection Authority generally meets monthly to review proposals and, on average, takes 2 months to complete its review before issuing a permit.

One function of the Data Protection Authority is to review requests and issue permits for researchers to access clinical records for the purposes of scientific research. A research protocol review by the Data Protection Authority includes, among other things, an assessment that the proposal limits access to and use of the minimum amount of personal data necessary for the study and a review of the protection and security of such information. According to the *Act on the Rights of Patients* (1997), access to clinical records is always subject to a permit granted by the Data Protection Authority. The same applies to genetic research according to amendments to the *Act on Protection of Individuals with Regard to the Processing of Personal Data* (2000). For example, a retrospective research study, whether genetic or other research, always requires a permit from the Data Protection Authority. However, prospective research that does not require access to clinical records, is not genetic research, and seeks an individual's informed consent only requires notification to the Data Protection Authority and does not require a permit if the researcher is not contacted by the Data Protection Authority within 10 business days. Likewise, a clinical research project that involves access to clinical records and the consent of a research participant to this access, requires a permit from the Data Protection Authority. An exception is genetic research, which always requires a permit from the Data Protection Authority. The Data Protection Authority Web site is <http://www.personuvernd.is/tolvunefnd.nsf/pages/english>. Figure 1 illustrates the interaction of Iceland's ethics review boards and the Data Protection Authority.

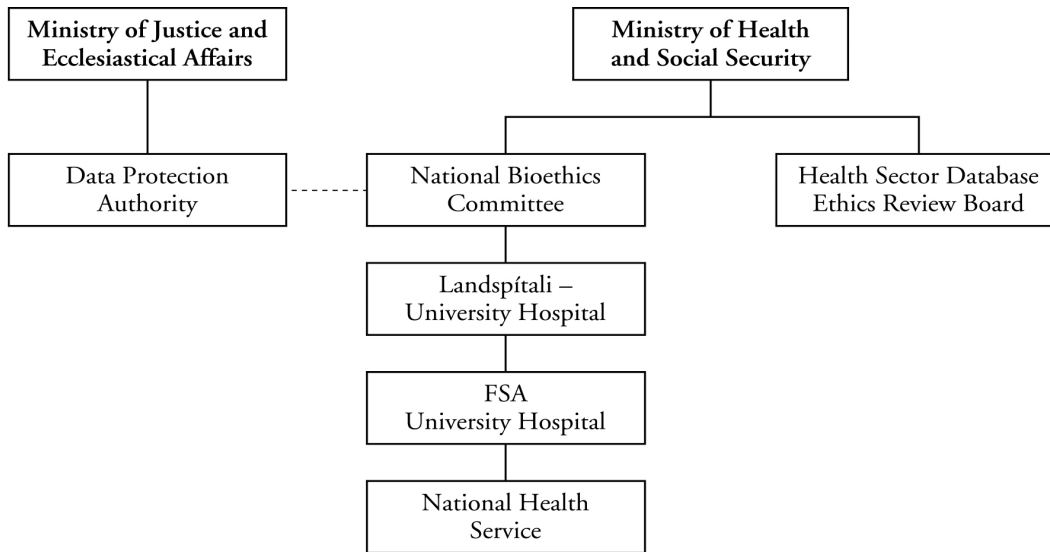


Figure 1. Interaction of Icelandic Ethics Review Boards and the Data Protection Authority

U.S. HHS Office for Human Research Protections

The mission of the U.S. Office for Human Research Protections (OHRP), an office within the HHS, is to develop and implement regulations, policies, and programs for protecting the rights and welfare of human subjects³ participating in research that is conducted or supported by the HHS. As such, the OHRP was asked in March 2002, through a letter to Dr. Greg Koski, then the Director of the OHRP (Appendix J), to assess the applicability of the HHS human subjects protections regulations to the Health Sector Database, deCODE Genetics, Inc.’s Genealogical Database, and biobanks. The OHRP’s assessments of whether the HHS human subjects protections regulations at 45 CFR part 46 would be applicable, and this report’s summaries thereof, were based on the NIH’s description of those research resources in March 2002 *and* subsequent discussions of these resources. The OHRP’s conclusions assume that the research in question would be conducted or supported by the HHS or conducted under an applicable OHRP-approved assurance. The OHRP’s response to the NIH’s March 2002 letter can be found in Appendix K. We note, however, that the OHRP updated its assessment of deCODE’s Genealogical Database in September 2003; this update is reflected in this report’s discussion of deCODE’s Genealogical Database.

³ Under 45 CFR part 46, “human subject” means a living individual about whom an individual (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.

Update on the Health Sector Database

Background Information

Iceland has systematically collected health data on its population since the 18th century. From 1930 to 1966 Iceland's Directorate of Health published individually identifiable health information about the Icelandic population, including information such as birth date, initials, and diagnoses. After 1966, however, only unidentifiable statistical data have been published. In 1998 Iceland approved an act to create a centralized database on nonpersonally identifiable health data—the Health Sector Database—with the aim of increasing knowledge to improve health and health services. The Health Sector Database, once completed, will be a centralized database of health information about the Icelandic population, approximately 280,000 people, and will serve as a resource to mine population-based medical data in an unbiased fashion.

The idea for the Health Sector Database was conceived in 1997 by Dr. Kári Stefánsson, a neurologist and cofounder of deCODE Genetics, Inc. Health information will be encrypted according to conditions set by the Data Protection Authority so that it is not individually identifiable to deCODE or others. Once established, this database will contain only quantitative information in health records (such as blood pressure levels) but not narrative information (such as physicians' notes). Genetic research data and results from genetic research, defined as information derived from an individual's DNA or other genetic information, will not be included in the Health Sector Database. For research purposes, linking health information within the Health Sector Database to genetic information may occur with the individual's informed consent, permission from an Icelandic ethics review board, and a permit from the Data Protection Authority.

Once the Health Sector Database is established, a researcher may post queries to it through deCODE, using set definitions that facilitate the search. Researchers may use the Health Sector Database to look for correlations among clinical, demographic, epidemiological, and disease data. Longitudinal studies also would be possible since the encryption system uses, for coding, the Icelandic personal identifier, which is similar to a U.S. Social Security number.

deCODE Genetics, Inc.

deCODE is under contract to the Icelandic Government to develop, operate, and maintain the database for 12 years. After that time, the disposal and operation of the Health Sector Database will be decided by the Ministry of Health and Social Security, and the rights and hardware necessary for the creation and operation of the Health Sector Database will be transferred to the Ministry of Health and Social Security or its designee, according to the *Regulation on a Health Sector Database* (2000). The Ministry of Health and Social Security has further clarified that deCODE will create and operate the database for research but that deCODE does not have exclusive rights to using the Health Sector Database. deCODE has established agreements with several Icelandic hospitals that would enable deCODE to incorporate health information into the Health Sector Database once its data security system is approved. Use of the Health Sector Database by researchers would not constitute a collaboration with, although access is through, deCODE.

The Health Sector Database is both different and separate from other databases owned and operated by deCODE. For example, deCODE's Genealogical Database and genotyping database, although separate from each other and from the Health Sector Database, may be linked to the Health Sector Database if approved by the Health Sector Database Ethics Review Board, the National Bioethics Committee (if applicable), and the Data Protection Authority. In

addition, deCODE has obtained informed consent from approximately 80,000 Icelanders (approximately 1/3 of the population) to study their health, genetic, and family information for certain diseases and conditions.

Status and Availability

The Health Sector Database is not yet complete. However, its security plans have been reviewed by the Icelandic Data Protection Authority, as required by the *Regulation on a Health Sector Database* (2000).⁴ deCODE reports that it is working with the Data Protection Authority on security plans.

After the Health Sector Database system is approved, it can be populated with health information pursuant to agreements that deCODE has established with Icelandic hospitals. As part of deCODE's agreements with several hospitals in Iceland, the hospitals will make encrypted electronic health information available to deCODE and initiate electronic recording of other health information in accordance with the above-mentioned agreements. deCODE expects the Health Sector Database to be populated with health information and be operable within 1 year after approval by the Data Protection Authority.

When the Health Sector Database becomes operational, researchers may submit queries through deCODE. Queries will be prioritized on a first-come, first-served basis. Researchers, however, may not gain direct access to the Health Sector Database. Queries will be returned to researchers as deidentified and aggregated (groups of at least 10 individuals) health information, such as a correlation between blood pressure and lipid levels; that is, certain characteristics within the population must be present in at least 10 individuals for such information to be provided by the Health Sector Database. In addition, the Health Sector Database also will have the ability to cross-reference data within deCODE's Genealogical Database, in accordance with security requirements set forth by the Data Protection Authority. A fee will be imposed by deCODE for posting a query to the Health Sector Database, but the amount of that fee has not yet been determined.

Human Subjects Protections

Although the Health Sector Database is not yet complete, many of the rules for its creation and operation have been developed, specifically the following:

- Individuals may opt out of having their health information included in the Health Sector Database.
- Information in the Health Sector Database is triple-coded, beginning at the time the information leaves the hospital to go to deCODE, and is designed to prohibit identification of individuals.
- The Genealogical Database developed by deCODE will be triple coded with the same encryption keys as the Health Sector Database to facilitate querying against the Health Sector Database.
- It is not possible to use the Health Sector Database to identify or contact an individual for any purpose, including seeking informed consent.

⁴ Criteria for approving plans for the Health Sector Database are located at [http://www.personuvernd.is/tolvunefnd.nsf/files/7163.method.../\\$file/7163.method.pdf](http://www.personuvernd.is/tolvunefnd.nsf/files/7163.method.../$file/7163.method.pdf).

- Genetic information on individuals who have specifically consented can be linked to their information in the Health Sector Database and the encrypted Genealogical Database data at the same time, provided the method meets the requirements of the Data Protection Authority to ensure that the information remains personally nonidentifiable.
- The encryption is one way and is constructed so that there is no backtracking to the individual by decryption. Possibilities of indirect identification will be limited, in effect, by access control, technical interventions, and limitations on queries.
- No raw data contained in the Health Sector Database will be disclosed to researchers. Researchers may, however, post questions to the Health Sector Database and receive answers to their questions in the form of aggregated data.
- The Health Sector Database Ethics Review Board must approve all proposed uses of the Health Sector Database.
- A Monitoring Committee,⁵ which oversees the creation and operation of this Database, will oversee research that uses the Health Sector Database.

Informed Consent

Encrypted health information will be added to the Health Sector Database without informed consent; however, individuals can request that their health information not be added, the so-called “opt-out.” Generally, genetic information will never be included in the Health Sector Database but can be analyzed in connection with the Database if informed consent is specifically granted by the individual and certain permissions are obtained from Icelandic ethics review boards and the Data Protection Authority.

Roles of the Health Sector Database Ethics Review Board and the National Bioethics Committee

The Health Sector Database Ethics Review Board will review and monitor requests to query the Health Sector Database. Queries that fall under predefined groups/types of queries (such as searches by type of cancer), which have been reviewed and approved, may not need prior review or approval but will be monitored. In addition, the National Bioethics Committee, or another ethics review board, will review query requests that are part of a research protocol. Thus, U.S. scientists wishing to query the Health Sector Database may have their request to *query* reviewed by the Health Sector Database Ethics Review Board and their *protocol* reviewed by the National Bioethics Committee.

Unlike other ethics review boards, as well as the Monitoring Committee of the Health Sector Database, the Health Sector Database Ethics Review Board does not report to the National Bioethics Committee. However, complaints and appeals of decisions made by the Health Sector Database Ethics Review Board will be directed to the Minister of Health and Social Security, who will seek the opinion of the National Bioethics Committee before returning a decision. The Health Sector Database Ethics Review Board will assess the inquiries that are made.

⁵ The role of the Monitoring Committee is to ensure that the creation and operation of the Health Sector Database are in keeping with the terms of the legislation, regulations, and conditions laid down in the operation license, insofar as this role does not fall within the ambit of the Data Protection Authority. One role of the Monitoring Committee is to supervise and protect the interests of the individual health institutions that are negotiating with deCODE the terms of the data transfer from the Health Sector Database. The Monitoring Committee will keep records of all the requests and inquiries made of the Health Sector Database and information as to its processing functionality.

Role of the Data Protection Authority

The Data Protection Authority reviews all research protocols in which the use of personal data,⁶ including clinical data, is proposed. Because the Health Sector Database will store clinical information from Iceland's population, the Data Protection Authority will play a key role in monitoring its creation and operation. More broadly, the role of the Data Protection Authority, in this respect, is to monitor the recording and handling of personal data and the security of the Database. To this end, a committee on the operation of the database will monitor all processes in the database, whereas an interdisciplinary ethics committee will assess studies carried out within deCODE and queries that are received. Once the Health Sector Database is established, the Data Protection Authority also will set conditions for encrypting identifiers and will play a key role in permitting the Health Sector Database to cross-reference the Genealogical Database and deCODE's genotype database.

Assessment From the U.S. HHS Office for Human Research Protections

The OHRP determined that research with the Health Sector Database does not constitute human subjects research under the HHS human subject protections regulations codified at 45 CFR part 46, because researchers would receive only aggregated data from this database and are prohibited by Icelandic law from having access to the raw or coded data that would enable linkage to an individual. Therefore, such research requires neither U.S. IRB review nor approval under the HHS human subjects protections regulations.

⁶ "Personal data" is defined as "all data on a personally identified or personally identifiable individual. An individual shall be counted as personally identifiable if he or she can be identified, directly or indirectly, especially by reference to an identity number, or one or more factors specific to his physical, physiological, mental, economic, cultural or social identity." "Personal data," under the *Act on Protection of Individuals with Regard to the Processing of Personal Data* (2000), covers information on both living and deceased individuals.

Update on the Icelandic Biobanks

Background Information

Human biological materials have been collected by Icelandic hospitals since the 1930s. In May 2000 the *Act on Biobanks* formalized the collection and use of human biological materials. Unlike the Health Sector Database, biobanks are not centralized; tissues are stored at various biobanks located throughout Iceland.

Status and Availability

Currently, three biobanks have been granted a license, including the Iceland Genomics Corporation, the Landspítali – University Hospital, and deCODE. Applications to operate biobanks are pending from the Icelandic Cancer Society and the National Health Service. Currently, tissues may be sent abroad when doing so is in the interest of the patient (e.g., for clinical diagnosis) and for research. A biological sample of a deceased person (including tissues from an autopsy) also may be stored in a biobank, provided he or she did not withdraw consent prior to his or her death, and may be used without the consent of surviving relatives.

Iceland Genomics Corporation Biobank

The Iceland Genomics Corporation (known in Icelandic as Urður Verðandi Skuld [UVS]) is a privately held biopharmaceutical company focused on population surveys of cancer and the use of clinical information, tissue samples, patient DNA, and genealogies to look for genes affecting cancer. Its research entails merging pedigree information from the Genetical Committee of the University of Iceland⁷ with clinical and genetic information. It was recently issued a license as a biobank, which contains blood samples and DNA from nearly 4,000 patients, 10,000 relatives, and 1,500 controls, which were collected with informed consent. These specimens are associated with medical history, epidemiology, and pedigree information. The biobank also contains nearly 400 snap-frozen cancer biopsies. It also reports having access to approximately 50,000 paraffin-preserved specimens from the Landspítali – University Hospital Department of Pathology and the FSA University Hospital in Akureyri. The Iceland Genomics Corporation Web site is <http://www.uvs.is/eng/scitech/icp.html>.

Landspítali – University Hospital Department of Pathology Biobank

The Department of Pathology at the Landspítali – University Hospital in Reykjavík is a licensed biobank. The Department stores tumor tissues, including associated clinical information dating from 1935 to the present, from more than 200,000 individuals, representing 95 percent of all cancer cases in Iceland. Included in this collection are 2,500 fresh-frozen cancer specimens from patients, with the remaining 500,000 specimens preserved mainly in paraffin. The Department also provides specimens to the Iceland Genomics Corporation, which may result in duplicate samples at both sites. Most specimens in the biobank were collected for clinical purposes and are available through the patient's assumed consent. Access to biological samples for scientific studies requires permission of the Data Protection Authority and approval of a research protocol by an ethics committee.

⁷ Iceland Genomics Corporation uses genealogy information provided by the Genetical Committee of the University of Iceland, which is different and separate from the Genealogical Database created by deCODE Genetics, Inc. The Genetical Committee has provided genealogy information on Icelanders to the research community for several decades, including all the genealogical information used by Iceland Genomics Corporation in its genetic research.

deCODE Genetics, Inc., Biobank

deCODE has also been granted a license to operate a biobank. Its biobank contains blood-derived products (such as DNA and serum), which were collected, with consent from over 80,000 Icelanders, for use in its genetic studies. deCODE's Web site is <http://www.decodegenetics.com/>.

Icelandic Cancer Society Biobank (Application Pending)

The Icelandic Cancer Society runs the population-based Icelandic Cancer Registry, which contains information on all cancers diagnosed in Iceland since 1955. The Registry contains information about the site of the tumor, morphology, year of diagnosis and age of the patient, and information on the cause of death—mostly from the pathology report. The Icelandic Cancer Society's Molecular and Cell Biology Laboratory runs the Society's tissue repository. The repository contains tissues and information on individuals receiving diagnoses of cancer or suffering from cancer-related diseases, in addition to information on relatives when possible. The Icelandic Cancer Society recently applied for a license as a biobank. The Icelandic Cancer Society Web site is <http://www.krabb.is>.

Human Subjects Protections

Informed Consent

The informed consent of the person who gives the biological sample will be sought when a biological sample is obtained for preservation in a biobank for a specified scientific study and/or for subsequent scientific studies that are consistent with the objective of the biological sample being taken. In addition, if a researcher wishes to store, for over 5 years, a biosample in a biobank that has been approved by the Ministry of Health and Social Security (be it for further research within the same project or for other research projects), the researcher must obtain the sample donors' informed consents for such storage; otherwise, the sample must be destroyed within 5 years. Donor consent to store a biosample in a biobank, however, does not preclude the requirement of specific informed consent for the use of the sample in future research.

For scientific research (including genetic research) based on biological samples, participants have a choice of giving either a limited informed consent or a broad informed consent. Either limited consent or broad consent may be executed for the use of biological tissues in research.

- “Limited consent” pertains only to the research project specified in the research plan in question and furthermore states that all information and samples originating from the participant shall be discarded after the research project ends.
- “Broad consent” allows participation in the research project specified in the research plan and preservation of the information and samples for possible later use in research projects. The Iceland Genomics Corporation reports that nearly 95 percent of research participants sign this consent. Where a broad consent is given, a subsequent informed consent may be needed if future research prompts a request for additional personal information about the individual that was not described in the original consent or if future use is unrelated to the purpose for which informed consent was initially sought. Broad consent has been coordinated with the legislation on biobanks; that is, signing a broad consent includes consenting to storage of the biosample in a biobank (since storage for further research normally and automatically encompasses over 5 years of storage); this information is detailed in the material provided to the donor.

Limited and broad consent forms approved for use by the Iceland Genomics Corporation can be found in Appendix L.

Biobanks operate under the following permissions for tissue collection and research:

- Individual consent is required for tissue samples obtained specifically for inclusion in a biobank. Consent can be withdrawn at any time. If consent is withdrawn, the tissue sample will be destroyed; however, the “products” of research (e.g., written text, numerical values, measurements, graphs, pictures, tissue cultures, gene sequences, isolated genes, or isolated molecules) may be retained in nonindividually identifiable form.
- Individual consent is assumed for tissue samples obtained for the treatment or clinical care of the individual. However, individuals must be informed that they may opt out of having their tissue samples used for any purpose other than their care. Furthermore, before research can be conducted with such tissue samples, individual consent is required unless the individual is deceased. Iceland’s National Registry⁸ is used to determine whether individuals are deceased.
- Researchers may access biobanks only if the following conditions are met:
 - The National Bioethics Committee or other ethics review board in Iceland approves the protocol.
 - The Data Protection Authority approves the protocol if identifiable information is to be accessed or for genetics studies.
 - Consent is obtained from living individuals.
 - The researcher agrees that if a patient opts out, the sample must be destroyed.
 - Foreign researchers may study material from Icelandic biobanks only if they collaborate with researchers in Iceland.

Roles of Ethics Review Boards and the National Bioethics Committee

In general, a scientific study may not be conducted using biological samples that have been gathered for preservation in a biobank unless the study has been approved by the National Bioethics Committee or by another ethics review board in Iceland. Also, the National Bioethics Committee must review research protocols requesting transportation of biological samples out of the country. For genetic studies, informed consent normally will be sought (always, if the data identify the individual); this decision is made by the National Bioethics Committee and the Data Protection Authority.

Role of the Data Protection Authority

The Data Protection Authority is required to review protocols pertaining to the use of biological tissues linked to personal data. In addition, it reviews requests to transport biological samples out of the country, which is also subject to the approval of the National Bioethics Committee. For genetic studies, informed consent normally will be sought (always, if the data identify the individual); this decision is made by the National Bioethics Committee and the Data Protection Authority.

Assessment From the U.S. HHS Office for Human Research Protections

Investigators who obtain identifiable human specimens from living individuals are conducting human subjects research; thus, the use of such specimens requires IRB review and approval under

⁸ Iceland’s National Registry is a publicly available list of Iceland residents’ births, deaths, and marriages. The Registry is a compilation of records from several censuses as well as church records.

the HHS regulations at 45 CFR part 46. However, the OHRP has noted that research using coded material would not ordinarily be considered human subjects research, for example, (1) if the investigator received only coded samples that were not collected for the currently proposed research through interaction or intervention with living individuals or (2) if a written agreement is obtained from the holder of the identifiable information related to the samples that identifiable information will not be released to the recipient-investigator under any circumstance.

