Icelandic Biobank  
A Report for GenBenefit (2007)

Dr. Garðar Árnason

The School of Law, The University of Manchester, Manchester, United Kingdom.

I Background

On August 26th, 1996, the research company deCODE genetics Inc. was established and incorporated in Delaware, USA. A wholly owned subsidiary, Íslensk erfðagreining, was established later that year in Reykjavík, Iceland. In this case report I will refer to both as deCODE genetics or simply deCODE. The company was founded by a group led by Kári Stefánsson, Icelandic medical doctor and at the time Professor at Harvard, with $12 million in funds from American venture capital firms.

The aim of deCODE genetics is to conduct population genetics research on common diseases in the Icelandic population, and use the results for the development of treatments and diagnostic tools. The Icelandic population is claimed to be of great value for genetics research because of the population’s (alleged) genetic homogeneity, good medical records and extensive genealogical records. Many geneticists and investors agreed with deCODE. For example, the renowned geneticist Mary-Claire King is quoted in the New Yorker saying that Iceland is an “amazing place” to do genetics and likens the population to a gift from heaven, and Elizabeth Silverman of BancAmerica noted in Nature Biotechnology that “the nation is extremely valuable.”

One key idea for the establishment of deCODE was the construction of a population database in Iceland, which would combine health data, genetic data and genealogical data from the entire population. The database would be the main resource for deCODE’s own research, but it would also be made commercially available to other researchers, companies and organizations. In effect, the database would turn the Icelandic population into a genetics laboratory for deCODE and anyone willing to pay deCODE for access to it. By constructing the database, deCODE hoped to create “a totally informative population with which to search for drug targets and to model both disease and host-drug interactions.”

In order to construct its database, deCODE wanted to collect data from medical records in what was called a “Health Sector Database” (HSD). The HSD would provide the medical data, which would be combined with a database with genetic data and a database with genealogical data. The genetic and genealogical databases could be rather easily constructed, the first by collecting biosamples from patients (with some sort of informed consent given) and the second by collecting public genealogical records. The first database (HSD), however, was more difficult, because the company would need access to confidential medical records in hospitals and other health care institutions. In order to be able to collect health data from medical records, deCODE proposed new legislation, which would allow the construction of the HSD with an exclusive operating license granted to an unnamed company (which would naturally be deCODE).

The Act on a Health Sector Database (No. 139/1998) was passed by the Icelandic Parliament on December 17th, 1998, after extensive debates in the Parliament and the society at large, and in the face of immense opposition from doctors, scientists, and the organized opposition group Mannvernd.

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1 For a further discussion of the homogeneity of the Icelandic population, see Garðar Árnason, “Interbreeding within the Icelandic population is high compared to that of mice or fruit-flies”, in Garðar Árnason, Salvör Nordal and Vilhjálmur Árnason (eds.), Blood and Data: Ethical, Legal and Social Aspects of Human Genetic Databases (Reykjavik: University of Iceland Press, 2004).
(although the majority of the public supported deCODE and the HSD Act).\textsuperscript{5} In January 2000, deCODE genetics was granted an exclusive operating license for the HSD for 12 years. An agreement was made between deCODE and the Minister of Health when the operation license was granted. According to the agreement, the company would pay the State an annual fee (approximately 800,000 EUR) for its license as well as 6% of profits made by the company, up to a maximum amount equivalent to the annual fee.

In February 1998, deCODE made a five-year agreement with pharmaceutical giant Hoffmann-La Roche, which could yield more than $200 million for deCODE. According to a Roche press release, Roche would “provide the Icelandic people free of charge with pharmaceutical and diagnostics products that emerge from the collaboration.”\textsuperscript{6} Two subsequent agreements between deCODE and Roche continue promising free medication and diagnostic products for Icelanders, if developed through the company’s collaboration.\textsuperscript{7}

The Icelandic Supreme Court decided in 2003 in the case of Gudmundsdóttir v. the State of Iceland (No. 151/2003), that the daughter of a deceased man could prevent his health information from being entered into the HSD.\textsuperscript{8} The Court came to the conclusion that the HSD Act was in violation of the Icelandic constitution by not sufficiently protecting the right to privacy. By ruling that the HSD Act was in conflict with the Constitution, the judgment destroyed the legal framework for deCODE’s plans to collect data from medical records in a centralized database. There had already been signs that deCODE had lost interest in constructing its database, but with this decision it became clear that the database would most likely never be established. However, deCODE continues to operate (at a considerable financial loss) and conduct genetic studies within the Icelandic population, and it did meet many but not all research milestones set in its first agreement with Roche.