Furthermore, under 45 CFR 46.101(b)(4), an institution or IRB is permitted to determine that research involving human subjects is exempt from the requirements of the HHS regulations if (1) the human subjects research involves only the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens (all data and specimens must be existing at the time the research is proposed) and (2) these sources are publicly available or the information is recorded by the investigator in such a manner that the subjects cannot be identified, either directly or through identifiers linked to the subjects.

Update on the Genealogy Databases

Background: deCODE's Genealogical Database

Iceland's Genealogical Database was created by deCODE solely from publicly available data using almost all known genealogy information for all Icelanders. Data used to create deCODE's Genealogical Database are taken from Iceland's National Registry as well as public input on their relatedness.

Status and Availability: deCODE's Genealogical Database

For Icelanders who wish to query their ancestry and relationships with other Icelanders, deCODE's Genealogical Database exists as a publicly available resource on the Web at "The Book of Icelanders," <http://www.islendingabok.is> (Íslendingabók). Use of the Web resource is free of charge; however, it is currently available only in Icelandic and requires an Icelandic identification number for access. English information and access for descendants of Icelandic emigrants will be added in the future. Public use of deCODE's Genealogical Database is limited to querying the potential relationship of oneself to any other Icelander and intervening relatives, using the Icelandic identifier number. For research, such as linking information in deCODE's Genealogical Database with genotyping information, the Genealogical Database is not available to investigators outside deCODE or absent a collaboration with deCODE. Genealogists at deCODE update the Genealogical Database regularly.

Individuals having an Icelandic identification number are granted access to the publicly available deCODE Genealogical Database by issuance, by deCODE, on an individual request basis only, of a user name and a unique password. This password allows that individual to search only for his or her relationship to any other Icelander of whom he or she knows the necessary identity (the Icelandic personal identifier or name and birth date). For the purpose of genetic research, deCODE's Genealogical Database is encrypted with the same key as the medical and genetic information of research projects at deCODE. In relation with the Health Sector Database, deCODE's Genealogical Database will be triple-coded with the same encryption keys as the Iceland Health Sector Database. However, this Genealogical Database is not useful for most biomedical research, as it, alone, does not contain genetic information.

Background: Genetical Committee of the University of Iceland Genealogical Database

The Genetical Committee of the University of Iceland was launched in the 1960s with funds from the U.S. Atomic Energy Commission and serves as a nonprivate source of genealogical information for researchers such as the Iceland Genomics Corporation. The main objective of the Genetical Committee is to link the demographic data of Icelanders born since 1840 into pedigrees for genetic studies. Information within this database is obtained from the Iceland National Registry and from biological data contained in other records (e.g., paternity tests).

Status and Availability: Genetical Committee of the University of Iceland Genealogical Database

The Genealogical Database of the University of Iceland is used for research, and the Data Protection Authority recently approved its use for genetic counseling. This database contains records on members of the Icelandic population from the 1800s to the present. It is based on the 1910 national census, birth records, and death certificates. The Genealogical Database also contains the best available public information from paternity tests. To obtain information from

the Genealogical Database of the University of Iceland, a researcher, with approval from an Icelandic ethics review board and the Data Protection Authority, is permitted to submit a request to the Genetical Committee for information needed for the research. For example, a researcher may submit to the Genealogical Database, through the Genetical Committee, the names and Icelandic identifier numbers of proposed research subjects. The Genealogical Database then would return to the investigator information about the relativity between these individuals. The fee for obtaining genealogic information about individuals in this database is based on the number of individuals about whom information is sought. For a foreign researcher, requests for such information can be made either through a collaborator in Iceland or through the University of Iceland.

Human Subjects Protections

Roles of Ethics Review Boards, the National Bioethics Committee, and the Data Protection Authority

To use either the deCODE Genealogical Database or the University of Iceland Genealogical Database for research purposes, the protocol and need for personal data generally are reviewed by an Icelandic ethics review board and the Data Protection Authority.

Assessment From the U.S. HHS Office for Human Research Protections⁹

The information in deCODE's Genealogical Database and the Genealogical Database of the University of Iceland appears to be "private" information since there are restrictions on how this information may be used and shared. Therefore, investigators' use of this identifiable private information from living individuals would constitute human subjects research under the HHS regulations at 45 CFR part 46. However, as noted with regard to the Icelandic biobanks, research using coded material would not ordinarily be considered human subjects research if, for example, the investigator received only coded samples and a written agreement, obtained from the holder of the identifiable information related to the samples, states that identifiable information will not be released to the recipient-investigator under any circumstance.

Furthermore, under 45 CFR 46.101(b)(4), an institution or IRB is permitted to determine that research involving human subjects is exempt from the requirements of the HHS regulations if (1) the human subjects research involves only the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens (all data and specimens must be existing at the time the research is proposed) and (2) these sources are publicly available, or the information is recorded by the investigator in such a manner that the subjects cannot be identified, either directly or through identifiers linked to the subjects.

⁹ The OHRP's assessment of deCODE's Genealogical Database is based on the description contained within this section of the report, instead of the description provided in the March 12, 2002, letter from NIH to Dr. Greg Koski.

Opportunities for Collaboration

Many Icelandic researchers in academic, nonprofit, and corporate organizations are interested in collaborating with U.S. researchers. Such collaborations may include the study of Icelandic biological specimens or of Icelandic residents who volunteer for research. International research involving the participation of Icelanders requires collaboration with an Icelandic specialist in the field. In addition, such research also would undergo review by the National Bioethics Committee—and the Data Protection Authority, if the research involves personal data.

Potential Partners for Collaboration

There are many opportunities for collaboration with Icelandic research groups and biobanks, including the following:

The Iceland Genomics Corporation uses population surveys of cancer, clinical information, tissue samples, patient DNA, and genealogies to look for genes affecting cancer. Its research entails merging pedigree information from the Genealogical Database of the Genetical Committee of the University of Iceland with clinical and genetic information. It currently collaborates with the NIH National Cancer Institute's Division of Cancer Epidemiology and Genetics.

Contact information:

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E-mail: gunnlaugurg@uvs.is
URL: www.uvs.is/eng/scitech/icp.html

The Icelandic Cancer Society runs the Icelandic Cancer Registry and Molecular and Cell Biology Laboratory. The Cancer Registry has information on all cancers diagnosed in Iceland since 1955. Among registered items are information about the site of the tumor, morphology, year of diagnosis and age of the patient, and information on the cause of death—mostly from the pathology report. The Molecular and Cell Biology Laboratory runs the biobank (application pending) of the Icelandic Cancer Society; the biobank contains tissues and associated information. It currently receives funding from the U.S. Army for breast cancer research aimed at all Icelanders with diagnoses of breast cancer and their relatives. Although the Icelandic Cancer Society is awaiting a decision on its pending biobank application, there are other opportunities for collaboration. Information on applying for information from the Icelandic Cancer Registry is available at www.krabb.is/cancer/icsreg2.htm.

Contact information:

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P.O. Box 5420
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Fax: +354-540-1910
E-mail: laufeyt@krabb.is
URL: www.krabb.is/cancer

The Department of Pathology at the Landspítali – University Hospital in Reykjavík has a licensed biobank. The Department stores tumor tissues from more than 200,000 individuals, dating from 1935 to the present. Included in this collection are 2,000 fresh-frozen cancer specimens, with the remaining specimens preserved mainly in paraffin. Those wishing to collaborate should contact the biobank chair.

Contact information:

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Tel: +354-543-8351/8068
Fax: +354-543-8349
E-mail: mariajen@landspitali.is
URL: www4.landspitali.is/lsh_ytri.nsf/htmlpages/index.html

The Icelandic Heart Association, a nonprofit organization founded to improve the cardiovascular health of the Icelandic population, established the Reykjavík Study in 1967, a longitudinal risk factor cohort of 30,000 persons. In 2001 the Icelandic Heart Association began a followup to the Reykjavík study in collaboration with the NIH's National Institute on Aging, National Eye Institute, National Institute on Deafness and Other Communication Disorders, and National Heart, Lung, and Blood Institute. This followup is a large-scale longitudinal study focusing on cognition, cardiovascular health, musculoskeletal conditions, and metabolic disease. The Icelandic Heart Association also has participated in other clinical cardiovascular studies and cohort studies, including those involving the offspring of the original Reykjavík Study cohort. Information on developing new or additional collaborations with the Icelandic Heart Association can be obtained from its director.

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deCODE Genetics, Inc., owns the Genealogical Database and is involved in several phases of clinical research, from preclinical studies to clinical trials. deCODE uses medical, genotypic, and genealogical information from 80,000 consenting research subjects to find genes affecting common diseases and develop drugs and diagnostics. On the basis of this number of subjects, deCODE can generate data for diseases with a penetrance greater than 0.2 percent.

Using its data integration and statistical analysis expertise, deCODE can process 30 million genotypes per month. It has the capability, and informed consent of subjects, to link its Genealogical Database with the genotypic information in its private database, which contains

genetic information from 80,000 research participants. Using these databases, deCODE is investigating genes that contribute to several conditions, including:

| | |
|---------------------------------------|----------------------------------|
| Breast cancer | Longevity |
| Prostate cancer | Age-related macular degeneration |
| Parkinson's disease | Rheumatoid arthritis |
| Essential tremor | Osteoarthritis |
| Alzheimer's disease | Non-insulin-dependent diabetes |
| Schizophrenia | Obesity |
| Asthma | Osteoporosis |
| Atopy | Stroke |
| Anxiety | Myocardial infarction |
| Chronic obstructive pulmonary disease | Familial combined hyperlipidemia |
| Peripheral arterial occlusive disease | Hypertension |
| Psoriasis | Preeclampsia |
| Migraine | |

Contact information:

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E-mail: kstefans@decode.is
URL: www.decode.com

The Genetical Committee of the University of Iceland operates a Genealogical Database that is available for research. This database contains information on Icelandic genealogy from public and biological records (e.g., paternity records) dating from the 1800s to 1995. Additional information about this research resource can be obtained from the University of Iceland.

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E-mail: margreto@landspitali.is
URL: www4.landspitali.is/lsh_ytri.nsf/htmlpages/index.html

Protocol Review Requirements for Collaboration

Researchers supported by, or conducting research within, the HHS who are seeking to use Iceland's research resources will need to consider U.S. requirements for research involving human subjects in addition to those required by Iceland. Table 1 summarizes the reviews that generally will be conducted by the Icelandic National Bioethics Committee, ethics review boards at health institutions, and the Data Protection Authority. It is important to note that, unlike in the United States, decedents are considered human subjects in Iceland.

Researchers requesting protocol review by the National Bioethics Committee can find the application form and instructions at <http://www.visindasidanefnd.is/>.

Table 1. Reviews To Be Conducted by the National Bioethics Committee, Ethics Review Boards, and the Data Protection Authority

| Type of Research | Icelandic Review Body | | | U.S. Review |
|---|------------------------------|-------------------------------------|---------------------------|---|
| | National Bioethics Committee | Health Sector Database Review Board | Data Protection Authority | Institutional Review Board, if study is conducted or supported by HHS or conducted under an applicable OHRP-approved assurance |
| U.S. collaborative research, not involving clinical information, genetic information, or biobanks with personal information | Yes | No | No | Yes, if the individuals are living and the information is individually identifiable and private, unless research meets conditions for exemption under 45 CFR 46.101(b)(4) |
| U.S. collaborative clinical research (such as a clinical trial) involving human subjects | Yes | No | Yes | Yes, probably, unless research meets conditions for exemption under 45 CFR 46.101 |
| U.S. collaborative genetic research involving biobanks and personal information (nonclinical) | Yes | No | Yes | Yes, if the individuals are living and the information is individually identifiable and private, unless research meets conditions for exemption under 45 CFR 46.101(b)(4) |
| U.S. research on decedent clinical data | Yes | No | Yes | No |
| U.S. access to/receipt of identifiable tissues in biobanks for research | Yes | No | Yes | Yes, if the individuals are living, unless research meets conditions for exemption under 45 CFR 46.101(b)(4) |

Table 1. Reviews To Be Conducted by the National Bioethics Committee, Ethics Review Boards, and the Data Protection Authority (continued)

| Type of Research | Icelandic Review Body | | | U.S. Review |
|---|------------------------------|-------------------------------------|---------------------------|---|
| | National Bioethics Committee | Health Sector Database Review Board | Data Protection Authority | Institutional Review Board, if study is conducted or supported by HHS or conducted under an applicable OHRP-approved assurance |
| U.S. query (not as part of a research protocol) to the Iceland Health Sector Database | No | Yes | Possibly | No |
| U.S. research protocol involving only the Iceland Health Sector Database | Yes | Yes | Probably | No |
| Research involving the Genealogical Databases | Yes | No | Yes | Yes, if the individuals are living and the information is individually identifiable and private, unless research meets conditions for exemption under 45 CFR 46.101(b)(4) |

The NIH welcomes comments or questions from U.S. researchers about this report. Please direct inquiries to:

Office of Science Policy and Planning
Office of Science Policy
National Institutes of Health
9000 Rockville Pike
Building 1, Room 218
Bethesda, MD 20892
U.S.A.
Tel: 301-496-1454
Fax: 301-402-0280

Appendix A: Letter of Intent Between the U.S. National Institutes of Health and the Icelandic Ministry of Health and Social Security

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Letter of Intent
Between
The National Institutes of Health
of the United States of America
and
The Ministry of Health and Social Security
of the Government of Iceland

The U.S. National Institutes of Health and the Icelandic Ministry of Health and Social Security intend to work to strengthen cooperation in the fields of biomedical and behavioral sciences, and related training, subject to the availability of resources.

Among the areas of mutual interest are cancer; cardiovascular disease; infectious diseases; aging research; mental health and addictive disorders such as alcoholism; women's health; and Arctic research. In addition, both sides intend to work in partnership and within the missions of their respective agencies to advance efforts that reduce global health disparities.

Mechanisms to support collaboration may include:


- Organization and conduct of workshops;
- Identification of training opportunities for researchers, including those from developing countries;
- Exchange of scientists;
- Exchange of information;
- Exchange of materials;
- Joint Research Projects
- Other forms of cooperation, including support for developing country scientists in joint U.S.-Iceland efforts, subject to the availability of resources.

Subject to the availability of funds and other resources, and the laws, policies, and regulations of the host and sponsoring countries, the activities under this Letter will be conducted and financed by mutually agreed upon written arrangements. Each side intends to cover the international airfare and subsistence costs of its participants.

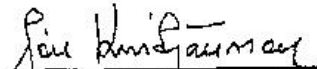
On behalf of Iceland, this Letter of Intent intends to cover cooperative activities undertaken or implemented by public health organizations falling under the Ministry of Health and Social Security. Participation in cooperative activities under this Letter of Intent is also open to other Icelandic scientific and research organizations engaged in related research activities, such as the Icelandic Research Council (RANNIS).

This letter of Intent becomes effective upon signature by the government representatives below.

Signed on 15th day of September 2002 in Reykjavik, Iceland.



The Honorable Tommy G. Thompson
Secretary of Health and Human
Services United States of America



The Honorable Jón Kristjánsson
Minister of Health and Social
Security of Iceland

(Note: This is one of two originals.)

Appendix B: Act on the Rights of Patients (No. 74/1997)

THE PRESIDENT OF ICELAND makes known: The Althing has agreed to this Act and I have confirmed it with my approval:

CHAPTER I

Introduction

Objective

Article 1

The objective of this Act is to ensure specific rights for patients in accordance with general human rights and human dignity and thus strengthen their legal status regarding the health service, and to support the confidential relationship which must exist between patients and health workers. It is prohibited to discriminate against patients on grounds of gender, religion, beliefs, nationality, race, skin colour, financial status, family relation or status in other respect.

Definitions

Article 2

Patient: Any person using the health service.

Health worker: Any person working in the health sector who has been authorized by the Ministry of Health and Social Security to perform such work.

Treatment: A test or examination, operation or other service rendered by a doctor or another health worker to diagnose, cure, rehabilitate, nurse or care for the patient.

Scientific research: Research conducted with the aim to achieve further knowledge, making it, inter alia, possible to improve health and cure diseases. An evaluation of the research made by the scientific ethics committee or an ethics committee, pursuant to Article 29, must have revealed that scientific and ethical views do not oppose its implementation.

Quality of the Health Service

Article 3

The patient has the right to the best health service available at each time. The patient has the right to service relative to his condition and prognosis at each time and the best knowledge available. The health worker shall endeavour to establish a sound relationship with the patient. The patient has the right to continuous service and cooperation between all health workers and institutions involved in the treatment.

Access to Information on the Rights of Patients

Article 4

The Ministry of Health and Social Security shall ensure that information is available concerning the rights of patients, patients' associations and social security schemes. This information shall be made accessible to patients on the premises and places of work of health institutions and self-employed health workers. Furthermore, an endeavour shall be made to inform the public of the causes and consequences of illnesses in children and adults.

CHAPTER II

Information and Consent

Information on Health and Treatment

Article 5

A patient has the right to obtain information regarding:

- a. his state of health, including medical information on his condition and prognosis,

- b. the proposed treatment, as well as information on its course, risks and benefits,
- c. possible remedies other than the proposed treatment and the consequences of lack of treatment,
- d. the possibility of seeking the opinion of another doctor or other health workers, as appropriate, regarding treatment, condition and prognosis.

It shall be entered in the clinical record of the patient that information pursuant to this Article has been provided.

Information pursuant to this Article shall be provided whenever there is reason to do so and in such a manner and under such circumstances that the patient can understand it. If the patient does not understand Icelandic or is dependent on sign language, an interpretation of the information pursuant to this Article shall be provided.

Exemptions from the Principle on Information on Health and Treatment Article 6

Information pursuant to Article 5 shall be withheld if the patient so requests. A patient can appoint another person to receive the information in his place. It shall be entered in the clinical record if the patient declines information on his health and prognosis or appoints another person in his place. The identity of the person receiving the information shall likewise be entered, cf. paragraph 1 of this Article and Articles 7 and 25. If the patient is unable to master the information pursuant to Article 5, the information shall be given to a close relative or, if the patient has been deprived of legal majority, to his legal guardian.

Article 7

The right of the patient to decide whether he will accept treatment shall be respected. The provisions of the Legal Majority Act apply to the consent to treatment of patients who, on account of lack of intelligence or for other reasons provided for by that Act, are incapable of making a decision regarding treatment. In such cases the patient shall nevertheless be consulted to the extent possible. Without prejudice to Article 9, no treatment may be given without the prior consent of the patient, cf. paragraphs 1 and 2. The consent shall be in writing whenever possible and indicate the information the patient has been provided with and that he has understood the information.

Treatment Refused Article 8

If the patient refuses to accept treatment, a doctor shall inform him about the possible consequences of his decision. The patient may discontinue treatment at any time, without prejudice to other laws. If the patient refuses to accept treatment, his doctor or the health worker supervising the treatment shall inform him of the possible consequences of his decision. Article 26 applies to a refusal to allow treatment of sick children. The decision of a patient to refuse to accept or to discontinue treatment shall be recorded in his clinical record and it shall be confirmed that he has received information on the possible consequences of his decision.

Exemptions from the Principle of Consent to Treatment Article 9

If a patient is unconscious or his condition is such that he is unable to express his will regarding urgent treatment, his consent shall be taken for granted unless it is known with certainty that he would have refused to accept treatment.

Consent to Scientific Research Article 10

A patient shall give his formal consent prior to participation in scientific research. Before such consent is given detailed information shall be provided on the scientific research, the possible risks and benefits

involved and what the participation entails. It shall be explained to the patient that he can refuse to participate in scientific research and that he can cease participation at any time after it has commenced. The provisions of Article 15 apply to access to information contained in clinical records, including biological samples, for the purposes of scientific research. It is prohibited to conduct scientific research on a patient which does not fulfill the conditions of Article 2 (4).

Participation in the Training and Instruction of Students
Article 11

The patient must be informed if students in the health sector are to be present during his treatment, as part of their training and instruction. A patient can refuse to take part in such training and instruction.

CHAPTER III
Confidentiality and Professional Secrecy
Professional Secrecy of a Health Worker
Article 12

A health worker shall fully respect the principle of professional secrecy regarding whatever he comes across in the course of his work regarding the health, condition, diagnosis, prognosis and treatment of a patient, as well as other personal information. Professional secrecy continues to apply after the death of a patient and after the worker has left his job. The worker may provide information for urgent reasons, with due regard to the wishes of the deceased and the interests of those concerned. When a worker is in doubt, he can seek the opinion of the Directorate General of Public Health.

Exemptions from the Principle of Professional Secrecy
Article 13

Professional secrecy pursuant to Article 12 does not apply to incidents on which a health worker is obliged to report pursuant to other legal provisions, such as the provisions of the Child Protection Act. In those cases, a worker is obliged to report the incident to the competent authorities. The worker is no longer bound by professional secrecy if the patient or his guardian has consented to it. The provisions of the Doctors' Act shall apply regarding the obligation of a health worker to testify in a court of law.

CHAPTER IV
Handling of Information in Clinical Records
Access to Clinical Records
Article 14

A clinical record shall be kept at the health institution where it is maintained or at the establishment of a doctor or another health worker who maintains it there. A doctor or another person maintaining a clinical record is obliged to show it to the patient, or his agent, in full or in part, and to give them a copy, if they so request. The same applies to official bodies which according to law examine complaints of patients or agents regarding treatment. It is permitted to charge for a copy of a clinical record according to the provisions of Article 12 of the Information Act.

Information contained in a clinical record, given by a person other than the patient himself or a health worker, shall not be shown to the patient without the consent of the informant. If the informant is deceased or has disappeared or refuses unjustly to give his consent, the Directorate General of Public Health can determine that the patient or his agent shall be given access to the information in question, in full or in part. If a doctor considers that it does not serve the interest of the patient to give the aforementioned parties a copy of the clinical record, the copy must be forwarded to the Directorate General of Public Health immediately for further consideration.

The Directorate General of Public Health shall determine within eight weeks whether the person concerned shall obtain a copy of the clinical record. A refusal from the Directorate General of Public Health is subject to a review by the Minister for Health.

The Minister shall lay down further rules on the delivery and safekeeping of clinical records, after obtaining proposals from the Directorate General of Public Health and the Icelandic Medical Association.

Article 15

It shall be kept in mind, regarding access to clinical records, that they contain delicate personal information of a confidential nature, cf. Article 12. Clinical records must be kept in a safe place and access restricted to those workers who must use them. 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, including biological samples, for the purposes of scientific research, provided that the research meets the conditions for scientific research, cf. Article 2 (4) of this Act. Such access may be subject to conditions considered necessary at each time. Every time a clinical record is examined for the purposes of scientific research, this shall be entered in the record, in keeping with paragraph 1 and 2.

Comments on Information in the Clinical Record

Article 16

If the information in the clinical record is considered wrong or misleading by a patient, or his agent, his comments shall be attached to the record.

CHAPTER V

Treatment

Respect for the Human Dignity of the Patient

Article 17

Health workers, or other individuals who on account of their work have to communicate with the patient, shall treat him with respect. Only those directly involved in the treatment of a patient shall participate in it. A health worker shall take care to administer the necessary treatment out of sight of uninvolved persons, and to ensure that information regarding treatment is inaccessible to individuals other than the health workers involved.

Waiting for Treatment

Article 18

If a patient has to wait for treatment, the doctor concerned shall explain the reasons for the delay and provide him with information on the estimated waiting time. If it is possible to receive the necessary treatment sooner elsewhere, the patient must be made aware of the fact.

Order of Priority

Article 19

If it is necessary to place patients waiting for treatment in order of priority, the order should be based on medical grounds first and foremost and other professional criteria, as the case may be.

Choice of a Health Worker

Article 20

Although the country is divided into health regions in accordance with the Health Service Act, a patient has the right to go to the doctor most convenient for him. A patient also has the right to seek the opinion of another doctor regarding diagnosis, treatment, condition and prognosis. The same applies in regard to other health workers.

The Patient's Responsibility for His Own Health

Article 21

A patient is responsible for his own health as far as he is able and his state of health permits. He shall, as the case may be, participate actively in the treatment he has consented to.

Rules on Admission and Discharge
Article 22

When a patient is admitted to a health institution, the health workers attending to him shall introduce themselves and their respective fields of work. Furthermore, he shall be informed about the relevant main rules and practices in force in the institution.

The patient shall be informed about the identity of the doctor who is in charge of his treatment in the health institution.

Before the patient is discharged, his circumstances shall be looked into and adequate home service or other remedies provided, as far as possible. On discharge from a health institution a patient shall be given, as is deemed necessary, instructions on important matters regarding follow-up, such as drug administration, diet, training and exercise. The instructions shall be in writing if requested. Medical discharge letters and certificates issued in relation to illness, accidents, hospitalization etc. shall be seen to without undue delay.

Easing of Suffering and Presence of Family and Friends
Article 23

The patient's suffering shall be eased to the best of current ability. A patient has the right to receive support from his family, relatives and friends during his treatment and stay. Furthermore, the patient and his closest relatives have the right to spiritual, social and religious support.

Treatment of Dying Patients
Article 24

A patient has the right to die with dignity. If a dying patient expresses clearly that he declines further life-prolonging treatment, or resuscitation efforts, his doctor must respect his decision. If a dying patient is mentally or physically too ill to decide on his treatment, the doctor shall endeavour to consult the relatives of the patient and his colleagues before he decides on the continuation or termination of treatment.

CHAPTER VI
Special Rules Concerning Sick Children
Information on the Health and Treatment of Sick Children
Article 25

If a patient is under 16 years of age, information pursuant to Article 5, as well as other information pursuant to this Act, shall be given to parents. Sick children shall be given information with regard to their age and maturity. However, they have the same right as others to decline information, cf. Article 6.

Consent to the Treatment of Sick Children
Article 26

Parents who have custody of the child shall give their consent to the necessary treatment of a patient under 16 years of age. Sick children shall be consulted as far as possible and always if they are over 12 years of age. If a parent who has custody of the child refuses to consent to the necessary treatment, cf. paragraph 1, a doctor or another health worker shall contact child welfare authorities, cf. the provisions of the Child Protection Act. If there is not enough time to seek the assistance of child welfare authorities, cf. paragraph 2, as the sick child is in need of acute life-sustaining treatment, the child's health must be the determining factor and the necessary treatment must be started immediately.

Miscellaneous Rules Concerning Sick Children
Article 27

Everything possible must be done to enable a sick child to develop and enjoy life, in spite of illness and medical treatment, depending on the child's state of health. Children shall be spared unnecessary tests and operations. Sick children staying in a health institution are entitled to the presence of their parents or other

close relatives, who shall be provided with facilities, as far as possible. The situation permitting, siblings and friends can visit a sick child in a health institution. Sick children of school-age shall be provided with tuition suited to their age and state of health. Surroundings and care of sick children in health institutions shall be suited to their age, maturity and condition.

CHAPTER VII

Right to Complaint

Comments and Complaints about Treatment

Article 28

The patient's comments regarding the service of a health institution shall be directed to the central administration of the institution concerned. If a patient wishes to make a complaint about his treatment, he may lodge his complaint with the Directorate General of Public Health or the Committee on Dispute Settlement, cf. Article 3 (5) of the Health Service Act No. 97/1990. Employees of health institutions are under obligation to guide a patient, or his relative, who wishes to forward his comments or make a complaint. Furthermore, the management of a health institution is obliged to look into comments of workers who believe that the rights of patients are being infringed on. A patient shall receive a reply to his comments and complaints in writing at the earliest opportunity.

CHAPTER VIII

Provisions Regarding Entry into Force etc. The Minister's Power to Issue a Regulation

Article 29

The Minister shall issue a regulation on scientific research in the health sector. It shall, inter alia, contain provisions on a scientific ethics committee and ethics committees, pursuant to Article 2 (4). Furthermore, the Minister is empowered to issue a regulation on the implementation of this Act.

Entry into Force

Article 30

This Act shall enter into force on 1 July 1997.

Done at Bessastaðir, 28 May 1997.

Ólafur Ragnar Grímsson
(L.S.)

Ingibjörg Pálmadóttir.

Appendix C: Act on a Health Sector Database (No. 139/1998)

SECTION I General terms

Art. 1 Objectives

The objective of this legislation is to authorise the creation and operation of a centralised database of non-personally identifiable health data with the aim of increasing knowledge in order to improve health and health services.

Art. 2 Scope

This legislation extends to the creation and operation of a centralised health sector database. The legislation does not apply to the medical record systems of individual health and research institutions, data collections made in connection with scientific research into individual diseases or groups of diseases, nor to records kept by health and social security authorities on users of the health service and operation of the health service. The legislation does not apply to the storage or handling of, or access to, biological samples.

Art. 3 Definitions

In this legislation the following definitions apply:

1. Health sector database: A collection of data containing information on health and other related information, recorded in a standardised systematic fashion on a single centralised database, intended for processing and as a source of information.
2. Personal data: all data on a personally identified or personally identifiable individual. An individual shall be counted as personally identifiable if he can be identified, directly or indirectly, especially by reference to an identity number, or one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.
3. Non-personally identifiable data: data on a person who is not personally identifiable as defined in clause 2.
4. Coding: the transformation of words or numbers into an incomprehensible series of symbols.
5. One-way coding: the transformation of words or series of digits into an incomprehensible series of symbols which cannot be traced by means of a decoding key.
6. Health data: information on the health of individuals, including genetic information.
7. Genetic data: any data; of whatever type, concerning the hereditary characteristics of an individual or concerning the pattern of inheritance of such characteristics within a related group of individuals. It also refers to all data on the carrying of any genetic information (genes) in an individual or genetic line relating to any aspect of health or disease, whether present as identifiable characteristics or not.

SECTION II Licence and committee on the creation and operation of a health sector database

Art. 4 Grant of operating licence and payments by licensee

The creation and operation of a health sector database are only permitted to those who have an operating licence by the terms of this legislation.

When an application has been received, the Minister of Health may grant an operating licence to create and operate a health sector database subject to the further terms of this legislation.

The licensee shall pay a fee for the grant of the licence in order to meet the costs of preparing and issuing the licence. The licensee shall also pay a yearly fee equivalent to the costs of the work of the committee under the terms of Art. 6, and other costs pertaining to service and monitoring of the operation, including

monitoring by the Data Protection Commission under the terms of legislation on the recording and handling of personal data, and costs of publication and publicity cp. Art.8.

The licensee shall pay all costs of processing information for entry onto the database, cp. Clause 8, Art 5. The minister and licensee may agree on further payments to the Treasury, which shall be devoted to promoting the health service, research and development.

Art. 5 Conditions of licence etc.

An operating licence for the creation and operation of a health sector database is contingent upon the following conditions:

1. The database must be located exclusively here in Iceland.
2. Technical, security and organisational standards meet the requirements of the Data Protection Commission.
3. The recording and processing of health data shall be carried out by, or under the supervision of, people who are professionally qualified in the health sector.
4. Detailed information shall be available on the area of activity and projects of the applicant for a licence.
5. A detailed work plan from the applicant shall be available, which shall fulfil the conditions and objectives of this Act regarding working arrangements and progress.
6. The operation of the database shall be financially separate from the licensee's other business.
7. The Ministry of Health and Social Security and the Director General of Public Health shall at all times have access to statistical data from the database in accessible form, so that they will be of use in statistical processing for compiling health reports and planning, policy-making and other projects of the parties specified.
8. The licensee shall pay all costs of processing data from health institutions and self-employed health workers for entry onto the database. The data shall be processed in a manner that fulfils the needs of the relevant institution or self-employed health worker for a standardised information system, the needs of medical specialist fields and the requirements of health authorities, cp. Clause 7, and so that it can be used in scientific research.
9. The licence shall be temporary, and it shall not be granted for more than 12 years at a time.
10. The licensee shall hand over to the committee cp. art. 6 a copy of the database, which shall be updated regularly, to be further specified in the licence. A copy of the database shall always be stored in a bank safety deposit box, or in some other secure manner, to be further specified in the licence.
11. The licensee shall ensure that after the expiry of the period of the licence, the Minister of Health and Social Security, or the party assigned by the Minister to operate the database, shall receive indefinite use of all software and right required for the maintenance and operation of the database.

The Minister may make the licence subject to further conditions than those specified above.

At the end of the period of the licence by the terms of the licence, the Minister shall make a decision on the operation of the database, after receiving the opinion of the committee cp. art. 6 and the Data Protection Commission. The same applies if the licence is revoked or if the licence is withdrawn from the licensee by the terms of this legislation.

The licence and database under the terms of this legislation cannot be transferred, nor can they be subjected to attachment for debt. Neither the licence nor the database may be used as collateral for financial liabilities.

Art. 6. Committee on the creation and operation of a health service database

The Minister shall appoint a committee on the creation and operation of a database under the terms of this legislation. The committee shall comprise three people and three substitutes, appointed for four years at a time. One shall be a health sector worker with a knowledge of epidemiology, another shall have knowledge of information technology and/or computer science, and the third shall be a lawyer, and shall chair the committee. Their substitutes shall fulfil the same conditions.

The role of the committee is to ensure that the creation and operation of the database are in keeping with the terms of this legislation, regulations made on the basis of the legislation, and conditions laid down in the operating licence, in so far as this does not fall within the ambit of the Data Protection Commission. The committee shall supervise the negotiation of contracts between the licensee on the one hand and

health institutions and self-employed health workers on the other. It shall protect the interests of health authorities, health institutions, self-employed health workers and scientists in the drawing up of agreements. The sum to be paid by the licensee under the terms of para.3 art. 4. shall be negotiated by the committee, as shall recompense in the form of access to data from the database for health institutions, self-employed health workers and their staff for purposes of scientific research.

The committee shall advise the Ministry of Health and the Director General of Public Health on the utilisation of data from the database. Should the operating licence be revoked or the licence withdrawn from the licensee, the database shall be operated by the committee until the Minister has reached a decision on its long-term operation, cp. Para. 3, Art. 5.

The committee shall be provided with staff and working facilities. The committee shall seek specialist assistance as deemed necessary.

The committee shall inform the Minister and the Data Protection Commission without delay if it believes that there is some defect in the operation of the database.

The committee shall, no later than 1 March each year, submit a report to the Minister on the operations of the past year

SECTION III Collection of information

Art. 7

Access to data from health records

With the consent of health institutions or self-employed health workers, the licensee may be provided with data derived from medical records for entry onto a health sector database. The health institutions shall confer with the physicians' council and specialist management of the relevant institution before contracts are concluded with the licensee.

In the handling of records, other data and information, the conditions deemed necessary by the Data Protection Commission at any time shall be complied with. Personal identification shall be coded before entry on the database, so that it is ensured that the licensee's staff work only with non-personally identifiable data. The staff of the relevant health institution or self-employed health workers shall prepare the data for entry on the health-sector database. Health data shall be transferred in coded form in order to ensure their security. Personal identification shall be coded one-way, i.e. by coding that cannot be traced using a decoding key. The Data Protection Commission shall carry out further coding of personal identification, using those methods that the commission deems to ensure confidentiality best.

With regard to access to data from medical records, this shall otherwise be subject to the Acts on the rights of patients, on physicians, on the health service and on the recording and handling of personal data.

Art. 8

Rights of patients

A patient may request at any time that information on him/her not be entered onto the health-sector database. The patient's request may apply to all existing information on him/her or that which may be recorded in the future, or to some specific information. Such a request must be complied with. The patient shall inform the Director General of Public Health of his/her wish. The Director General of Public Health shall produce forms for giving such notice, and shall ensure that these are available at health institutions and at the premises of self-employed health workers. The Director General of Public Health shall ensure that a coded register of the relevant patients is always accessible for those who carry out the entry of data onto the health-sector database.

The Director General of Public Health shall ensure that information on the health-sector database and on the rights of patients cp. para. 1 shall be accessible to the public. Health institutions and self-employed health workers shall have this information available to patients on their premises.

SECTION IV
Access to the database and utilisation of data, etc.

Art. 9
Access by health authorities to data on the health-sector database

The Ministry of Health and Director General of Public Health shall always be entitled to statistical data from the health sector database so that it may be used in statistical processing for the making of health reports and planning, policy-making and other projects of these bodies. This information to the specified parties shall be provided free of charge.

Art. 10.
Utilisation of the health sector database

Data recorded or acquired by processing on the health-sector database may be used to develop new or improved methods of achieving better health, prediction, diagnosis and treatment of disease, to seek the most economic ways of operating health services, and for making reports in the health sector. The licensee shall be authorised to process data on the health sector database from the health data recorded there, provided that data are processed and connected in such a way that they cannot be linked to identifiable individuals. The licensee shall develop methods and protocols that meet the requirements of the Data Protection Commission in order to ensure confidentiality in connecting data from the health-sector database, from a database of genealogical data, and from a database of genetic data. With regard to linking the data on the health-sector database with other databases than those specified here, the Act on recording and handling of personal data shall apply. It is not permissible to give information on individuals, and this shall be ensured e.g. by limitation of access. The licensee may not grant direct access to data on the database. The licensee is authorised during the period of the licence to use the data on the database for purposes of financial profit, under the conditions laid down in this legislation and the licence. The health service database may not be transported out of Iceland, and processing of it may only be carried out here in Iceland.

Art. 11
Confidentiality

Employees of the licensee, including contractors, are bound by an obligation of confidentiality on matters that they become aware of in their work which should remain confidential, by law or by their nature. They shall sign an oath of confidentiality before they begin work. The obligation of confidentiality remains in force, even if employment ceases.

SECTION V
Monitoring

Art. 12
Monitoring of the creation and operation of a health-sector database

The Data Protection Commission shall monitor the creation and operation of the health sector database with regard to recording and handling of personal data and the security of data on the database, and is responsible for monitoring compliance with conditions laid down by the commission.

The committee on the operation of the database, cp. Art. 6, shall be responsible for monitoring the compliance in every way of the activities of the health sector database with the terms of this legislation, regulations issued under the terms of this legislation, and the conditions of the licence. The committee shall monitor all questions to and processing from the database. It shall regularly send to the Science Ethics Committee a record of all questions processed on the database, together with information on the enquirers.

The minister shall issue regulations on an interdisciplinary ethics committee which shall assess studies carried out within the licensee's company and questions which are received. The committee's evaluation must reveal that there is no scientific or ethical reason to prevent the study in question being carried out, or the questions processed from the database.

SECTION VI Penalties

Art. 13 Revocation of licence

The Minister may revoke the licence under the terms of this legislation if the licensee or the licensee's employees violate the terms of legislation, if the conditions of the licence are not fulfilled, or if the licensee becomes unable to operate the database. Should the licensee violate the terms of this legislation or not comply with the conditions of the licence, the Minister shall give the licensee a written warning, allowing a reasonable period of grace to rectify matters. Should the licensee not comply with such a warning, the licence shall be revoked. In the case of deliberate violation or gross negligence, the Minister may revoke the licence without notice and without allowing time for rectification.

Art. 14 Penalties

Violation of the terms of this legislation entails fines or imprisonment for up to three years, unless a more severe penalty is prescribed in other legislation.

The same penalties apply to failure to comply with the conditions for granting of an operating licence under the terms of this legislation, or government regulations under the terms of the legislation, or failure to comply with a command or prohibition under the terms of the legislation, or government regulations under the terms of the legislation.

A legal entity may be sentenced to pay fines due to violation of this Act or regulations based on it. A legal entity may be fined regardless of the guilt of its employees. The legal entity shall be responsible for payment of a fine imposed upon an employee of the legal entity, provided that the offence is connected to the employee's work for the legal entity.

Art. 15 Withdrawal of licence etc.

The licensee may, in addition to the penalties specified in Art. 14, be subject to revocation of the licence by legal verdict, in the case of deliberate violation or gross negligence.

Equipment which has been used for serious violation of this legislation may be confiscated, together with the profits of the violation, cp. Art. 69 of the Penal Code no. 19/1940.

Art. 16

Attempted violation, and participation in violation, of this legislation are subject to penalties as stated in section III of the Penal Code, no. 19/1940.

Art. 17 Compensation

Should the licensee, an employee of the licensee or a person assigned to process data violate the provisions of this Act with regard to confidentiality, regulations issued on the basis of them, or the conditions laid down by the Data Protection Commission, the licensee shall compensate the person to whom the data relate for financial loss which this has caused.

The licensee, however, is not obliged to compensate for loss which the licensee proves not to be attributable to a mistake or negligence on the licensee's part, or that of an employee or processor.

SECTION VII
Various provisions

Art. 18
Regulations

The Minister may prescribe further terms on the practice of this Act by issuing regulations.
The Minister shall issue regulations on the activity of the committee on operation of a health sector database under Art. 6, and on limitation of access under para. 2 art. 10.

Art. 18
Enactment

This Act shall take force immediately.
This Act shall be reviewed no later than 10 years after its enactment.

Provisional clauses

I

The licensee's licence fee under para. 3, Art. 4 shall for the first year be based upon estimated costs pertaining to the preparation and monitoring of the operations of the health sector database.

II

The entry of data onto the health-sector database shall not commence until six months after the enactment of this Act.

III

Before processing begins on the health-sector database, the committee on the operation of the database cp. art. 6 shall ensure that the assessment of an independent expert on the security of information systems has been sought.

**Passed by the Alþingi
17 December 1998.**

Appendix D: Regulation on Scientific Research in the Health Sector (No. 552/1999)

Article 1

The Minister of Health and Social Security shall establish a National Bioethics Committee comprising five people, appointed for a period of four years at a time, to deal with scientific research in the health sector. One member of the committee shall be appointed by nomination of the Minister of Education and Culture, one by nomination of the Minister of Justice, and one by nomination of the Director-General of Health. Two members shall be appointed by the Minister of Health and Social Security without prior nomination, and one of these two shall chair the committee. Substitutes shall be nominated in the same way. Care shall be taken to ensure that the committee is manned by people with specialist knowledge in the fields of health sciences, scientific ethics and human rights.

Article 2

In the National University Hospital, the Reykjavík Hospital and the Akureyri Central Hospital, interdisciplinary ethics committees shall be appointed by the boards of the respective hospitals. One member of the committee shall be appointed by the Director-General of Health, and shall have no connection to the relevant hospital. Within the health care service, an ethics committee of three people shall be appointed by the Minister of Health and Social Security for a term of four years. One of the committee members shall be appointed by nomination from the Federation of Health Care Centres, one by nomination of the Director-General of Health, and one without prior nomination, who shall chair the committee. Substitutes shall be appointed in the same way.