Although the database never materialized, the case of the Icelandic database is significant from the perspective of benefit sharing. In this case a private company sets out to use a population for commercial gain by turning it into a genetics laboratory, and this is accepted by the majority of the population and its political representatives because of the perceived benefits, part of which result from direct benefit sharing. Since this case concerns a very wealthy, Western nation with a high level of education and a strong public health system, the negotiations between the principal parties, the nature of benefit sharing, and the many ethical and political issues involved will offer an interesting comparison with other cases where benefit sharing is an issue.

\textsuperscript{5} Mannvernd means literally “human protection”. Despite Mannvernd’s subtitle, “Association of Icelanders for Ethics in Science and Medicine”, it is specifically the “organized opposition to the Icelandic government’s Act on a Health Sector Database (HSD)”, according to its website (www.mannvernd.is). Its members are primarily medical doctors, scientists, and academics. Mannvernd, and its members individually, was highly active and visible during the parliamentary debates on the HSD Act in 1998 and, to lesser extent, during the following 3–4 years as the association encouraged people to opt-out of the database.


II. Legal and Institutional Environment

II.i. National Laws, Regulations and Institutions

In order to allow the establishment of a centralized health database, the *Health Sector Database Act* was passed in December 1998. This act was complemented by a *Regulation on a Health Sector Database*, issued by the Ministry of Health in January 2000. An operation license was granted to deCODE at the same time and an agreement made between deCODE and the Ministry of Health. The HSD Act explicitly allows the health data in the HSD to be connected to genetic and genealogical data, but no laws apply specifically to the combined database, which deCODE had aimed to establish. An Act on Biobanks was passed in 1999 (*Act on Biobanks* no. 110/2000).

The *Act on Health Sector Database* (no. 139/1998) authorizes “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. 1). The Act does not foresee the State creating and operating the database, but an external party who is granted an operation license for a maximum of 12 years. The licensee is to pay an annual license fee, to meet all costs to the State incurred by the creation and operation of the database, including the costs of the monitoring committees (see below for more information about institutions), and all costs involved in retrieving and processing information for the database. There is no requirement of benefit sharing of any kind in the Act, but art. 4 implicitly leaves benefit sharing to negotiations with the licensee: “The minister [of health] and licensee may agree on further payments to the Treasury, which shall be devoted to promoting the health service, research and development.”

The most controversial aspect of the HSD Act was the implied “presumed consent.” There is no consent required by the Act for entering health data from medical records onto the Health Sector Database. Patients have, however, the right to “opt-out” at any time (art. 8), but the Act does not give them the right to have their data removed from the database, once it has been entered. The confidentiality of the data was to be secured through a system of coding (art. 7), monitoring institutions (art. 12) and confidentiality oaths taken by all employees of the licensee (art. 11).

The *Act on Biobanks* (no. 110/2000) provides the legal framework for collecting and storing biosamples for scientific research. It applies therefore to deCODE’s collection and storing of biosamples to process genetic data for the combined database. The Act requires informed consent of biosample donors, with one striking exception: “If biological samples have been collected for the purpose of clinical tests or treatment, the consent of the patient may be assumed” (art. 7). During parliamentary debates on the Biobank Bill, one opposition MP and member of the parliamentary committee on health explained, in support of the Bill, that this was a compromise between the interests of scientists and the interests of patients, and that important research might thus proceed even when patients are refusing to directly donate biosamples.

Following the HSD Act, a new institutional environment was created for the database. The four most important institutions involved are the Monitoring Committee of the Health Sector Database, the Interdisciplinary Ethics Committee, the Data Protection Commission and the National...
Bioethics Committee. The Monitoring Committee and the Interdisciplinary Ethics committee were first introduced in the HSD Act, with further specifications given in the Regulation on a Health Sector Database (chapters V and VI, respectively).

The Data Protection Commission and the National Bioethics Committee operate on a national level. The Data Protection Commission was given a new name in 2001 (it was previously, and mysteriously, called “Tölvunefnd,” literally “The Computer Committee”) with a wider mandate following new legislation on personal data and privacy. The National Bioethics Committee was established in 1999, following a change in regulation whereby its predecessor, the National Science Ethics Committee, was dissolved. The main change introduced by the regulation was that committee members were no longer nominated by academic and medical institutions, such as the University of Iceland and the main hospitals, but by various Ministries and the Directorate of Health. In other words, the power to nominate members of the Bioethics Committee was moved from academic and medical institutions to the executive branch of government. This change in regulation followed a bitter dispute between the Science Ethics Committee and deCODE when the operating license was being prepared. I have argued elsewhere that this political maneuver gravely undermines the trustworthiness of the National Bioethics Committee. It is particularly damaging when trustworthy institutions are given greater importance in order to justify not requiring informed consent for participation in research such as that planned for the Health Sector Database.