Article 3

Ethics committees as provided in art. 2 shall evaluate plans for scientific studies to be conducted by the relevant parties.

Ethics committees as provided in Art. 2 shall communicate their conclusions to the National Bioethics Committee.

The National Bioethics Committee shall evaluate collaborative projects, multinational studies and other plans for scientific studies which do not fall under the aegis of ethics committees as provided in Art. 2.

A request for evaluation shall be accompanied by a detailed protocol, as well as other data which the National Bioethics Committee may require.

The National Bioethics Committee may seek expert opinion when necessary.

Article 4

A scientific study means research conducted with the aim of achieving further knowledge, making it possible, among other things, to improve health and cure diseases.

An evaluation of a scientific study made by the National Bioethics Committee or an ethics committee as provided in Art. 2, must have revealed that there are no scientific and/or ethical grounds to oppose its implementation.

Biological research on human beings shall not be permissible without prior evaluation of possible risks on the one hand, and benefits on the other hand. In such evaluation, the interests of the individual shall invariably be given priority over the interests of science or of society as a whole.

It is prohibited to conduct scientific research on humans without prior approval of the ethics committee as provided in Art. 2 or the National Bioethics Committee as provided in Art. 1.

A participant shall give his/her formal consent prior to participation in a scientific research. Before such consent is given, he/she shall be provided with detailed information on the scientific study, the possible risks and benefits involved and what the participation entails. The information shall be given in such a manner that the participant can understand it. It shall be explained to the participant that he/she can

refuse to participate in a scientific study and that he/she can cease participation at any time after it has commenced.

Article 5

Access to clinical records for the purpose of scientific research is prohibited without prior approval of the Data Protection Commission as provided in Art. 30 of Act No. 121/1989 on the Registration and Handling of Personal Data, and the consent of an ethics committee as provided in Art. 2 or of the National Bioethics Committee.

Scientific research on tissue samples from humans is prohibited without prior consent for the study from an ethics committee as provided in Art. 2 or the National Bioethics Committee as provided in Art. 1.

Registration and processing of personal data is subject to the terms of Act No. 121/1989 on the Registration and Handling of Personal Data.

Article 6

The National Bioethics Committee shall monitor the progress of scientific studies which it has approved. The committee may require the researcher to submit progress reports and results. The National Bioethics Committee may revoke its permit for the study, should the committee believe that the implementation of the study is not consistent with the protocol and data submitted by the researcher, and that the study no longer meets the conditions stated in Art. 4 for approval by the National Bioethics Committee. Should the permit be revoked, the study shall cease immediately. The same rules apply to ethics committees as provided in Art. 2.

Article 7

The Minister establishes rules of procedure for the National Bioethics Committee as provided in Art. 1 after receiving its proposals, and the rules shall also apply to ethics committees as provided in Art. 2, as appropriate.

The rules shall be in accordance with Recommendations of the Committee of Ministers of the Council of Europe for the Member States, the Helsinki Declaration made by the International Medical Association, Recommendations to Guide Doctors in regard to Medical Scientific Research on Humans, and International Ethical Recommendations on Medical Scientific Research on Humans.

Rules regarding controlled pharmaceutical trials on humans shall be in accord with the provisions of Regulation No. 284/1986 on Clinical Research on Medicinal Products and Guidelines on Good Clinical Practices in regard to Pharmacological Trials, in force in the European Economic Area.

The Minister may lay down further rules on the evaluation of specific studies such as genetic studies.

Article 8

The National Bioethics Committee, and ethics committees as provided in Art. 2, shall respect the terms of the Act on Public Administration no. 37/1993 in their decisions. The conclusions of an ethics committee as provided in Art. 2 may be appealed to the National Bioethics Committee.

Article 9

This Regulation is laid down pursuant to the provisions of Article 29, cf. Article 2 para. 4 of Act No. 74/1997 on the Rights of Patients, and it comes into force on publication. From the same time, Regulation no. 449/1997 on Scientific Research in the Health Sector shall cease to apply.

Ministry of Health and Social Security
29 July 1999

Appendix E: Regulation on a Health Sector Database (No. 32/2000)

CHAPTER I General Provisions

Article 1 Scope

This Regulation applies to the creation and operation of a centralised Health Sector Database, cf. Article 2 of Act No. 139/1998 on a Health Sector Database.

Article 2 Definitions

In this Regulation, the following terms shall have the respective meanings indicated below:

Operating Licence: An operating licence for the creation and operation of a centralised Health Sector Database pursuant to Act No. 139/1998 on a Health Sector Database, issued by the Minister for Health and Social Security.

Monitoring Committee: A committee on the creation and operation of a centralised Health Sector Database pursuant to Article 6 of Act No. 139/1998.

Science Ethics Committee: The Science Ethics Committee pursuant to Article 1 of Government Regulation No 552/1999 on scientific health research, cf. Article 29 of Act No.74/1997, on Patients' Rights.

Technology, Security and Organization Terms: The technology, security and organization terms of the Data Protection Commission pursuant to Article 5, Paragraph 1, Sub-Section 2 of Act No. 139/1998 on a Health Sector Database.

Query layer: Software intended to process research or queries in the Health Sector Database.

Query Classes: Specific types of queries which are comparable and processed using the software in the query layer in the Health Sector Database.

Article 3 Assessment of Conditions

The issue of the Operating Licence for the creation and operation of a Health Sector Database is subject to the provisions of Act No. 139/1998 on a Health Sector Database. The Minister for Health and Social Security shall assess whether the conditions laid down in Paragraph 1 of Article 5 of the Act are met before issuing an Operating Licence. Prior to the issue of the Operating Licence the Technology, Security and Organisation Terms of the Data Protection Commission shall be available, cf. Article 5, Paragraph 1, Sub-Section 2 of the Act.

Article 4 Further Conditions in the Operating Licence and Monitoring of Compliance

The Minister may attach further conditions to the Operating Licence beyond the conditions established in Paragraph 1 of Article 5 of the Act. The Minister may set the condition in the Operating Licence that individual work components in the preparation, creation and operation of the Health Sector Database shall not begin until such time as certain conditions further elaborated in the Operating Licence have been met. The Monitoring Committee and Data Protection Commission shall be responsible for monitoring that conditions established in the Operating Licence regarding individual work components are met as further provided in the Operating Licence and in accordance with the division of tasks among the Monitoring Committee and Data Protection Commission pursuant to Act No. 139/1998 and this Regulation.

The Minister may, at a later stage, e.g. on the recommendation of the Monitoring Committee, the Data Protection Commission, the Interdisciplinary Ethics Committee or the Licensee, establish new conditions in addition to the conditions stipulated in the Operating Licence regarding the security of data in the Database, its creation and other aspects in the event of issues or difficulties requiring action.

Article 5

Assessment of an Independent Systems Security Expert

Processing in the Health Sector Database shall not begin until an assessment has been performed by an independent expert on the security of information systems. The Monitoring Committee shall ensure that such an assessment is conducted.

Article 6

Rules on Science Ethics

The collection, transfer and processing of data in the Health Sector Database shall at all times be conducted in full compliance with recognised international rules on science ethics and rules established on their basis and current in Iceland at any time.

CHAPTER II Financial Segregation

Article 7

Segregated Accounts

The operation of the Health Sector Database shall be financially segregated from other activities of the Licensee, cf. Paragraph 2 of Article 14 of the Competition Act No. 8/1993. The operation of the Health Sector Database shall be conducted within a separate operating unit or department, and keep separate accounts. Accounting shall be conducted pursuant to the Act on Financial Accounts. A separate Initial Balance Sheet shall be made. Assets regarded as pertaining to the activities covered by the Operating Licence shall be appraised at market value where possible, or at the replacement value following reasonable depreciation. Liabilities of the activities covered by the Operating Licence shall include only liabilities connected with such activities alone.

Article 8

Pricing of Joint Use and Day-to Day Management

All joint use of the operation subject to the Operating Licence and the competitive operations of the Licensee, such as use of real estate, machinery and human resources, shall be valued at market price on an arm's length basis. In the event that market price is not available, the value shall be based on cost price plus a reasonable mark-up. Similarly, business between the operation subject to the Operating Licence and other departments shall be conducted on an arm's length basis.

When the utilisation of the Health Sector Database has begun, the party responsible for the day-to-day administration of the operation subject to the Operating Licence shall not be responsible for the administration of the departments of the Licensee engaged in competitive activities.

CHAPTER III Collection, Handling and Processing of Information

Article 9

Licensed Health-Care Professionals

The employees of the health institutions in question or self-employed health service workers shall prepare data for transfer to the Health Sector Database and such work shall be performed or managed by employees who are licensed health-care professionals. The handling of health data by the Licensee shall also be performed or managed by personnel who are licensed health-care professionals. Those employees of health institutions and self-employed health service workers who are directly employed in the transfer of health data to the Health Sector Database shall not be involved in the Licensee's operation of the Database. The Operating Licence shall be accompanied by a list of licensed health-care professions at the time of issue of the Operating Licence.

Article 10

Access to Data by Health Authorities

The Ministry of Health and Social Security and the Directorate of Health shall at all times have access to statistical data from the Database, cf. Article 9 of Act No. 139/1998. The data shall be in accessible form and meet the specifications of the health authorities as current at any time.

Article 11
Medical Records System

The Operating Licence shall establish general specifications for medical records systems. The Licensee shall meet all conditions and requirements contained in the specifications of the Operating Licence and also any later requirements and conditions which the Minister may regard as necessary to achieve the objectives of Act No. 139/1998.

Article 12
Patients' Rights

A patient may at any time request that information concerning him is not transferred to the Health Sector Database. A patient's request may involve all information already available on the patient in medical records or which may be recorded, or further specified information. Such a request from a patient shall also be observed after his death.

In the event that a patient wishes to have information on him transferred to the Health Sector Database, despite the fact that a health institution or self-employed health service worker has not entered into an agreement on such transfer of information, the patient shall submit a request to this effect to the Directorate of Health. The Directorate of Health shall ensure that such a request from a patient is carried out.

**CHAPTER IV
Access Control**

Article 13
Access to the Health Sector Database

The Licensee may not grant direct access to the Health Sector Database. Before processing is begun in the Database, the Licensee shall inform the Monitoring Committee which parties in his employ work with the Database, its operation and development of software and which parties in his employ have access to the query layer. Furthermore, their roles and responsibilities shall be defined, as well as their access authorisation. The Licensee shall notify the Monitoring Committee of any intentions to confer responsibilities on new parties pursuant to this provision and ensure that the Security Terms of the Data Protection Commission are strictly observed.

Article 14
Data from the Health Sector Database

Providing information on individuals from the Health Sector Database is prohibited. Only statistical information involving groups of individuals may be provided.

**CHAPTER V
Monitoring Committee**

Article 15
Composition, Staff and Facilities

The Minister for Health and Social Security shall appoint a committee of three members, the Monitoring Committee, for a term of four years to supervise the creation and operation of the Health Sector Database. One member shall be a health sector worker with knowledge in the field of epidemiology, another shall be knowledgeable in the field of information and/or computer science. The third shall be a lawyer and serve as Chairman of the Committee. Alternate members shall be appointed in the same way.

The Committee shall be provided with staff and working facilities. The Committee shall employ a Managing Director with a law degree. The Committee shall seek expert advice as required.

Article 16
Supervision of the Making of Agreements

The Monitoring Committee shall oversee the making of agreements between the Licensee, on the one hand, and health institutions and self-employed health service workers, on the other hand. The Committee shall protect the interests of the public health authorities, health institutions, self-employed health service workers and scientists in negotiating agreements. The negotiating parties shall inform the Committee of

the status of negotiations. Members of the Committee are permitted to attend meetings of the negotiating parties at their discretion.

The Monitoring Committee shall, i.a., ensure co-ordination of the terms of the Licensee's agreements with individual institutions to the extent possible, e.g. as regards processing of health data, design of software, costs and payments.

The Monitoring Committee shall ensure that software for use in standardised recording in health institutions and self-employed health service workers is consistent with the specifications included in the Operating Licence and any later specifications and requirements, cf. Articles 10 and 11 hereof. The Committee shall ensure that the software enables data processing that will meet the needs of individual health institutions and self-employed health service workers for a co-ordinated information system, the needs of specialist fields and the needs of public health authorities for access to statistical data from the Database in accessible form so as to be useful in the preparation of health reports, plans, policies and other projects of these parties. Measures shall also be taken to ensure that the data can be used for scientific research.

Confirmation by the Monitoring Committee of an agreement between the Licensee and individual health institutions or self-employed health service workers is a prerequisite for the validity of the agreement. The parties shall be notified of the Committee's conclusion within two weeks from the time that the agreement was delivered to the Committee for confirmation.

Article 17 Surveillance

The Monitoring Committee shall monitor the day-to-day operation of the Database and ensure that its creation and operation are consistent with the provisions of law, regulations and the Operating Licence to the extent that such is not the role of the Data Protection Commission under law.

Article 18 Access to Data

The Monitoring Committee may require from the Licensee and persons in the employ of the Licensee any information necessary for the Committee to perform its tasks pursuant to Act No. 139/1998, this Regulation and provisions of the Operating Licence.

The Licensee shall ensure, e.g., that the Monitoring Committee always has access to information on all research or queries or classes of queries submitted to the Licensee for processing as well as to information on the research parties and parties submitting queries in a form permitted by the Security Terms of the Data Protection Commission.

The members of the Monitoring Committee and persons directly or indirectly in its employ shall not divulge any confidential information that they acquire in the course of their duty. The confidentiality obligation shall remain in force even when employment ceases.

Article 19 Advice on Use of Data

The Monitoring Committee shall advise the Ministry of Health and Social Security and the Directorate of Health on utilisation of data in the Database.

Article 20 Backup Copies

The Monitoring Committee shall preserve backup copies of the Database in a bank safety deposit box or in some other secure manner. The Backup copy shall be updated regularly pursuant to the further decision of the Committee as new data is entered into the Database. The Operating Licence shall contain further provisions on backing up the Database pursuant to the Technology, Security and Organization terms of the Data Protection Commission.

Article 21 Information to the Science Ethics Committee

The Monitoring Committee shall deliver to the Science Ethics Committee at least once every three months a list of all queries or query classes submitted to the Health Sector Database together with information on the parties submitting the queries, in a form permitted by the Technology, Security, and Organization Terms of the Data Protection Commission.

Article 22

Notification of Impropriety

The Monitoring Committee shall inform the Minister and the Data Protection Commission without delay if the Committee has reason to believe that there is any impropriety in the operation of the Database.

Article 23

Temporary Operation of the Health Sector Database

In the event of revocation of the Operating Licence, or if the Licensee is deprived of the Operating Licence, the Monitoring Committee shall operate the Database in the interests of the public health authorities, health institutions and self-employed health service workers, e.g., in the interests of scientific research, until such time as the Minister has arrived at a decision on its future operation.

The Committee shall submit to the Minister its opinion regarding the continued operation of the Health Sector Database following the expiration of the term of the Licence pursuant to its provisions. The same applies if the Operating Licence is revoked or the Licensee is deprived of his Licence.

Article 24

Report to the Minister

No later than 1 March of each year, the Monitoring Committee shall submit to the Minister a report on the operation of the Health Sector Database and the work of the Committee over the preceding year.

Furthermore, the Committee shall keep a record of its minutes and deliver a copy of the minutes to the Minister following each meeting.

CHAPTER VI

Interdisciplinary Ethics Committee

Article 25

Composition of the Committee and Expert Assistance

The Minister for Health and Social Security shall appoint an Interdisciplinary Ethics Committee of three members for a term of four years. One member shall be appointed pursuant to the nomination of the Directorate of Health; one member shall be appointed pursuant to the nomination of the Minister for Education, and one member shall be appointed by the Minister for Health and Social Security without nomination to serve as Chairman of the Committee. Alternate members shall be appointed in the same manner. Steps shall be taken to ensure that the Committee is composed of individuals with expert knowledge in the field of health sciences, research ethics and human rights. The Committee may summon experts for consultation as necessary.

Article 26

Role

The Interdisciplinary Ethics Committee shall ensure that processing of data in the Health Sector Database is at all times conducted in full compliance with recognised international rules on science ethics and rules established on the basis of such international rules and current in Iceland at any time. The Committee shall base its opinions on those rules.

The Licensee shall submit to the Interdisciplinary Ethics Committee a request for research and individual queries or query classes which are intended for processing using data from the Health Sector Database. This applies to research which is conducted exclusively within the enterprise of the Licensee or in co-operation with other parties. A request pursuant to this provision shall be accompanied by a detailed description and other data pursuant to further provision of the rules of procedure of the Committee. Research, queries or query classes shall not be processed without the prior consent of the Interdisciplinary Ethics Committee.

The Interdisciplinary Ethics Committee shall respond to requests within two weeks of receiving all documents. In the event of unusually extensive research or queries, the Committee may extend this deadline by two weeks.

Article 27

Appeal

Decisions of the Interdisciplinary Ethics Committee may be appealed to the Minister for Health and Social Security. The Minister shall seek the opinion of the Science Ethics Committee before returning a decision.

Article 28

Surveillance and Revocation

The Interdisciplinary Ethics Committee shall monitor the progress of research and processing of queries which it has approved in the Health Sector Database. The Committee may require that the Licensee submit reports to the Committee to enable the Committee to ascertain that work is conducted in accordance with information submitted to the Committee and/or instructions of the Committee on processing.

The Interdisciplinary Ethics Committee may withdraw its permission to use specific classes of research or queries if it is of the opinion that their conduct is not consistent with the documents submitted information submitted to the Committee and/or the instructions of the Committee on their use. If the permission of the Committee is revoked, the research or processing of queries shall be stopped immediately.

Article 29

Rules of Procedure

The Minister shall establish rules of procedure for the Interdisciplinary Ethics Committee pursuant to the recommendations of the Interdisciplinary Ethics Committee and comments of the Science Ethics Committee.

CHAPTER VII

The Data Protection Commission

Article 30

Requirements for Technology, Security and Organisation

The Data Protection Commission shall establish Technology, Security and Organisation terms to be met by the Licensee in the creation and operation of the Health Sector Database.

The Data Protection Commission may review the Technology, Security and Organisation Terms to be met by the Licensee in the light of new technology, experience or changed assessment of the Technology, Security, and Organization Terms, and establish a deadline for the Licensee to comply with the new requirements.

The Licensee shall not make any alterations in matters of Technology, Security and Organisation, including changes in software or hardware, except pursuant to rules established by the Data Protection Commission.

In the event of circumstances where the security of data may be at risk, the Data Protection Commission may prohibit further processing in the Database until such time as the Data Protection Commission is satisfied that data security is adequate.

Article 31

The Data Protection Commission Encryption Agency

The Data Protection Commission shall operate an Encryption Agency which shall carry out the transfer of all data to the Health Sector Database.

Personal identifiers shall be encrypted by one-way encryption at Health Institutions or at the location of self-employed health service workers who have concluded an agreement with the Licensee. Medical data processed by these parties shall be sent in encrypted form to the Encryption Agency of the Data Protection Commission. The Directorate of Health shall provide the Encryption Agency of the Data Protection Commission with an encrypted list of those patients who have requested to be excluded from the Health Sector Database, and the Encryption Agency shall delete all data processed from their medical records. The Encryption Agency of the Data Protection Commission is responsible for further encryption of personal identifiers before the data is sent to the Health Sector Database using methods which in the opinion of the Agency will best ensure personal privacy.

Article 32

Cross-referencing of Data

The Licensee shall establish rules of procedure and work processes which meet the conditions of the Data Protection Commission in order to ensure privacy protection in the cross-referencing of data from the Health Sector Database, a genealogical database and a database containing genetic data.

The Data Protection Commission shall attach such conditions to its approval of the rules of procedure and work processes of the Licensee as it considers necessary at any time to ensure privacy protection and data security in the Health Sector Database. Data from the Health Sector Database shall not be cross-referenced with genetic data unless such data has been obtained in accordance with the rules current in Iceland at any time.

Among the conditions for the approval of the Data Protection Commission is that the results should be non-personally identifiable. If it becomes evident that results obtained from cross-referencing of data are personally identifiable, the Data Protection Commission may withdraw its approval and order the destruction of such results in their entirety or in part. During the course of investigation, the Data Protection Commission may prohibit further cross-referencing of data on the basis of its approval and take custody of the results

In the event that the Licensee does not observe the conditions of the Data Protection Commission on the cross-referencing of data, the Data Protection Commission may revoke its approval pursuant to this provision.

Article 33

Transfer of Medical Data

In order to preserve the security of personal data, the Data Protection Commission may establish rules to be observed during the collection, registration and processing of medical data in the medical records system in preparation for their transfer to the Encryption Agency of the Data Protection Commission. Health Institutions and self-employed health service workers are responsible for the delivery of health data to the Encryption Agency of the Data Protection Commission, and shall observe the conditions established by the Data Protection Commission.

Article 34

Inspections and Monitoring Activities of the Data Protection Commission

The Data Protection Commission is responsible for monitoring the creation and operation of the Health Sector Database as regards the recording and processing of personal data and the security of data in the Health Sector Database.

The Data Protection Commission shall take measures to monitor observance of the conditions established by the Commission.

The Data Protection Commission may inspect the technology, security and organisation aspects of the Health Sector Database whenever necessary. The Data Protection Commission may conduct any test, inspection or take any surveillance action it may regard as necessary and demand the required assistance of the personnel of the Licensee in taking such action.

The Data Protection Commission may require from the Licensee and any of the Licensee's employees any information necessary for the Commission to perform its tasks, including information to determine whether a particular activity falls under the provisions of this Regulation and the Act on a Health Sector Database. The Data Protection Commission may also summon personnel of the Licensee and persons employed by the Licensee to appear before the Commission and provide oral information and explanations.

In the course of its surveillance duties, the Data Protection Commission shall have free access to the premises where the Health Sector Database is preserved and processing takes place.

The Data Protection Commission may, by a special resolution, entrust specific employees and consultants with certain aspects of the work entrusted to the Data Protection Commission pursuant to this Regulation and the Act on a Health Sector Database.

Article 35

Report of the Data Protection Commission

The Data Protection Commission shall advise the Minister on the continued operation of the Health Sector Database following the expiration of the term of the Operating Licence pursuant to its provisions. The same applies if the Operating Licence is revoked or the Licensee deprived of his Licence.

CHAPTER VIII
Disposal of the Health Sector Database Following the End of the Term of the License

Article 36
Disposal and Operation Following the
End of the Term of the Licence

When the term of the Licence expires pursuant to the provisions of the Operating Licence, or if the Licence is terminated for other reasons, the Minister for Health and Social Security shall, on the recommendation of the Monitoring Committee and the Data Protection Commission, decide on the disposal and operation of the Database.

Article 37
Rights to Software, Database and other Rights
Necessary for the Operation of the Database

The Licensee shall ensure that the Ministry of Health and Social Security, or such party as the Minister may entrust with the operation of the Database, is granted, without time limits, the use of all software and rights necessary for the creation and operation of the Health Sector Database, as further provided in the Operating Licence, following the expiration or termination of the Operating Licence.

On the termination or expiration of the Operating Licence the Licensee shall deliver to the Ministry of Health and Social Security, or such party as the Minister may entrust with the operation of the Database, the software, rights and hardware necessary for the creation and operation of the Health Sector Database, as further provided in the Operating Licence.

Article 38
Limitations on Disposal Rights

The Licence and the Health Sector Database are neither assignable nor subject to enforcement of claims. The Operating Licence and the Database may not be pledged against any financial liability.

CHAPTER IX
Payment of Costs

Article 39
Payment of costs, Budget and Procedure in the Event of Disputes

The Licensee shall bear all costs incurred by the Ministry of Health and Social Security, the Monitoring Committee, Data Protection Commission, Interdisciplinary Ethics Committee and Directorate of Health from the tasks assigned to those parties pursuant to Act No. 139/1998 on a Health Sector Database, this Regulation, or the Operating Licence for the creation and operation of a Health Sector Database.

Prior to 15 August of each year, the Ministry of Health and Social Security and the Ministry of Justice, acting on behalf of the Data Protection Commission, shall present to the Licensee their budgets and work plans, referred to in Paragraph 1 of this Article [39], in respect of the activities of the Licensee in the creation and operation of a Health Sector Database in the subsequent operating year. The Licensee shall, before 15 September of each year, submit his comments on such plans if he sees reason to do so.

Following the end of each month the State Treasury shall invoice the Licensee for costs incurred in the preceding month, cf. Paragraph 1 hereof. The Licensee shall pay the invoice within 15 days of its issue. In the event of any dispute regarding payments, the opinion of the National Audit Bureau shall be sought. The opinion of the National Audit Bureau shall be binding on both parties.

Article 40
Costs Pursuant to Agreements

The Licensee shall pay all costs incurred in the processing of data for transfer to the Health Sector Database, as well as the cost of producing an integrated information system for health institutions and self-employed health service workers pursuant to further provisions in agreements [of the Licensee] with health institutions and self-employed health service workers.

CHAPTER X
Confidentiality, Procedural Rules, Further Claims and Conditions Etc.

Article 41
Confidentiality

Parties working for public authorities in the enforcement of Act No. 139/1998 on a Health Sector Database, regulations issued pursuant to that Act or the Operating Licence shall not divulge any matters on which they may obtain information in the course of their work and which are subject to confidentiality. The confidentiality shall remain in force even when work is ceased.

Article 42
Administrative Law

To the extent applicable, the provisions of the Administrative Act No. 37/1993 shall be observed in all procedure pursuant to Act No. 139/1998 on a Health Sector Database, this Regulation and the provisions of the Operating Licence, cf., i.a., the provisions of the Administrative Act on competence, speed of procedure, proportionality, the right to be heard and the publication and revocation of decisions.

Article 43
Further Requirements and Conditions

Through amendment of this Regulation, the Minister may establish further requirements and conditions regarding the creation and operation of a Health Sector Database following the issue of the Operating Licence in the event of any issues arising on which Act No. 139/1998 on a Health Sector Database, this Regulation or the Operating Licence contain no provisions.

Article 44
Effect and Legal Basis

This Regulation, issued on the basis of Article 18 of Act No. 139/1998 on a Health Sector Database, cf. Article 6, Paragraph 2 of Article 10, and Paragraph 3 of Article 12 of the same Act, shall take effect on its publication.

Temporary Provisions Payment of Incidental Costs Prior to the Issue of the Operating Licence and Costs Incurred in the Year 2000

Following the issue of the Operating Licence the costs which can reasonably and fairly be regarded as relating to the preparation and issue of the Operating Licence pursuant to Act No. 139/1998 on a Health Sector Database shall be calculated and the Licensee invoiced for such costs. The Licensee shall have 15 days to comment on the invoice and itemisation of costs if he so chooses. In the event of any dispute regarding individual items the binding opinion of the National Audit Bureau shall be sought regarding the dispute.

The Licensee shall reimburse the State Treasury for all costs pursuant to this Paragraph 1 with six equal monthly payments, the first such payment to be made no later than 45 days after the date of the invoice pursuant to this Article.

Following the end of each month of the year 2000 the Ministry of Health and Social Security shall, in respect of costs incurred by the Monitoring Committee, the Interdisciplinary Ethics Committee and the Directorate of Health and the Ministry of Justice, instruct the State Treasury to collect the accrued costs of the said parties in the preceding month arising from the performance by such parties of the tasks entrusted to them pursuant to Act No. 139/1998 on a Health Sector Database.

The Licensee shall have 15 days to submit his comments on invoices pursuant to Paragraph 3. In the event of disputes regarding individual cost items the binding opinion of the National Audit Bureau shall be sought regarding the dispute.

Ministry of Health and Social Security, 22 January 2000

Ingibjörg Pálmadóttir [sign.]

Davíð Á Gunnarsson [sign.]

Appendix F: Act on Biobanks (No. 110/2000)

SECTION I

General provisions

Art. 1

Objectives

The objective of the Act is to authorise the collection, keeping, handling and utilisation of biological samples from human beings, in such a way that confidentiality is ensured, the interests of donors of biological samples is safeguarded and that the utilisation of the biological samples serves the purposes of science and medicine, and is conducive to the public good.

The interests of science and of the community shall never be given priority over the interests of the donor of a biological sample. It is prohibited to discriminate against a donor of a biological sample on the grounds of data derived from a biological sample.

Art. 2

Scope

This Act applies to the collection of biological samples, and their keeping, handling, utilisation and storage in biobanks.

The Act does not apply to temporary keeping of biological samples taken for purposes of clinical testing, treatment, or for specific scientific study, provided such samples are destroyed when the tests, treatment or research are completed. Temporary keeping means storage for up to five years, unless the National Bioethics Committee authorises a longer period of storage. Should the long-term preservation of such samples be desired, they shall be stored in a biobank.

The Act does not apply to the storage of gametes and embryos under the provisions of the Act on Artificial Procreation, to organs under the provisions of the Act on Organ Removal, or to bodily remains under the terms of the National Heritage Act.

Art. 3

Definitions.

In this Act the following terms have the following meanings;

1. Biological sample: organic material from a human being, alive or deceased, which may provide biological information about him/her.
2. Biobank: a collection of biological samples which are permanently preserved.
3. Scientific study: a study whose primary aim is to add to knowledge, with the purpose among other things of improving health and curing disease.
4. Clinical test: test carried out in order to provide health service to an individual.
5. Free, informed consent: consent granted in writing of the person's own free will, after the donor of a biological sample has been informed of the purpose of taking the biological sample, its usefulness, risks attendant upon the process, and that the biological sample will be permanently preserved in a biobank for use under the terms of art. 9
6. Assumed consent: Consent that consists in the donor of a biological sample not expressing any unwillingness for a biological sample taken from him/her for a clinical test to be permanently preserved in a biobank for use by the terms of art. 9, information in writing on this possibility having been available to him/her.
7. Donor of a biological sample: A person from whom a biological sample is taken.
8. Licensee: Individual or legal entity granted a licence by the Minister to operate a biobank under the terms of art. 4 of this Act.

SECTION II

Establishment and operation of biobanks

Art. 4

Authority to found and operate a biobank

The establishment and operation of a biobank, i.e. collection, keeping, handling, utilisation and storage of biological samples, is permissible only for those who have been granted a licence from the Minister under the provisions of this Act, following the receipt of recommendations from the Medical Director of Health and the National Bioethics Committee.

Art. 5
Conditions of licence

A licence for the establishment and operation of a biobank is contingent upon the following conditions:

1. The terms of this Act, and government directives on the basis of the Act, shall be complied with.
2. The biobank shall be located in Iceland.
3. The objectives of the operation of the biobank, and the operational basis of the bank, shall be clearly defined.
4. Conditions of storage for biological samples shall be described.
5. Protocols of the biobank shall have been drawn up, including regulations of the biobank on arrangements for collaboration with foreign parties.
6. A governing board shall be nominated, as provided in art. 6, and one individual shall be nominated to be answerable for the biobank.
7. The answerable party for the biobank shall be a physician and shall have practised independent research and development work within the health sector. In the case of the biobank comprising exclusively biological samples gathered for purposes of scientific study, the answerable party is not required to be a physician.
8. That evaluation of security, and security measures in gathering of biological samples, shall be consistent with the rules laid down by the Data Protection Authority on security of personal data in biobanks.

The Minister may lay down further conditions.

Art. 6
Board of a biobank

The licensee shall appoint a board of at least three people for each biobank, which shall monitor its operations. The board shall be under an obligation to keep the Director General of Health, the Data Protection Authority and the National Bioethics Committee informed regarding the biological samples and operations of the biobank.

SECTION III
Collection, handling and access to biological samples

Art. 7

Consent of donor of a biological sample and withdrawal of consent

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, risks associated with its collection, and that the biological sample will be permanently stored at a biobank for use as provided in art. 9. In addition the provisions of Art. 20 of the Act on personal privacy and handling of personal data shall be observed where applicable.

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. 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.

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.

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. The request of a donor of a biological sample may apply to all biological samples which have been taken or may be taken from him/her. Such a request must be complied with. The donor of a biological sample shall inform the Director General of Health of his/her request. The Director General of Health shall be responsible for preparation of forms for giving such notice, and shall ensure that these are available at health institutions, and at the premises of self-employed health care professionals. The Director General of Health shall ensure that a coded register of those who have opted out in this way shall always be available to the boards of biobanks. Staff of the Director General of Health who carry out this work are subject to an obligation of confidentiality regarding information they may become aware of in the course of their work, which should remain confidential by law or by its nature. Such staff shall sign an oath of confidentiality before their employment begins. The obligation of confidentiality remains in force after employment ceases.

Art. 8

Preservation of biological samples

Biological samples shall be kept securely and labelled, but stored without personal identification. The linking of biological samples with personal identification shall be in keeping with standards laid down by the Data Protection Authority.

Biological samples shall be stored in such a way that they are not lost or damaged, and that they are not accessible to those who are not entitled to use them.

Should the licensee decide to cease operation of the biobank, the licence having been revoked as provided in Art. 14, the Minister shall, after receiving recommendations from the Director General of Health, the Data Protection Authority and the National Bioethics Committee, decide on the future of the biobank, taking into account the wishes and proposals of the licensee.

Art. 9

Access to biobank and use of biological samples.

Biological samples shall be acquired for clearly defined and lawful purposes, and not used for other purposes, but see para. 2, 3 and 4.

The answerable party for the biobank grants access to biological samples for further diagnosis of diseases.

He/she may also grant access to biological samples for purposes of quality control, development of methods and tuition, provided that they are not personally identified.

The board of the biobank shall negotiate with scientists on access to biological samples. Access to biological samples for scientific studies may not, however, be granted until the permission of the Data Protection Authority has been granted on the basis of the Act on personal privacy and handling of personal data, and a research protocol has been approved by the National Bioethics Committee or the ethics committee of the relevant health institution, as provided in the Act on the Rights of Patients and of regulations issued on the basis of the Act.

The board of the biobank may, if approved by the Data Protection Authority and the National Bioethics Committee, authorise 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 potential inconvenience to the donor of a biological sample or other parties.

The Minister shall, having received proposals from the Director General of Health, the National Bioethics Committee and the Data Protection Authority, issue regulations defining more precisely the use of biological samples.

Art. 10

Rights and fees

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 being consistent with the provisions of this Act, and of government directives based on it. The licensee may thus not pass the biological samples on to another party, nor use them as collateral for financial liabilities, and they are not subject to attachment for debt.

The licensee may take a fee for a biological sample, or access to a biological sample, equivalent to the cost of gathering, storage and access to the sample. Any further fee is prohibited.

A biological sample may be sent out of the country in the interests of the donor of a biological sample, for diagnosis or quality control. Other transportation out of the country of biological samples is subject to the approval of the National Bioethics Committee and the Data Protection Authority and on the conditions they lay down.

Art. 11

Confidentiality

All staff of biobanks and those who have access to them shall preserve confidentiality regarding matters relating to their work which should be kept confidential, by law or by their nature. The obligation of confidentiality remains in force after employment, research or tuition ceases.

SECTION IV
Monitoring and obligation to supply information

Art.12

Monitoring

The answerable party for the biobank shall be responsible for the implementation of internal monitoring and that security assessments be carried out regularly, in accord with the provisions of arts 11 and 12 of the Act on personal privacy and handling of personal data.

The Data Protection Authority shall monitor the security of personal data in biobanks. The Data Protection Authority's monitoring of biobanks is subject to the terms of para. 4 art. 35, paras. 2 and 4, art. 37 and arts 38-43 of the Act on personal privacy and handling of personal data.

The Director General of Health shall monitor biobanks in so far as this monitoring does not fall within the ambit of the Data Protection Authority or the National Bioethics Committee.

Art. 13Obligation to supply information: government and biobank boards

The Director General of Health is under an obligation to promulgate in detail to the general public the terms of this Act on biobanks, especially the provisions on assumed consent of a donor of a biological sample regarding a clinical test, and also the rights of the individual by the terms of art. 7 and of para. 3 of the article.

The Director General of Health shall annually issue a register of biobanks, their purposes, activities and protocols. The register shall contain information on the membership of the board of each bank, and the identity of the answerable party. This register shall be made public and shall be accessible to the general public.

The board of the biobank or the Director General of Health is obliged to provide individuals with information on whether biological samples from him/her are stored in a biobank, and on the nature of such biological samples.

SECTION V

Penalties

Art. 14

The Minister may revoke the licence under the terms of this Act, if the licensee or its employees violate the terms of the Act or government directives on the basis of the Act, if the conditions of the licence are not fulfilled, or if the licensee proves unable to operate the biobank. Should the licensee violate the terms of this legislation or not comply with the conditions of the licence, the Minister shall give the licensee a written warning, allowing a reasonable period of grace to rectify matters. Should the licensee not comply with such a warning, the licence shall be revoked. In the case of deliberate violation or gross negligence, the Minister may revoke the licence without notice and without allowing time for rectification.

Art. 15

Violation of the terms of this Act or government directives based on it entails fines or imprisonment for up to three years, unless a more severe penalty is prescribed in other legislation.

A legal entity or an individual may be sentenced to pay fines due to violation of this Act. A legal entity may be fined whether or not the guilt of an employee of the legal entity has been proved. Should a member of the staff of the legal entity violate the terms of this Act or of government directives based on it, the legal entity may also be fined. The legal entity shall be responsible for payment of a fine imposed upon a member of its staff, for violation of the terms of this Act, provided that the offence is connected to the employee's work for the legal entity.

SECTION VI

Various provisions

Art. 16

Government directives

The Minister may issue regulations on the further implementation of this Act.

The Minister shall issue regulation on how information on assumed consent by the terms of para. 3 art. 7 shall be provided, on how to ensure that withdrawal of assumed consent by a donor of a biological sample by the terms of para. 4 art. 7 is complied with, on the register of those opting out and its form cp. para. 4 art. 7, and how to ensure equal treatment of those who request access to biobanks for purposes of scientific studies , cp. para. 3 art. 9.

Art. 18
Entry into force

This Act shall take force on 1 January 2001.

Provisional clauses

1. Before the Act comes into force, the Minister of Health and Social Security shall assign the Directorate General of Health to carry out detailed publicity among the general public on biobanks and regulations applying to collection and utilisation of biological samples.
2. Biological samples gathered before this Act came into force may be stored in a biobank, unless the donor of a biological sample declares his/her opposition to this. Otherwise the provisions of the Act shall apply to the storage, handling and utilisation of such biological samples.

Passed by the Parliament 13. May 2000

Appendix G: Regulations on the Keeping and Utilization of Biological Samples in Biobanks (134/2001)

Section I

Scope and definitions

Art. 1

Scope

These regulations apply to the collection of biological samples, their storage, handling, utilisation and preservation in biobanks.

Art. 2

In these Regulations the following terms have the following meanings;

1. *Biological sample*: organic material from a human being, alive or deceased, which may provide biological information about him/her.
2. *Biobank*: a collection of biological samples which are permanently preserved.
3. *Scientific study*: a study whose primary aim is to add to knowledge, with the purpose among other things of improving health and curing disease.
4. *Clinical test*: test carried out in order to provide health service to an individual.
5. *Free, informed consent*: consent granted in writing of a person's own free will, after the donor of a biological sample has been informed of the purpose of taking the biological sample, its usefulness, risks attendant upon the process, and that the biological sample will be permanently preserved for use under the terms of art. 9 of Biobanks Act no. 110/2000.
6. *Assumed consent*: Consent that consists in the donor of a biological sample not expressing any unwillingness for a biological sample taken from him/her for a clinical test to be permanently preserved in a biobank for use by the terms of art. 9 of the Biobanks Act, no. 110/2000, information in writing on this possibility having been available to him/her.
7. *Donor of a biological sample*: A person from whom a biological sample is taken.
8. *Licensee*: Individual or institution granted a licence by the Minister to operate a biobank under the terms of art. 4 of the Biobanks Act no. 110/2000.
9. *Temporary preservation of biological samples*: Storage for up to five years of biological samples collected for clinical tests, treatment or specific scientific study, unless the National Bioethics Committee grants authority for a specified extension period.

Section II

Establishment and operation of biobanks

Art. 3

Establishment and operation

Establishment and operation of a biobank is only permissible by those who have received a licence from the Minister under the terms of Biobank Act no. 110/2000. A licence to establish and operate a biobank is contingent upon the criteria stated in arts. 5 and 6 of the Biobanks Act no. 110/2000 being fulfilled. The majority of the board of a biobank as provided in art. 6 of the Biobanks Act no. 110/2000 shall have specialised knowledge in the professional field of the biobank. Facilities for storage of the biobank shall be consistent with the guidelines of the Director of Public Health.

Section III

Obligation to provide information

Art. 4

Biological samples gathered for storage in a biobank for scientific study

Before a biological sample is gathered on the basis of informed consent as provided in para. 1 art. 6, the donor of the biological sample shall be provided with information on;

- a. the name and address of the person answerable for the biobank,
- b. objectives of taking the biological sample, and its usefulness,
- c. the nature of the biological sample to be taken,
- d. risks attendant upon taking the sample,

e. that the biological sample will be preserved in a biobank for use according to the terms of art. 9 of the Biobanks Act no. 110/2000, the content of the article being explained to the donor of a biological sample,
f. security measures applying to the taking and preservation of the biological sample, and the nature of personal identification pertaining to them.
g. to whom the biological sample will be entrusted,
h. that he/she is free to grant authority for the preservation of the biological sample in a biobank, and that refusal to grant such authority will have no effect upon his/her legal rights. The rules of procedure of the biobank shall be available to the donor of a biological sample.
The donor of a biological sample shall be made aware that he/she can at any time withdraw his/her consent for gathering a biological sample, and for the biological sample to be preserved in a biobank. It shall also be made clear to the donor that he/she may at any time cease participation in a scientific study. The significance of this shall be explained to him/her, cp. art. 7 of these regulations.

Art. 5

Biological samples gathered for clinical tests

The Director of Public Health shall publicise the terms of the Biobanks Act no. 110/2000, the provisions on presumed consent under item 6 art. 2, and on withdrawal of presumed consent under para. 4 art. 7 of the above-mentioned Act. He shall also provide information on how notice is to be given of opting-out, for registration as provided in art. 10 of these regulations, and he shall undertake the production of information material and forms for giving such notice, and ensure that these are on display at health institutions, on the premises of self-employed health workers, and in other places where biological samples are taken.

Before a biological sample is taken for clinical tests or treatment, health workers shall draw the attention of the donor of the biological sample or his/her guardian to information provided by the Director of Public Health, cp. para. 1. Should the donor of a biological sample be temporarily incapable of receiving such information, he/she shall be given the information when he/she is able to understand it; otherwise the information shall be provided to the next of kin.