II.ii. International Laws and Regulations

There are little or no international laws or regulations that apply to the Icelandic Database. The Convention on Biodiversity (CBD) and the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization exclude human genetic resources. UNESCO’s Universal Declaration on the Human Genome and Human Rights does apply in this case, in particular regarding informed consent (art. 5(b)), but it is very vague about benefit sharing. Art. 12(a) states: “Benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard for the dignity and human rights of each individual.” UNESCO’s Universal Declaration on Bioethics and Human Rights (October 2005) also applies to this case, but again it is very vague on the issue of benefit-sharing. Article 15 specifies examples of sharing benefits of scientific research in general.

The HUGO Ethics Committee Statement on Benefit Sharing (9 April 2000) is relevant, but like UNESCO’s declarations it is not legally binding. The Statement suggests that “in the case of

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15 UNESCO, Universal Declaration on Bioethics and Human Rights, adopted by the General Conference of UNESCO at its 33rd Session on 19 October 2005.
profit-making endeavours, the general distribution of benefits should be the donation of a percentage [recommendation 6 suggests 1%-3%] of the net profits (after taxes) to the health care infrastructure or for vaccines, tests, drugs, and treatments, or, to local, national and international humanitarian efforts.” This is the case for the database project in Iceland, at least in terms of the promise of providing free drugs and treatments resulting from the Roche-deCODE collaboration, but no such products have been developed yet. Concerning donation of a percentage of profits, deCODE was to pay 6% of profits, but with a limited maximum amount, this is not so much a donation as a negotiated payment for using a common resource, and the payments are not ear-marked for the health care infrastructure or humanitarian efforts. Since the database has not been constructed however, no such payments have been made, or are likely to be made.

III Negotiation and Decision Making

There were no formal negotiations, or a single decision-making procedure, for the Icelandic database project. There were, however, a number of negotiations of various kinds (financial, legal, political, social) at various times. There were, for example, negotiations:

(1) between deCODE’s founders and the venture capitalists who provided funds to start the company (this is relevant because the main, and possibly only, selling point was the promise of access to the Icelandic population as a resource for genetics research);
(2) between deCODE and Hoffmann-La Roche resulting in a $200 million research contract;
(3) between deCODE and Iceland’s Ministry of Health in order to establish the legal framework for the project;
(4) between deCODE, politicians, critics and others concerned, and the population in general, during the period when the HSD bill was debated in Parliament;
(5) between deCODE and the Ministry of Health to set the terms of the Operating License;
(6) between deCODE and health care institutions in order for deCODE to get access to medical records.

The negotiations between deCODE’s founder, Kári Stefánsson, and the American venture capital firms, which provided the funds needed to start the company, were confidential, but it is clear that the selling point of Stefánsson’s business plan was his access to the Icelandic population as a resource for genetics research. Stefánsson was already conducting promising research in Iceland on hereditary factors in Multiple Sclerosis (MS) as a Professor at Harvard, and could claim connections to Iceland’s genetics research community. At this point (1995–1996), however, no legal framework existed in Iceland for the database and it is not clear how Stefánsson could have claimed to have access to the Icelandic population without the support of the Icelandic government, which only became official during the negotiations with Roche in late 1997 and early 1998.

One result of deCODE’s negotiations with American venture capital firms, was that the company had to be incorporated in the USA to be within US jurisdiction. Although Stefánsson owned a large share of the company (entirely in virtue of his expertise since he did not contribute any funds), more than half of the shares were owned by the American investors, and their representatives were in the majority on the company’s Board of Directors. The company’s incorporation in the USA, and its American majority ownership and control, conflicted with Stefánsson’s insistence that the company be Icelandic. His justified worry was that the company’s plans would only get sufficient support in Iceland if the company was considered Icelandic. A wholly owned subsidiary of deCODE,

Íslensk erfðagreining, was established in Iceland in late 1996, and the company successfully presented itself to the Icelandic population as an Icelandic company, with “deCODE” being its international brand name rather than its American mother corporation. When deCODE became publicly traded on the American stock market NASDAQ\(^ {18} \) the venture capital firms sold their shares and their representatives left the company board, but deCODE remains incorporated in the USA: none of the board members save Kári Stefánsson are Icelandic, and it is for most legal and financial purposes an American corporation.\(^ {19} \)

In 1997, deCODE was actively negotiating with both Roche and the Icelandic government (in particular the Prime Minister, Davíð Oddsson, and the Minister of Health, Ingibjörg Pálmdóttir). The negotiations and the resulting contract with Roche are confidential, but according to a press release from Roche, the companies agreed to “collaborate in genetic research with the aim of developing new therapeutic and diagnostic products to combat disease.”\(^ {20} \) On reaching set milestones, deCODE was to earn possibly more than $200 million. The research was to “focus on the discovery of genes with alleles or mutations that predispose people to the development of up to twelve common diseases including four cardiovascular diseases, four neurological/psychiatric diseases and four metabolic diseases.” The press release does not mention the database project, but it does imply that deCODE has access to the Icelandic population as research subjects in general, and in particular that deCODE has access to medical records.