Section IV

Consent of donor of a biological sample, and withdrawal of consent

Art. 6

Informed consent for preservation of biological samples in a biobank and for scientific study

The free, informed consent of the person who gives the biological sample shall be sought, cp. item 5 art. 2, when a biological sample is gathered for preservation in a biobank for a specified scientific study and/or subsequent scientific studies which are consistent with the objective of the biological sample being taken. A scientific study may not be carried out on biological samples which have been gathered for preservation in a biobank unless the study has previously received the consent of the National Bioethics Committee, and unless the terms of Act No. 77/2000 on protection of individuals with regard to the processing of personal data are fulfilled.

Art. 7

Withdrawal of informed consent.

A donor of a biological sample may at any time withdraw his/her consent for the preservation of a biological sample in a biobank and/or participation in a scientific study. He/she shall inform the person answerable for the study of the collection of samples of his/her decision. The answerable person shall give the donor written confirmation of the withdrawal. The person answerable for the study or collection of samples shall inform the National Bioethics Committee and the Data Protection Authority of the withdrawal of consent. When a donor of a biological sample has withdrawn his/her consent as provided in para. 1 art 7 of the Biobanks Act no. 110/2000, the biological sample shall be destroyed.

On withdrawal of informed consent, the biological sample shall be destroyed, i.e. samples of tissue, blood samples, cells and isolated genetic material (DNA/RNA), and it is not permissible to carry out further tests on the sample, whether the original biological sample or isolated parts of it, cells or genetic material.

The results of studies already carried out, based upon the use of the biological sample of the person who has withdrawn consent, shall not, however, be destroyed, but shall be stored in non-personally-identifiable form, so that it is not possible to trace the results to the donor. Results of studies shall be results of all kinds; written text, numerical values, measurements, graphs and pictures. Also results that contain

molecules or molecule fragments (including those from nucleic acids or proteins) in the form of stripes or spots in gel, on membrane or on glass slides. Their use for further research is not permitted. The results of studies originating in biological samples, such as tissue cultures, gene sequences, isolated genes or isolated molecules, original or mutated, shall not be destroyed, but all personal identification shall be removed, so that they cannot be traced back to the donor. With regard to security of personal data, the rules laid down by the Data Protection Authority shall apply. cp. mainly item 8 art. 5 and para. 1 art. 12 of the Biobanks Act no. 110/2000.

Art. 8

Presumed consent for clinical tests

Should biological samples have been gathered in connection with clinical tests or treatment, the presumed consent of the donor of the biological sample may be assumed, cp. item 6 art. 2, for the biological sample to be stored in a biobank, provided that this is stated in written information which is available to the donor of a biological sample where the sample is taken, cp. para. 2 art. 5 of these regulations. A biological sample from a deceased person may be stored in a biobank, provided that he/she has not withdrawn consent prior to his/her decease. Otherwise the terms of the Biobanks Act no. 110/2000 shall apply to biological samples from deceased persons. Surviving relatives have no rights over biological samples of the deceased. Should the use of samples be a matter greatly affecting the interests of the surviving relatives, the National Bioethics Committee may decide that they shall be informed, and that their views be solicited.

Art. 9

Withdrawal of assumed consent

A donor of a biological sample may at any time withdraw his/her assumed consent for a biological sample to be stored in a biobank for use under the provisions of art. 9 of the Biobanks Act no. 110/2000, whether with regard to all biological samples or a specific sample, to all studies or a specific study. Such a request must be complied with. On withdrawal of assumed consent, the biological sample shall not be destroyed, but preserved for use in the interests of the donor of a biological sample. When access is provided in accord with the above, a record shall be kept. Other use is contingent upon the donor's specific permission, but see also para. 4. The donor of a biological sample shall inform the Director of Health of his/her wish. The Director of Health shall prepare forms for giving such notice, and ensure that they are displayed at health institutions, on the premises of self-employed health workers and at other places where biological samples are taken. With regard to the security of such data, regulations laid down by the Data Protection Authority, as provided in item 8 para. 1 art. 5 of the Biobanks Act no. 110/2000, shall apply. A biobank board may, in exceptional circumstances, with the permission of the Data Protection Authority and the National Bioethics Committee, authorise use of biological samples for other purposes than that for which they were taken, provided that important interests are at stake and that the benefit outweighs possible inconvenience to the donor of a biological sample, or other parties.

Section V

Registers of persons who have opted out

Art. 10

Register of those who have opted out, and arrangements

The Director of Health shall ensure that the wishes of the donor of a biological sample with regard to withdrawal of consent are respected. He shall maintain a coded register of donors who have opted out, which shall always be available to the boards of biobanks. The register shall contain only those data necessary to the work of the bank, and to ensure that the wishes of the donor of a biological sample are respected.

When access to a biobank is sought for purposes of scientific study, the party answerable for the bank shall gather information on those who have opted out, before access to biological samples in the bank is authorised.

Staff of the Director of Health who are employed in the above work are subject to confidentiality regarding matters of which they become aware in their work, which should be kept confidential, by law or by their nature. They shall sign an oath of confidentiality before commencing employment. The obligation of confidentiality remains in force after employment ceases.

Section VI
Access to biobanks for scientific study

Art. 11

Obligations of biobank boards

When access is granted to a biobank, the bank board shall ensure that the access for purposes of scientific study does not adversely affect the possibility of further diagnosis of disease in the interest of the donor of a biological sample.

Before access to a biobank is granted by the terms of art. 9 of the Biobanks Act no. 110/2000, a research protocol shall exist, that has been approved by the National Bioethics Committee or the ethics committee of the relevant health institution, cp. Regulations no 552/1999 on scientific studies in the health sector. In the case of a genetic study, the informed consent of the person in question shall normally be sought if he/she is alive, and always if the data can be traced back to a certain individual, and this shall be subject to the judgement of the Bioethics Committee and the Data Protection Authority. The criteria laid down by the Data Protection Authority, under the provisions of the Act on protection of individuals with regard to the processing of personal data, shall be met.

In biobanks which have come into existence at public health institutions or other publicly-funded institutions, the bank board shall, in the making of agreements with scientists, maintain consistency and fairness in the granting of access to the biobank. Access to a biobank shall be based upon professional and scientific criteria, taking into account the interests of the donor of a biological sample.

The biobank board shall give substantiated reasons for refusing a request for access.

A biological sample may be sent out of the country in the interests of the donor of a biological sample, for purposes of diagnosis or for quality control. Other transportation of biological samples out of the country is subject to the approval of the National Bioethics Committee and the Data Protection Authority, and on conditions laid down by them. Samples shall normally be sent without personal identification. The person answerable for the study is responsible for samples being sent without any personal identification, and for remnants of the samples being returned at the end of the study.

A bank board may not transfer a biological sample to another biobank without the permission of the National Bioethics Committee and the Data Protection Authority, and on the conditions laid down by them.

The bank board may preserve at the biobank special collections of biological samples which have been gathered for a specific study; access to these shall be in accord with an agreement made with the person answerable for the study, with the permission of the National Bioethics Committee and the Data Protection Authority, and on the conditions laid down by them.

Section VII

Operation of biobanks

Art. 12

Obligation to provide information

Biobanks shall supply on request standardised information on the following factors;

1. names and addresses of members of the bank board, and the person answerable for the biobank,
2. who is responsible on a daily basis for the biobank,
3. objectives of operating the biobank,
4. types of biological samples,
5. origin of biological samples,
6. who has access to the biological samples, and whether transfer of samples out of the country is possible,
7. where the biobank's rules of procedure are available.

Art. 13.

Public register of biobanks in operation

The Director of Health shall maintain a register of those biobanks which have received an operating licence from the Minister of Health. This shall include at least the information specified in art. 12. The register shall be available to the public on the website of the Director of Health.

Art. 14.

Donor's right to information

At the request of a donor of a biological sample, the Director of Health or the biobank board must provide the donor with information on the following matters with regard to his/her biological samples;

1. whether biological samples from him/her are kept in a biobank, and if so the nature of the samples,

2. for what purpose the sample was taken,
3. who has had access, or may have access, to the biological samples,
- 4 on what grounds such access is granted,
5. what security measures apply to gathering and storage of the biological samples.

Section VIII
Various provisions

Art. 15

Amendments to these regulations shall be made in consultation with the National Bioethics Committee, the Data Protection Authority and the Director of Health.

Art. 16

Entry into force

These regulation are issued on authority in arts. 9 and 16 of the Biobanks Act no. 110/2000, and shall take force immediately.

Ministry of Health and Social Security
6. February 2001.

Appendix H: Act on Protection of Individuals with Regard to the Processing of Personal Data (No. 77/2000)

CHAPTER I

Object, definitions and scope

Section 1

Purpose

The purpose of this Act is to promote that personal data are processed in conformity with the fundamental principles and rules governing protection of such data and the right to privacy, to ensure reliability and quality of such data and the free flow of personal data in the internal market of the European Economic Area.

A particular authority, the Personal Data Protection Authority, shall control the implementation of this Act and any administrative rules issued in conformity with it, as further provided for in Section 36.

Section 2

Definitions

For the purposes of this Act, words and terms shall mean as follows:

1. *Personal data*: Any information relating to an identified or identifiable natural person, i. e. information that can be directly or indirectly traced to a particular individual, living or dead.
2. *Processing*: Any operation or set of operations performed upon personal data, whether manually or by automatic means.
3. *File*: Any structured collection of personal data where data on certain individuals can be located.
4. *Controller*: The party who determines the purpose of the processing of personal data and decides what equipment and methods are to be used, and what shall be done with the data.
5. *Processor*: A party processing personal data on behalf of the controller.
6. *Electronic monitoring*: Monitoring of natural persons, constant or regular, including surveillance by digital equipment.
7. *Consent*: An explicit signified declaration, freely given, indicating that the data subject consents to the processing of certain personal data relating to him and that he is aware of the purpose of the processing, how it is to take place, how privacy is to be ensured, that he or she is free to revoke the consent, etc.
8. *Sensitive data*:
 - a. Data revealing a person's racial or ethnic origin, skin colour, political opinions, religious beliefs and other convictions.
 - b. Data revealing on whether a person has been suspected of, charged with, indicted for, or sentenced on account of a punishable offence.
 - c. Health data, including genetic data and data revealing any medical or non-medical use of drugs or alcohol.
 - d. Data on sexual life.
 - e. Data on trade union membership.
9. *Automated individual decision*: A decision which produces legal rights and/or duties of one or more particular individuals based solely on automated processing of data.

Section 3

Scope

This Act shall apply to any automated processing of personal data. It shall also apply to manual processing of personal data that are, or are intended to be, a part of a file.

The provisions of Sections 16, 18 to 21, 24, 26, 31 and 32 shall not apply to the processing of personal data relating to public security, national defence, state security, or the activities of the state's criminal justice system. The Act shall not apply to a private individual's processing of data solely relating to his or her private affairs, or solely intended for personal use.

Section 4

Video surveillance and image recording

Video surveillance, involving the use of television, video equipment, cameras and similar image recording techniques, not constituting digital data processing, shall be governed by the following provisions: Section

7 as regards the general principles concerning data processing; Section 24 as regards warning of video surveillance; Section 40 as regards cessation of processing, etc., and Section 41 on daily penalties, and, as applicable, the provisions of Section 31 on notification, Section 32 on periods of notice, and Section 38 on the Personal Data Protection Authority's access to data etc.

Section 5

Connection with freedom of expression

To the extent necessary in order to achieve a balance between the right to privacy on the one hand and the freedom expression on the other, exemptions may be made from the provisions of this Act in the interests of journalism, art and literature. When personal data are processed solely for the purposes of journalism or literary or artistic expression, only the provisions of Section 4, Section 7 (1) and (4), Sections 11 to 13, Section 24 and Sections 42 to 43 shall apply.

Section 6

Geographical application

The Act shall apply to the processing of personal data on behalf of a controller established in Iceland. The Act shall also apply to the processing of personal data on behalf of a controller established in a state outside the European Economic Area, if his equipment is located in Iceland. In such cases the controller shall nominate someone established in Iceland to represent him, and the provisions of the Act concerning controllers shall then apply to the representative as applicable. The provisions of the second paragraph shall not apply if the equipment in question is solely used to send personal data through Iceland.

CHAPTER II

General principles concerning processing of personal data

Section 7

General principles concerning processing of personal data

When processing personal data, all the following shall be observed:

1. that they are fairly, appropriately and lawfully processed, and that they are processed as required by good practice in processing such data;
2. that they are obtained for an explicit and clear purpose and not processed any further in a different and incompatible purpose; however, further processing for historical, statistical or scientific purposes shall not be deemed incompatible provided reasonable security precautions are observed;
3. that they are adequate and relevant, and that they do not exceed what is necessary with a view to the purpose of the processing;
4. that they are accurate and updated as necessary. Personal data that are unreliable or incomplete, having regard to the purpose for which they were collected, shall be erased or rectified;
5. that they are not kept in a form which permits identification of the data subjects for a longer time than necessary with a view to the purpose for which they were collected.

Section 8

Processing of general personal data

Processing of personal data is legitimate if one or more of the following requirements are met:

1. that the data subject has provided his or her consent;
2. that the processing is necessary for the performance of a contract concluded by the data subject, or in order to take measures upon the request of the data subject before a contract is concluded;
3. that the processing is necessary in order for the controller to comply with a legal obligation;
4. that the processing is necessary in order to protect the vital interests of the data subject;
5. that the processing is necessary for the performance of a task in the public interest;
6. that the processing is necessary in exercising public authority vested in the controller or a third party to whom the data are transferred;
7. that the processing is necessary in order to enable the controller, a third party or any other parties to whom the data are transferred, to safeguard lawful interests, if this is not prevented by the fundamental rights and freedoms of the data subject given protection in law.

Places generally frequented by a limited number of people may be monitored if there is a particular need to do so by reason of the nature of the activities conducted there.

Section 9

Processing of sensitive personal data

Processing of sensitive personal data is prohibited unless one or more of the following requirements have been met:

1. that the data subject has given his consent to the processing;
2. processing is specifically allowed in other acts of law;
3. that the controller is obliged to process the data according to an agreement concluded by the social partners;
4. that the processing is necessary in order to protect important interests of the data subject or other person who is unable to provide consent as required in Point 1 above;
5. that the processing is conducted by a trade-union or other non-profit-seeking organisation, such as an organisation with cultural, humanitarian, social or idealistic aims, provided the processing is a part of such organisation's lawful activity and only relates to its own members or persons who have, or have had, regular connection with the organisation in the context of its aims. Such personal data may however not be disclosed to others without the data subject's consent.
6. that the processing only relates to data that the data subject himself has made public;
7. that the processing is necessary in order to delineate a claim, submit a claim or present a defence against a claim in litigation or on account of other similar legal needs;
8. that the processing is necessary on account of medical treatment or in the routine exercise of public administration in the field of public health, and the processing is performed by an employee of the health care system subject to the duty of maintaining secrecy;
9. that the processing is necessary on account of statistical or scientific research.

The Personal Data Protection Authority may allow the processing of sensitive personal data in other instances than enumerated under the first paragraph, if the Authority deems that important public interests recommend this. For this the Authority may set the conditions it deems necessary in each case in order to secure the interests of the data subjects, and that privacy is ensured by specific safeguards as applicable.

Having obtained the opinion of the Science Ethics Committee, the Personal Data Protection Authority shall issue rules on how people can be selected and approached for participation in scientific research, and what information they shall be given before they are asked to give their consent.

The Personal Data Protection Authority shall resolve any disputes as to what personal data shall be deemed sensitive.

Section 10

The use of national identification numbers

National identification numbers may only be used for pertinent purposes and if it is necessary in order to ensure reliable personal identification. The Personal Data Protection Authority may prohibit or order the use of the national identification numbers.

Section 11

Reliability and quality of personal data

The controller shall be responsible for security assessment and safeguards as required by the standards of the Personal Data Protection Authority and other rules set by the Authority concerning data security. The controller shall also make certain that personal data are processed as required by Section 7.

The controller is responsible for conducting regular security assessments and taking systematic safety measures in order to comply with the requirements of the first paragraph.

The controller shall maintain a register of his security assessments and the safety measures taken, to which the Personal Data Protection Authority shall have access at any time.

Section 12

Internal control

The controller shall exercise internal control and prepare regular reports thereon. The reports shall include information on the system used for the control and how it ensures compliance with the requirements of this Act and the conditions set in permits issued under Section 35 and/or orders issued under Section 40. The Personal Data Protection Authority may issue further instructions on internal control.

Section 13

A processor's processing of personal data

A processor may not use personal data for any other purpose than originally decided, unless the controller requests so. A processor may not deliver data to others for safekeeping or for processing except in consultation with the controller.

Section 14

Time limits for compliance

A controller shall act upon any communication sent him under the provisions of Sections 16, 18, 22, 25, 26, 27 and 28 as soon as possible, and no later than one month after receiving it.

If, due to extraordinary circumstances, a controller can not bring a matter to a conclusion within one month, he may do so later. In such cases the controller shall, within the time limit of one month, explain the reasons for the delay to the party in question, in writing, and state when a reply may be expected.

Section 15

Payment of costs

Communications received as provided for in Sections 16, 18, 22, 25, 26, 27 and 28 shall be acted upon free of charge. If the costs involved are high, for example due to photocopying of documents, payment may however be collected in accordance with a rate issued by the Minister of Justice in the form of an administrative regulation.

CHAPTER III

Right to receive, and duty to provide, information

Duty to provide guidance and warning

Right to reasoning

Section 16

The right to general information on the processing of personal data

A controller has the duty of providing any person with general information on the processing of personal data taking place on his behalf.

As regards any particular category of processing, any person who so requests shall furthermore be provided with information on the following points:

1. the name and address of the controller and, as the case may be, his representative under Section 6;
2. the identity of the party responsible for routine compliance with the duties if a controller under this Act;
3. the purpose of the processing;
4. a definition or other characterisation of the kind of personal data processed;
5. the origin of the data;
6. the recipients of the data, including whether the plan is to send the data abroad, and if so, to whom.

A request according to the first paragraph shall be directed to the controller or his representative according to Section 6. A clarification in writing may be requested of the points on which information is asked.

Section 17

Publicizing of processing operations

The Personal Data Protection Authority shall maintain a record of all processing notified to the Authority as provided for in Section 31, and any processing it permits as provided for in Section 33. The record shall contain, as a minimum, the points enumerated in the second paragraph of Section 16.

The record shall be accessible by the public in a manner to be decided by the Personal Data Protection Authority.

Section 18

The data subject's right of access

A data subject shall be entitled to obtain from the controller information about:

1. what data on relating to him are being, or has been, processed;
2. the purpose of the processing;
3. who receives, has received or will receive, data relating to him;
4. the origin of the data;

5. what safeguards have been established for the processing, provided this does not compromise the security of the data.

A request for access as provided for in the first paragraph shall be directed to the controller or his representative under Section 6. The information shall be provided in writing if requested.

Section 19

Restrictions of the data subject's right of access

The right of the data subject's right of access under Section 18 does not cover data solely used for statistical processing or scientific research in cases where its processing can not directly affect his interests.

The provisions of Section 18 shall not apply if the data subject's right under that section is deemed subordinate, in part or in whole, to the interests of others, or other interests of his own. In this, the considerations to be taken into account shall include the data subject's health and the interests of his family members. A representative of the data subject may however be provided the information if there are no specific reasons against this.

The right of the data subject under Section 18 does not cover data to which access is restricted by the Information Act or the Administrative Procedures Act. As regards data in the possession of other controllers than administrative authorities, the provisions of Section 18 shall not reach to information contained in preparatory documents and other similar data prepared by the controller himself or persons working on his behalf, such as councillors or experts.

Even if the data subject is not entitled to access by reason of the provisions of the third paragraph, he may request a written exposition of the contents of the data or an excerpt or summary thereof, unless he is able to acquaint himself with the facts of the matter by other means.

If the provision of certain data compromises the possibility of concluding a matter for resolution, such data may be withheld until the matter has been prepared for resolution.

The Minister may, by an administrative regulation, issue provisions setting conditions for exercise of a data subject's access to data.

Section 20

The duty to provide information in cases of collection of data from the data subject

When personal data are obtained from the data subject, he or she shall be provided with information on the identity of the controller, the purpose of the collection of the data, how the data will be identified, to whom the data will be disclosed, and whether the data subject is under a duty to provide the requested data or whether he may decline to do so, and what effect a denial may have. This duty rests with the controller, or, as the case may be, the processor, but shall not apply if the data subject has already been informed of these facts.

Further information shall be provided if this is necessary in order to enable the data subject to guard his interests; he shall then for example be informed of his right to information under Section 18, cf. Section 19, and of his right to demand correction or erasure of data.

Section 21

Duty to provide warning when personal data are collected from others than the data subjects

When personal data are collected from others than the data subject, the controller shall at the same time notify the data subject and inform him of the points enumerated in the second paragraph of Section 16. If the plan is to disclose the data within a reasonable period of time from its collection, such warning may be delayed until the data are disclosed for the first time. Any controller engaged in dissemination of data on financial matters and credit rating shall however provide such warning within 14 days before the data are disclosed for the first time.

The provisions of the first paragraph shall not apply if:

1. the Personal Data Protection Authority deems a warning impracticable or that a warning would place a heavier burden upon the controller than can reasonably be demanded;
2. the data subject may be assumed to be already aware of the processing, or
3. filing and disclosure of that data is allowed by law.

Section 22

Reasoning to be provided For automated individual decisions

If an automated decision has been taken, which is exclusively based on automated processing of personal data, the party to whom the decision relates can request reasoning for the decision. In the reasoning, the rules applying to the automated data processing, on which the decision is based, shall be explained.

Section 23

Warnings concerning use of personal profiles

When a personal profile defining a certain behaviour, taste, ability or need is used as a basis for

1. bringing in automated individual decision as referred to in the second paragraph of Section 9;
2. contacting a data subject, selecting a sample or a target group, etc,

the Personal Data Protection Authority can, when it has received a notification of such processing, order the controller to notify the data subject and inform him who controls the processing, what data are being used and where that data comes from.

In taking a decision in accordance with the first paragraph the Personal Data Protection Authority's assessment of whether a warning is practicable, or whether it places a heavier burden upon the controller than can reasonably be demanded, shall be among the factors taken into consideration.

Section 24

Warnings of video surveillance

When a workplace or a public space is monitored by video surveillance, a clear warning shall be given of that fact by a sign or otherwise, stating the controller's identity.

CHAPTER IV

Corrections, deletions, closures etc.

Section 25

Correction and deletion of incorrect or incomplete data

If incorrect, misleading or incomplete personal data have been processed, or if the processing of such data has not been legitimate, the controller shall have the data corrected, deleted or improved, if the shortcoming in question is suited to affect the interests of the data subject. If such data have been disclosed or used, the controller shall to the extent possible prevent it from affecting the interests of the data subject. If deletion or change of the data referred to in the first paragraph is not allowed by reason of the provisions of other laws, the Personal Data Protection Authority may prohibit use of the data.

Section 26

Deletion of, and prohibition of use of, personal data that is neither incorrect nor incomplete

When there is no longer a valid reason to preserve personal data, the controller shall have it deleted. Valid reasons to preserve data may include provisions of law, or that the controller is still processing the data in conformity with the original purpose of their collection.

If the provisions of other laws do not stand in the way, a data subject may nevertheless request deletion of data concerning him, or a prohibition of their use, if this is deemed justified following a comprehensive assessment of the interests involved. In making such interest assessment the interests of others, general considerations of privacy, public interests, and the measures necessary for complying with the request shall be taken into account.

The Personal Data Protection Authority may, in individual cases as well as by the issue of general provisions, prohibit the use of such data or order their deletion.

Section 27

The right to a decision based on manual processing of data

If an automated decision, as defined in Section 2 (9), has been taken, the party to whom the decision relates, or any party otherwise directly affected by the matter, may request a manual processing of the decision, provided that decision relates to the personal situation or traits of the party in question and is of significance for him.

The provisions of the first paragraph shall not apply if adequate measures have been taken in order to guard the privacy interests of the party in question, and the decision is based on the provisions of law or relates to the preparation or performance of a contract.

Section 28

Processing for marketing purposes etc.

The Statistical Bureau of Iceland shall maintain a registry of individuals not willing to allow the use of their names in product marketing. Controllers engaged in direct marketing, and those who process names, addresses, etc., or disseminate such data to third parties in connection with direct marketing shall, before such data is used for that purpose for the first time, and subsequently at one-monthly intervals, compare such files with the registry of the Statistical Bureau in order to prevent target mail being sent to people who is opposed to it and to prevent them being contacted by telephone. The Personal Data Protection Authority may make exemptions from this duty in special cases.

The name of the controller shall be prominently displayed on sent target mail, with information stating whom persons, unwilling to receive such mail and telephone calls, can turn to. Any person receiving target mail is entitled to know the origin of the information leading to the sending of mail or a telephone call. This does not, however, apply to a controller's marketing of his own products or services using his own customer registry, provided the identity of the sender is stated.

The provisions of the first and second paragraphs shall also apply, as applicable, to market surveys, consumer surveys and opinion polls as the Personal Data Protection Authority may provide for in further detail. The Authority may waive the requirements provided for in the first paragraph in relation to scientific and similar research, if such requirements are deemed likely to compromise to a significant extent the reliability of the outcome.

CHAPTER V

Transfer of personal data to foreign countries

Section 29

Transfer of personal data to a state providing for adequate protection of such data

Personal data may be transferred to another state, provided its laws ensures for an adequate level of protection for such data.

A state that implements Directive of the European Communities No. 95/46/EC, on the protection of individuals with regard to the processing of personal data and on the free movement of such data, shall be deemed to fulfil the condition set in the first paragraph.

When considering whether a state that does not implement Directive No. 95/46/EC fulfils the condition set in the first paragraph, the rules in effect in that state concerning the processing of personal data, the rules on good business practices and the security measures taken by the recipient shall be among the factors taken into account. Ratification by the state in question of the Council of Europe's Convention No. 108 of 28 January 1981 for the protection of individuals with regard to automatic processing of personal data, shall also be taken into consideration.

Section 30

Transfer of personal data to a state not providing for adequate protection of such data

Transfer of personal data to a state not ensuring adequate protection for such data is prohibited, unless:

1. the data subject has provided his consent to the transfer;
2. this is necessary in order to comply with obligations under international law or by reason of Iceland's membership of international organisations;
3. the transfer is allowed by other acts of law, or
4. delivery of the data is necessary in order to prepare or perform a contract between the data subject and the controller, or
5. the transfer is necessary in order to prepare or perform a contract for the benefit of the data subject, or
6. delivery of the data is necessary in order to protect important interests of the data subject.

The Personal Data Protection Authority may allow the transfer of data to a state referred to in the first paragraph if it deems that there are special reasons to do so, even if the conditions set in the paragraph are not fulfilled. In such cases the nature of the data, the planned purpose of the processing, and its duration, shall be among the factors taken into account. The Personal Data Protection Authority may issue further provisions on transfer of personal data to other countries.

CHAPTER VI
Duty of notification; licence requirements, etc.

Section 31
Duty of notification

Any controller carrying out any wholly or partly automatic processing of personal data as allowed in Section 8 and the second paragraph of Section 9 shall, in a timely manner before it commences, notify the Personal Data Protection Authority of the processing on a form designed for the purpose. Notification shall also be made of any changes occurring from the original notification.

The duty of notification does not apply to processing of already collected data that is accessible to the public.

The Personal Data Protection Authority may decide that certain categories of processing shall be exempt from the duty of notification, or that simpler notification requirements shall apply to them. The Authority may furthermore decide that certain categories of processing shall be subject to prior checking and permits. The Authority may issue orders relating to processing that is exempt from notification requirements, which may include the matters referred to in the second paragraph of Section 35. The Authority may also order measures to be taken in order to minimise the inconvenience such processing of personal data may cause the data subject.

Section 32
The contents of notifications

A notification to the Personal Data Protection Authority shall contain the following:

1. The name and address of the controller and, as the case may be, his representative as provided for in Section 6;
2. The identity of the person responsible for the daily fulfilment of the controller's duties;
3. The purpose of the processing;
4. A definition or other clarification of the kind of data to be processed;
5. Where the data has been obtained;
6. In what manner collection of the data is authorised;
7. To whom the data will be delivered;
8. Whether transfer of the data abroad is planned;
9. Whether publication of the data on the Internet is planned;
10. What security measures will be taken in the course of processing;
11. Whether, and when, the personal data or identifying data will be erased.

The Personal Data Protection Authority may issue provisions on the form and contents of notifications in further detail, and provide for the manner in which the duty of notification is to be complied with.

The controller shall at any particular time see to that the Personal Data Protection Authority possesses correct information on his processing of the data. When three years have passed since the Personal Data Protection Authority was sent a notification, the Authority shall be sent a new notification with updated information, unless changes in processing have already been notified. The Authority may order measures to be taken for securing the quality of notifications and the reliability of notified information, and decide on different notification periods depending on the category and nature of processing.

Section 33
Prior checking

In cases of processing of general or sensitive personal data which may entail particular danger of infringement of the rights and freedoms of the data subjects, the Personal Data Protection Authority may suspend the commencement of the processing until the Authority has examined and approved the processing by the issue of a permit. The Authority may decide that permits shall no longer be required when general rules and security standards have been issued for processing of that kind.

Section 34
Prerequisites for the issue of permissions, etc.

A controller may only be issued a permit in accordance with Section 33, or any other permits provided for in this Act, if he is likely to be able to comply with his duties under this Act and the orders issued by the Personal Data Protection Authority.

When handling applications for a permission to process sensitive personal data the Authority shall, within the limits provided for in Chapter II of this Act, assess whether the processing may cause the data subject inconvenience that is impossible to relief by means of conditions set as provided for in Section 35. If such inconvenience can not be relieved, the Personal Data Protection Authority shall assess whether the interests recommending processing outweigh the interests of the data subject.

Section 35

Conditions defined in permissions for processing personal data

When a controller is granted a permit under Section 33, the Personal Data Protection Authority shall make this subject to any conditions the Authority deems necessary in each instance for preventing or diminishing any possible inconvenience resulting from the processing for the data subject. The same shall apply, as applicable, when the Personal Data Protection Authority receives a notification of the processing of sensitive personal data coming within the scope of the first paragraph of Section 9.

When assessing what conditions shall be set for processing, the factors to be considered by the Personal Data Protection Authority shall include:

1. Whether the data subject is certain to be able to exercise his rights under this Act, including by ceasing participation in a particular project, and, as applicable, have personal data deleted and receive information on his rights and his exercise of them;
2. Whether the personal data will be sufficiently safe and reliable, and updated as required by the purpose of processing, cf. Section 7;
3. Whether the personal data will be treated with the care demanded by the rules on secrecy and the purpose of processing;
4. Whether any decisions have been taken on the manner in which information and guidance will be provided to the data subject within the limits found reasonable with a view to the purpose of processing and other safety measures taken;
5. Whether safeguards have been established that are reasonable with a view to the purpose of the processing.

The Personal Data Protection Authority may decide that the controller and the processor, and any personnel working on their behalf, shall sign a declaration to the effect that they promise to keep secret any sensitive data coming to their knowledge in the course of processing. The controller or his representative shall attest to the correct signature and the date of the declaration, and forward it to the Personal Data protection Authority within the time limit to be stated. A violation of the duty of maintaining secrecy constitutes a criminal offence under Section 136 of the General Penal Code. The duty of maintaining secrecy shall survive the duration of employment.

The Personal Data Protection Authority may grant a petition relating to the processing of sensitive personal data on the condition that a supervisor is appointed to oversee, on behalf of the Authority, that the processing takes place in the manner required by law, and that the controller will pay all costs ensuing from this arrangement.

CHAPTER VII Control and sanctions

Section 36

Organisation and administration of the Personal Data Protection Authority

The Personal Data Protection Authority shall be an independent authority with a board of its own, administratively subject to the Minister of Justice.

The Personal Data Protection Authority shall discharge its functions independently, and its decisions can not be referred to any superior administrative authority.

The Minister shall appoint five persons to the board of the Authority, and the same number of alternates, for a term of four years at a time. The Minister shall appoint the chairman and the vice-chairman without nomination. They shall be lawyers with the qualifications required for the office of district court judge.

The Supreme Court of Iceland shall nominate one board member, and the Icelandic Society for Information Processing shall nominate another board member possessing expert knowledge of electronic data processing and technology. The alternate members shall have the same qualifications as the principal members.

The Minister shall decide on the remuneration of the board members.

When the board members do not agree, the matter in question shall be decided by majority vote. If votes are equal for and against, the vote of the chairman shall be decisive.

The Minister, having received the recommendations of the board, shall appoint a managing director for the Personal Data Protection Authority for a term of five years. The managing director shall attend meetings of the board, and shall have the right to speak and make proposals.

The managing director shall be in charge of daily management and shall engage other personnel for the authority.

The managing director shall be responsible for the financial and personnel management of the Authority.

The board of the Authority shall in other respects decide on the distribution of responsibilities between the board and the Authority's personnel.

Section 37

The functions of the Personal Data Protection Authority

The Personal Data Protection Authority shall control that this Act, and any administrative provisions issued in accordance with it, is duly complied with.

The Personal Data Protection Authority shall decide in cases of dispute concerning the processing of personal data. The Authority may consider individual cases on its own accord, or upon the reception of a communication from someone alleging that data have not been handled as required by this Act, any administrative provisions issued in accordance with it, or individual orders.

The tasks of the Personal Data Protection Authority include:

1. Deciding on applications for permits, receiving notifications, and ordering, as necessary, any measures relating to technology, safety and organisation of data processing in order to ensure that this takes place as required in this Act;
2. Controlling that laws and regulations on the processing of personal data are complied with, and that any shortcomings and mistakes are rectified;
3. Monitoring the general trends within the field of personal data protection domestically as well as abroad, and maintaining an overall view of, and providing information on, the chief issues in the field of personal data protection;
4. Defining and circumscribing where the protection of personal data is endangered and providing counsel on possible solutions;
5. Providing guidance to parties planning to process personal data, or developing systems for such processing as regards protection of personal data, including by provision of assistance in the compilation of professional and ethical codes for individual groups and professions;
6. Providing statements, upon request or of its own initiative, on issues concerning the processing of personal data, and providing opinions on bills and proposed administrative provisions of significance for the protection of personal data;
7. Issuing an annual report on its activities.

The Personal Data Protection Authority may decide that a controller shall pay the cost ensuing from controlling that he fulfils the requirements of his Act, any administrative provisions issued in accordance with it, or individual orders. The Authority may also decide that a controller shall defray the costs of examining his procedures when the issue of a permit or other service is in preparation.

Section 38

Access of the Personal Data Protection Authority to information, etc.

The Personal Data Protection Authority may request from a controller, a processor and any party working on their behalf any information and written explanations necessary in order for it to perform its functions, including any information necessary in order to determine whether this Act applies to a certain operation or processing. The Authority may also summon a controller, a processor or any party working on their behalf to a meeting for provision of oral information and explanations concerning a certain processing of personal information.

When exercising its control functions, the Personal Data Protection Authority shall, without judicial warrant, have access to premises where personal data are being processed and where data are stored, including places where files, pictures, cf., Section 4, personal data in electronically accessible form, and equipment for accessing them, are kept. The Authority may perform any test or control measure it deems necessary, and can request the necessary assistance of personnel on the scene for performing a test or control measure. The Authority may request police assistance if an attempt is made to hinder the performance of its duties.

The right of the Personal Data Protection Authority to demand information and its right to access to premises and equipment can not be restricted by a reference to the duty of maintaining secrecy.

Section 39

Exemptions from the duty of maintaining secrecy

The provisions on secrecy shall not prevent the Personal Data Protection Authority from providing information to similar foreign agencies when this is necessary in order to enable the domestic or foreign authority to decide on, or to perform, measures safeguarding privacy.

Section 40

Cessation of processing

The Personal Data Protection Authority may order cessation of the processing of personal data, including collection, registration and disclosure, order partial or total erasure of personal data or deletion of files, prohibit further use of personal data, or order the controller to take measures that ensure lawful processing. When assessing whether to take such measures, and what measures to take, the Authority shall take its decision with a view to all considerations including those enumerated in the second paragraph of Section 35.

In the case of processing of personal data in a manner that is contrary to this Act, or any administrative provisions issued in accordance with it, the personal Data Protection Authority may commit to the commissioner of police to stop the activity provisionally, and to close immediately the premises used for the purpose.

If someone does not comply with the orders of the Personal Data Protection Authority, the Authority may revoke any permits it may have issued under the provisions of this Act, until the Authority deems that the necessary improvements have been carried out.

Section 41

Daily penalties

If an order of the Personal Data Protection Authority issued in accordance with the provisions of Sections 10, 25, 26 or 40 is not complied with, the Authority may impose daily penalties upon the addressee of the order, until the Authority deems that improvements have been made. Such penalties may amount to up to ISK 100,000 for each day that commences without the order having been complied with.

If a decision of the Personal Data Protection Authority on daily penalties is referred to the courts, daily penalties shall only begin to accrue when a final judgement has been rendered. The penalties shall convert to the State Treasury, and they may be collected by distress without prior judgement.

If an offence has been committed in the course of the operations of a legal person, the legal person may be fined as provided for in Chapter II A of the General Penal Code.

Section 42

Criminal sanctions

Subject to other acts of law providing for heavier criminal sanctions, any person who commits a violation against this Act or any administrative provisions issued in accordance with it shall be fined or imprisoned for up to three years. The same sanctions shall be ordered if orders issued by the Personal Data Protection Authority have not been complied with.

Section 43

Compensation

If a controller or a processor has processed personal data in a manner contrary to the provisions of this Act or the rules or orders of the Personal Data Protection Authority, the controller shall compensate the data subject for any loss he may have suffered in consequence. A controller shall however not be obliged to compensate for any loss he may establish was not caused by his own or the processor's negligence or mistake.

CHAPTER VIII
Connection to other laws, entry into force, etc.

Section 44
Connection to other laws

This Act shall apply to processing and processing of personal data taking place subject to the provisions of other laws, unless a different arrangement is provided for there.

This Act shall not limit access to information as provided for in the Information Act and the Administrative Procedures Act.

Section 45
Administrative regulations on individual categories of activity

Administrative regulations may be issued to govern the processing of personal data in certain fields of activity and with the members of individual professions.

The activity of processing data revealing financial matters, and the credit standing of enterprises and other legal persons, in the purpose of disseminating such data, shall be governed by an administrative regulation. For such activity the permission of the Personal Data Protection Authority shall be required, and the following provisions of this Act shall apply to it: Section 11 on the security and quality of information; Section 12 on internal control, Section 13 on a processor's processing; Section 18 on the right of the data subject to information; Section 21 on the duty to provide a warning when data are being collected from others than the data subject; Section 25 on correction and deletion of incorrect and incomplete data; Section 26 on deletion and prohibition of use of data that are neither incorrect nor incomplete ; Section 33 on processing for which permits are required; Section 34 on the conditions for the issue of permits; Section 35 on conditions to be laid down; Section 38 on the Personal Data Protection Authority's access to information, etc.; Section 40 on cessation of processing, etc., Section 41 on daily penalties, Section 42 on criminal sanctions, and Section 43 on compensation.

The Minister shall, having received the opinion of the Personal Data Protection Authority, issue a regulation providing in further detail for the Authority's control of automated processing of personal data by the police. This shall include provisions on the duty of the police to notify the Personal Data Protection Authority of any automated processing by the police, and the contents of such notifications. There shall furthermore be provisions regulating when and how a data subject shall have a right to access personal data relating to him that is or has been processed by the police, and the right of the police to delay the disclose of data in certain situations. There shall finally be provisions on the security of personal data and the police's duty to carry out internal control to secure that personal data is processed as required by law. There shall also be provisions on the period of time during which personal data shall be stored.

A regulation shall also be issued to provide in further detail on activities involving the use of name lists and the preparation of name inscriptions, including in marketing and in the preparation of market surveys and opinion polls.

Section 46
Entry into force

This Act shall enter into force 1 January 2000. At the same time Act No. 121/1989, on Registration and Processing of Personal Data, shall be repealed.

At the time of entry into force, the following amendments of the following acts of law shall also enter into force:

1. The words "Act on Registration and Processing of Personal Data, No. 121/1989" in the final sentence of Section 20 of the Child Welfare Act, No. 58/1992, shall be replaced by the words "Act on Protection of Private Information and Processing of Personal Data".
2. The words "Data Protection Committee, cf. Act No. 121/1989 on Registration and Processing of Personal Data" in the fourth paragraph of Section 24 of the Pharmaceuticals Act, No. 93/1994, shall be replaced by the words "Personal Data Protection Authority, cf. Act on Protection of Private Information and Processing of Personal Data".
3. The words "Data Protection Committee" in the third paragraph of Section 15 of the Rights of Patients Act, No. 74/1997, shall be replaced by the words "Personal Data Protection Authority".
4. The words "Data Protection Committee" in the second paragraph of Section 14 of the Act on Electronic Ownership Registration of Securities, No. 131/1997, shall be replaced by the words "Personal Data Protection Authority".

5. The words "Data Protection Committee" in Section 4 of the Act on a Database in the Health Sector, No. 139/1998, and the same words in Sections 5, 6, 7, 10, 12 and 17, shall be replaced by the words "Personal Data Protection Authority".

6. The words "Data Protection Committee" in Sections 18 and 19 in the Act on the Schengen Information System in Iceland, No. 16/2000, shall be replaced by the words "Personal Data Protection Authority".

Temporary provision

When this Act has been published, the Minister shall immediately appoint the members of the board of the Personal Data Protection Authority and advertise the office of the Authority's Director vacant. When the Director has been engaged he shall, as necessary, engage other personnel to prepare the entry into effect of this Act and to exercise administrative functions as provided for in the second paragraph.

Notwithstanding the provisions of the first paragraph of Section 46, the Personal Data Protection Authority shall, immediately when its board has been appointed, assume control of that personal data are, in the Schengen Information System in Iceland, handled as required by Act No. 16/2000 on the Shengen Information System.

Any controller who makes use of electronic technology for processing personal data at the time this Act enters into force shall notify the Personal Data Protection Authority of his processing on a form made for the purpose, as required in Sections 31 and 32, within six months from when the Act enters into force.

Permits issued by the Data Protection Committee shall retain their validity, provided they do not conflict with the provisions of this Act.

Appendix I: Summary of Icelandic Human Subjects Regulations

Act on a Health Sector Database
(No. 139/1998: passed on December 17, 1998)

This Act authorizes “the creation and operation of a centralized database of non-personally identifiable health data with the aim of increasing knowledge in order to improve health and human services.”

The following are the main points of the Act:

- Allows the creation of a database of existing and future medical records.
- Consent is not obtained. Consent is presumed unless individual opts out. If individual opts out, any data existing in the database will remain in the database, but no new data will be entered.
- Data will be prepared and entered in coded form by the employees of the originating health care entity.
- Database to be run by a licensee. The licence will be for 12 years, and will be renewable. Of note: deCODE has been granted the licence for 2000-2011. DeCode is to pay the Iceland government 70,000,000 Iceland krona (\$950,000 US dollars) per year as well as 6% of pre-taxable profits.
- Access to the data:
 - Licensee has direct access and can process data as long as it cannot be linked
 - All processing must be done in Iceland. The database cannot leave Iceland.
 - Ministry of Health and Director General of Public Health shall always be entitled to statistical data.

Act on Biobanks: (No. 110/2000) Passed May, 2000

“The objective of the Act is to authorize the collection, keeping, handling and utilization of biological samples from human beings, in such a way that confidentiality is ensured, the interests of donors of biological samples is safeguarded and that the utilization of the biological samples serves the purposes of science and medicine, and is conducive to the public good.”

Highlights from the law include:

- Biobanks will require a license from the Minister following receipt of recommendations from the Director General of Public Health and the National Bioethics Committee.
- There are two separate types of samples:
 1. **Samples obtained for the purpose of preservation in a biobank.** For these samples, written, free, informed consent is required. If consent is withdrawn, the samples must be destroyed, but any “material produced from the biological sample” can be retained.
 2. **Samples collected for purposes of treatment/diagnosis.** For these samples, consent is assumed. The donor must have received written material regarding the biobank. If the donor does not express unwillingness for his/her sample to be preserved in the biobank, then permission is assumed. If consent is withdrawn, the samples can only be used for the purposes for which it was provided.
- Samples will be kept without personal identification.

- Access to samples:
 - Free access for further disease diagnosis, quality control and development of methods.
 - For scientific study–need permission of the Data Protection Authority and the research protocol must have approval from the National Bioethics Committee or the local ethics committee.
 - For other purposes–the board of the biobank can authorize other uses if approved by the Data Protection Authority and the National Bioethics Committee and important issues are at stake and the potential benefit outweighs potential “inconvenience to the donors.”
 - Exporting of sample–is allowed if it is in the interest of the donor. For any other reason, must have approval of the Data Protection Authority and the National Bioethics Committee.

**Act on Protection of Individuals with regard to the Processing of Personal Data
(No. 77/2000) Passed May, 2000**

“The purpose of this Act is to promote that personal data are processed in conformity with the fundamental principles and rules governing protection of such data and the right to privacy, to ensure reliability and quality of such data and the free flow of personal data in the internal market of the European Economic Area.”

Highlights from the Act include:

- Scope: “Any automated processing of personal data. It shall also apply to manual processing of personal data that are, or are intended to be, a part of a file.”
- General principle: Data must be obtained for an explicit purpose and not processed further. However, processing without a person’s consent is allowed for “historical, statistical or scientific purposes.”
- “Personal data” is defined as: “Any information relating to an individual or identifiable natural person; i.e., information that can be directly or indirectly traced to a particular individual living or dead.”
- “Sensitive data” is defined as: “data revealing a person’s racial or ethnic origin, skin colour, political opinions, religious beliefs and other convictions; data revealing on whether a person has been suspected of, charged with, indicted for, or sentences on account of a punishable offence; health data, including genetic data and data revealing any medical or non-medical use of drugs or alcohol; data on sexual life; data on trade union membership.”
- There are more stringent rules for the processing of sensitive personal data. However, processing of sensitive personal data is permitted without a person’s consent if necessary for statistical or scientific research.
- Individuals may request complete disclosure of what personal information is maintained and how it has been processed by whom. There are few restrictions to a person’s full access, including an exception if the data is used solely for statistical processing or scientific research, if processing cannot directly affect the person’s interests..
- Individuals must be informed when personal data is collected from someone other than themselves.
- Exportation of personal data: Allowed if receiving country has adequate protection

Appendix J: Letter from NIH to OHRP Regarding Icelandic Research Resources



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

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MEMORANDUM

To: Dr. Greg Koski
Director, Office for Human Research Protections

From: Director, Office of Science Policy, NIH

Subject: Icelandic Biobanks and Databases: Application of 45 CFR 46

As you may recall from our meeting on January 30 of last year, NIH has been considering how the DHHS human subjects regulations (45 CFR 46) and the FDA's human subjects regulations (21 CFR 50 and 21 CFR 56) would apply to the use of three Icelandic data sources that are of interest to researchers: (1) the Health Sector Database, (2) biobanks, and (3) the Genealogical Database. After several discussions with the Icelandic Health Delegation and an examination of the relevant Icelandic laws and regulations, NIH has concluded that the Icelandic laws and regulations are compatible with 45 CFR 46 and the FDA regulations for the protection of human subjects. Since several NIH investigators are interested in using Iceland's data resources, a formal OHRP determination about this would be very useful as researchers begin to develop studies that would rely on these Icelandic data.

During the summer of 1999, we discussed this issue with several former OPRR staff and obtained a preliminary determination of how 45 CFR 46 would govern researchers' use of these Icelandic data. However, we now have more information about Iceland's implementation efforts, so we wanted to revisit this issue with you. Below is background information about Iceland's data resources and a summary of our findings that may be helpful as you consider this issue.

The Health Sector Database: In December 1998, the Act on a Health Sector Database was passed by the Icelandic Parliament, which authorized the Icelandic government to create and operate a centralized health database. The Health Sector Database (HSD) is expected to include selected health data, derived from medical records, that will be coded and stored in a computerized form in one location. DeCODE genetics Inc. was selected to operate the HSD on behalf of the Icelandic government for 12 years. While the Health Sector Database has not yet been created, many of the rules for the creation and operation of the database have been developed. The following are a few of the key features of the database that are pertinent for research:

- **Consent:** Consent will not be sought from each individual for entry of data into the database, with the exception of genetic information. However, individuals may opt-out of having their health information included in the HSD by giving a written and signed notice to the Icelandic Director of Health using a special form that has been widely distributed in Iceland. The form provides options to exclude data from the HSD that are in existing medical records, future medical data, and/or specified data.

In addition, an individual who initially chose to opt-out of having his/her data included in the database may withdraw their refusal at anytime. Similarly, an individual who initially chose not to opt-out, but later changes his or her mind, can demand that information be deleted from the HSD and that further data not be entered into the HSD. Such demands can be made by submitting a refusal form to the Icelandic Director of Health.

- **Coding/Linking of Data:** Personal identifiers will be coded before the data are entered into the HSD. Coding will be one-way so that it cannot be reversed. In fact, the Act on a Health Sector Database prohibits the identification of individuals from their data. However, the Act on a Health Sector Database permits the linking of information in the HSD as permitted by Iceland's Data Protection Authority. It is our understanding that the written informed consent of the donors will be required prior to the linkage of information to the HSD.
- **Conditions for Research:** The Icelandic Act on a Health Sector Database prohibits researchers or any others from obtaining information on an individual from the database and from having direct access to data in the database. However, for a fee, researchers may pose questions to deCODE, and will receive an answer in the form of aggregated data. Therefore, it is our understanding that Icelandic law prohibits researchers from having access to individually identifiable data.

All research queries or studies to be performed using the HSD must be approved by a multidisciplinary ethics committee as defined by Icelandic law. This ethics committee must comply with international regulations and guidelines, and shall report every three months to the Icelandic National Bioethics Committee about all applications received and about their approval/rejection.

***Conclusion:** It is our understanding that researchers will only receive aggregated data from the HSD, and will never have access to the raw or coded data that would enable linkage back to an individual. Furthermore, the law authorizing the creation of the database prohibits the identification of individuals from their data. If this understanding is correct, it is our interpretation that the information obtained by researchers is not individually identifiable since the individual's identity is not readily ascertainable by the investigator or associated with the information—and thus, such research is not covered by the human subjects regulations.*

Furthermore, there is precedent for this conclusion. For example, data from surveys conducted by the National Center for Health Statistics are compiled into public use datasets that are exempt from IRB review. Even though these datasets are coded, OPRR and now OHRP, have treated them as exempt from the human subjects regulations because the code is protected under the Public Health Service Act 308(d) Assurance of Confidentiality.

Biobanks: In May 2000, the Icelandic Parliament passed the Act on Biobanks, which governs the collection and use of human biological materials in Iceland. The Act became effective on January 1, 2001. Unlike the HSD, which is centralized, there will be no central biobank in Iceland. Tissue will be stored at various biobanks located across the country. As of August 2001, however, no biobank sites had been granted a license. Although the protocol approval criteria are still under development by the National Bioethics Committee and the Data Protection Authority, the following is what we know about the operation of the Icelandic biobanks:

- **Consent:** Individual consent is required for tissue samples obtained specifically for inclusion in a biobank. Consent can be withdrawn at anytime. Furthermore, before research can be conducted with such tissue samples, individual consent is required for the specific research study. If consent is withdrawn, the tissue sample will be destroyed. However, the “products” of research can be retained.
- **Coding/Linking of Data:** Biological samples will be stored in the biobanks without personal identifiers, but the linking of samples to individuals and their personal information will be permitted under rules established by the Data Protection Authority.
- **Conditions for Research:** The linking of personal information to information in the biobanks for research purposes, will only be allowed if the research study has been approved by the National Bioethics Committee. Unlike the HSD, a biological sample may be sent out of the country for research purposes, but only with the approval of the National Bioethics Committee and the Data Protection Authority. In addition, although the Act on Biobanks does not require collaboration with an Icelandic researcher for samples to be sent outside the country, we were informed by the Icelandic government that the National Bioethics Committee will request that foreign researchers collaborate with an Icelandic researcher, if samples are to be transported outside of Iceland.

Since the biobanks are not yet operational, we do not yet know how long the approval process by the National Bioethics Committee and Data Protection Authority will take nor do we know any details about how an investigator will request such approval. However, we have been informed that if the study involves genetic research of personally identifiable biological samples, the National Bioethics Committee will require that written informed consent be sought from living donors.

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Conclusion: *It is our understanding that researchers may receive human biological material that is either explicitly individually identifiable, or individually identifiable through a code. We believe that research using such individually identifiable human biological material would be considered human subjects research and would, therefore, be covered by the human subjects regulations.*

Genealogical Database: DeCODE genetics Inc. created the Genealogical Database solely from publically available data. This database is currently available to the public without restriction.

Conclusion: *Since this database is publically available, it is our understanding that research using only the Genealogical Database would be exempt from the human subjects regulations as provided by 45 CFR 46.101(b)(4).*

Thank you for your guidance on this matter. In particular, please let me know if you disagree with any of our conclusions, or if you will require additional information before reaching a determination. I would be happy to meet with you to discuss this further. You can reach me by phone at x6-2122 or by e-mail at lane_skirboll@nih.gov.

Lana R. Skirboll, Ph.D.

cc:
Irene Stith-Coleman
Julie Kaneshiro

Appendix K: OHRP Response to NIH on Assessment of Icelandic Research Resources

09/02/03 TUE 14:13 FAX 301 402 2071

OHRP

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Public Health and Science

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APR 12 2002

TO: Dr. Lorna Skirboll
Director, Office of Science Policy, NIH

FROM: Director, Office for Human Research Protections

SUBJECT: Icelandic Biobanks and Databases: Application of 45 CFR 46

Thank you for your March 12 letter regarding the applicability of the Department of Health and Human Services (HHS) regulations for the protection of human subjects (Title 45 CFR Part 46) to the use of health information and human specimens maintained in Iceland. Before addressing your conclusions about whether the three research scenarios you described would be subject to 45 CFR 46, I have identified the applicable sections of the HHS regulations below:

"HHS regulations for the protection of human subjects at 45 CFR 46.102(f) define a *human subject* as a living individual about whom an investigator obtains either (1) data through interaction with the individual, or (2) identifiable private information. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be *individually identifiable* (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects."

"Research that uses human biological or tissue specimens is generally considered to involve human subjects whenever (1) some or all of the individuals from whom those specimens or tissues were obtained are alive at the time the research is proposed, and (2) the identity of these living individuals is or may be readily ascertained by the investigator or associated with the information obtained from the specimens or tissues. Therefore, research involving the use of individually identifiable specimens from living individuals, such as cells, blood or urine, tissues and organs, including specimens obtained for routine patient care (even if to be discarded) or specifically for research, is human subjects research. Unless such human subjects research qualifies for exemption under HHS regulations at 45 CFR 46.101(b)(4), the research requires Institutional Review Board (IRB) review and approval whenever the research is Federally conducted or supported or conducted under an applicable Assurance of Compliance."

Page 2 - Dr. Lana Skaraboll

Based on your description of the Icelandic laws and regulations governing the Icelandic Health Sector Database, the Icelandic biobanks, and the Icelandic Genealogical Database, below are OHRP's responses to the three conclusions you described in your letter. It is important to note, however, that even if research does not meet the definition of human subjects research in 45 CFR Part 46 or qualifies for exemption from the requirements of the regulations to protect human subjects, institutions may still choose to require IRB review and approval for such studies, and may find that the research ought not be conducted due to ethical concerns.

First, your letter described pertinent characteristics of the Icelandic Health Sector Data Base. You concluded that since interested NIH researchers will only receive aggregated data from the Health Sector Database, and are prohibited by Icelandic law from having access to the raw or coded data that would enable linkage back to an individual, such research is not human subjects research and thus does not require IRB review and approval. OHRP agrees with this conclusion. In this scenario, the research may be considered to not involve human subjects under the HHS regulations at 45 CFR Part 46 because the identity of the individuals about whom the information pertains could not be "readily ascertained" by the investigator or associated with the information.

Second, your letter described pertinent characteristics of biobanks that will be maintained in Iceland under the conditions required by the May 2000 Icelandic Act on Biobanks. You concluded that research using such human biological materials, which were either explicitly individually identifiable or retained a code that enabled linkage to the donor, would be human subjects research, and thus would require IRB review and approval because the identity of the individual from whom the samples were obtained could be readily ascertained by the investigator or associated with the sample. OHRP agrees that the use of identifiable human specimens from living individuals would constitute human subjects research and would require IRB review and approval. However, please note that not all research using human specimens from the biobanks would necessarily be human subjects research. Research where a recipient-investigator uses biological or tissue specimens from living individuals that retain a link to identifying information ordinarily would not be considered human subjects research if: (1) the recipient-investigator does not have access to identifiable private information (i.e. only received coded samples), and (2) a written agreement is obtained from the holder of the identifiable private information related to the sample providing that such information will not be released to the recipient-investigator under any circumstances. As with the research project that would use information from the Health Sector Database described above, research in this scenario may also be considered to not involve human subjects because the identity of the individual from whom the samples were obtained could not be "readily ascertained" by the investigator or associated with the sample. Therefore, in this case, an institution or IRB could determine that IRB review of the research using the coded sample(s) was not required under the HHS regulations for the protection of human subjects.

Finally, your letter described an Icelandic Genealogical Database that is composed entirely of publicly available data and is available to the public without restriction. You concluded that such research would be exempt from the HHS human subjects regulations as provided by 45 CFR 46.101(b)(4). However, since this database was created solely from publicly available data and is publicly available, research involving this database would not involve human subjects as defined

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by HHS regulations at 45 CFR 46.102(f) because the information in the database is not private. Therefore, research using information from the database would not be subject to the requirements of the HHS regulations for the protection of human subjects. If an institution or an IRB determined that the research would involve the use of existing data that was identifiable, private, and publically available, then the research would be exempt under 101(b)(4).

I hope these responses are helpful to you. If you would like to discuss any of these issues further, please feel free to call me at 301-496-7005 or Julie Kaneshiro at 301-402-7565.



Greg Koski, Ph.D., M.D.

Appendix L: Limited and Broad Consent Forms from the Iceland Genomics Corporation

Translated from the Icelandic:

Form intended for individuals who have contracted cancer or associated preinvasive changes

Agreement to participate in the Icelandic Cancer Initiative and in certain stages of the Initiative:

Cancer of the kidneys and associated preinvasive changes

Option A Research on one type of cancer

With my signature I hereby agree to participate in a limited and specific part of the Icelandic Cancer Initiative. The research in question is on cancer of the kidneys and associated preinvasive changes. My signature attests that I have been fully advised of the project and the import of this statement of consent, among other things, by receiving and reading specific informational material about the Icelandic Cancer Initiative, and that I have received satisfactory answers to all my questions.

I hereby give my consent for 50 ml of arterial blood to be taken from me for research purposes. I also give my consent for the use of tissue samples taken from me during treatment for cancer (operation, endoscopy or other type of tissue sampling procedure carried out for medical treatment) together with any older tissue samples related to the disease and which are in the tissue banks of health institutions, with the requirement that the tissue samples be used for the Icelandic Cancer Initiative. I hereby grant authorization for the research parties to preserve the above-specified blood and tissue samples during the course of the research. I furthermore consent to answer all questionnaires related to the above project.

I hereby grant authorization to the research parties to give to the health institutions information on any treatment given me in relation to my illness and to store this information during the course of the research.

The above-defined blood and tissue samples and information shall only be used in connection with that part of the Icelandic Cancer Initiative which deals with cancer of the kidney and any associated preinvasive changes and are not to be used for comparison or in connection with other types of cancer. The specific research stages within the Icelandic Cancer Initiative are dependent on the approval of the Committee on Ethics in Science and the Data Protection Authority.

I hereby direct that all blood and tissue samples and information about me that have been collected in connection with the above-defined research shall be destroyed on completion of the Icelandic Cancer Initiative. However, the results of the research that has been carried out shall not be destroyed.

Translated from the Icelandic:

Form intended for individuals who have contracted cancer or associated preinvasive changes

**Agreement to participate in the Icelandic Cancer Initiative
and in certain stages of the Initiative:**

Cancer of the kidneys and associated preinvasive changes

Option B

Research on all types of cancer regardless of the original organ involved

With my signature I hereby agree to participate in research on cancer of the kidney and associated preinvasive changes, together with participation in the Icelandic Cancer Initiative. My signature attests that I have been fully advised of the project and the import of this statement of consent, among other things, by receiving and reading specific informational material about the Icelandic Cancer Initiative, and that I have received satisfactory answers to all my questions.

I hereby give my consent for 50 ml of arterial blood to be taken from me for research purposes. I also give my consent for the use of tissue samples taken from me during treatment for cancer (operation, endoscopy or other type of tissue sampling procedure carried out for medical treatment) together with any older tissue samples related to the disease and which are in the tissue banks of health institutions, with the requirement that the tissue samples be used for the Icelandic Cancer Initiative. I hereby grant authorization for the research parties to preserve the above-specified blood and tissue samples during the course of the research. I furthermore consent to answer all questionnaires related to the above project.

I hereby grant authorization to the research parties to give to the health institutions information on any treatment given me in relation to my illness and to store this information during the course of the research.

Neither the above-defined blood and tissue samples nor any information obtained shall be used in any other way than in connection with the Icelandic Cancer Initiative, other research stages, and integration and comparison with other types of cancer as part of the Icelandic Cancer Initiative. The specific research stages within the Icelandic Cancer Initiative are dependent on the approval of the Committee on Ethics in Science and the Data Protection Authority.

I hereby direct that all blood and tissue samples and information about me that have been collected in connection with the above-defined research shall be destroyed on completion of the Icelandic Cancer Initiative. However, the results of the research that has been carried out shall not be destroyed.

Translated from the Icelandic:

Form intended for individuals who have contracted cancer or associated preinvasive changes

**Agreement to participate in the Icelandic Cancer Initiative
and in certain stages of the Initiative:**

Cancer of the kidneys and associated preinvasive changes

Option C

**Research on all types of cancer regardless of the original organ involved
Permanent storage of information and blood and tissue samples
for other cancer research**

With my signature I hereby agree to participate in research on cancer of the kidney and associated preinvasive changes, together with participation in the Icelandic Cancer Initiative. My signature attests that I have been fully advised of the project and the import of this statement of consent, among other things, by receiving and reading specific informational material about the Icelandic Cancer Initiative, and that I have received satisfactory answers to all my questions.

I hereby give my consent for 50 ml of arterial blood to be taken from me for research purposes. I also give my consent for the use of tissue samples taken from me during treatment for cancer (operation, endoscopy or other type of tissue sampling procedure carried out for medical treatment) together with any older tissue samples related to the disease and which are in the tissue banks of health institutions, with the requirement that the tissue samples be used for the Icelandic Cancer Initiative. I hereby grant authorization for the research parties to preserve the above-specified blood and tissue samples during the course of the research. I furthermore consent to answer all questionnaires related to the above project.

I hereby grant authorization to the research parties to give to the health institutions information on any treatment given me in relation to my illness and to store this information during the course of the research.

The above-defined blood and tissue samples and any information obtained may be used in connection with the Icelandic Cancer Initiative, other research stages, and integration and comparison with other types of cancer as part of the Icelandic Cancer Initiative. The specific research stages within the Icelandic Cancer Initiative, integration and comparisons are dependent on the approval of the Committee on Ethics in Science and the Data Protection Authority. The above-defined blood and tissue samples and any information obtained may also be used for other research on cancer that has been approved by the Committee on Ethics in Science and the Data Protection Authority.