Given that Iceland is a wealthy Western nation, with universal health care which provides medication to patients at nominal costs, it is perhaps surprising that deCODE negotiated benefit sharing at all for the Icelandic population. According to Roche’s press release, “Roche will provide the Icelandic people free of charge with pharmaceutical and diagnostics products that emerge from the collaboration.” One possible explanation for Roche’s generosity is the fact that deCODE’s database would be able to track the use of Roche’s free products in Iceland and closely monitor their effectiveness and reported side-effects in a population that in most cases would be considerably larger than those available for clinical trials, and much easier to manage and monitor than those available for studies after a product has been approved and put on the market. deCODE did want to create “a totally informative population with which … to model both disease and host-drug interactions” (emphasis added).\(^ {21} \)

When the agreement between deCODE and Roche was signed in Reykjavik on 2 February 1998, the Prime Minister, Davíð Oddsson, showed his support for deCODE by passing the pen between the representatives of the two companies, and by announcing that “the government of

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\(^{18}\) NASDAQ is “the largest electronic screen-based equity securities market in the United States,” (see its ‘Factsheet 2007’ at \[www.nasdaq.com/about/Corp_FS_2007.pdf\]).

\(^{19}\) In one important respect the company has became more Icelandic. The American venture capitalists who invested in deCODE in 1997 sold half of their shares in 1999 to Icelandic investors, before deCODE became traded on NASDAQ. After the trade, roughly 70% of the company’s shares were owned by Icelanders, but that trade did not change the composition of the Board of Directors. The ownership of the company has changed again after it became publicly traded, and Kári Stefánsson is the only Icelandic investor who owns more than 5% of the company stock. The founding investors paid $1 per share in 1997 and the Icelandic investors bought their shares for $16.50 per share in 1999, but the shares never took off on the stock market: the official close price on 2 July 2007 is only $3.88.

\(^{20}\) Roche–Corporate Media News, ‘Roche and DeCode Genetics Inc. of Iceland collaborate in genetic disease research’.

Iceland will do its best to assist the two parties in the agreement to achieve the goals of the collaboration.\textsuperscript{22}

As deCODE negotiated with Roche in 1997, it was also in talks with Icelandic authorities about the legal framework for a centralized Health Sector Database. A preliminary draft of the HSD Bill was in fact written by deCODE and faxed to the Ministry of Health on 3 September 1997.\textsuperscript{23} In this first version of the bill, there were no consent requirements for collecting health data from medical records and no possibility of opting out. The Ministry of Health accepted the main ideas of deCODE’s preliminary draft, but disagreed with some details. A first official draft of the Bill, somewhat changed but in fundamental areas the same as deCODE’s draft, was introduced in the Parliament in the spring of 1998 to be passed through quickly, but it soon became clear that some sort of consent requirement would have to be added and that a proper debate in Parliament was necessary. The bill was withdrawn and a second draft introduced in the autumn of 1998, this time with a clause which permitted patients to opt out of the database, and stricter measures for monitoring the database and for ensuring privacy and confidentiality of the data. During the summer of 1998, Kári Stefánsson toured Iceland and held community meetings in health care centers to inform the public about the database project. The choice of venue shows the close connection between the company and health authorities in Iceland, as well as deCODE’s effort to present the database project as a public health project and not a commercial venture. deCODE also ran an extensive advertising and PR campaign through most of the year, which included not only advertisements, but also information booklets and a website. This resulted in wide public support for the project and the HSD bill, but there was also extensive criticism, both within Iceland and abroad.

The second draft of the HSD Bill was debated in Parliament in the autumn of 1998, where it received severe criticism from the opposition, not least when an important change was made to the Bill just before the third and last round of debates. Someone had noticed that the Bill did not say anything about the possibility of connecting the health data of the HSD with genetic and genealogical data, but clearly that was what deCODE wished to do. Two sentences were added to paragraph 2 of article 10, which specifically allows the health data to be connected to genealogical and genetic data, but the licensee was to develop processes and methods for the connection, meeting privacy conditions set by the Data Protection Commission (or the Computer Committee, as it was called at the time). This, the opposition pointed out, completely changed the nature of the HSD. It was no longer a health database for epidemiological research, but part of a larger database containing not only health data but also genetic and genealogical data, in other words, containing the sort of “rich information” which later would lead the Supreme Court to rule that the Act contradicted the provisions on privacy of the Icelandic Constitution. The revised Bill was forced through the third and last round of debates, and was passed as law on 17 December 1998.

Two companies applied for the operation license for the HSD in April 1999. In May, the Ministry of Health started negotiations with one of the two companies; not surprisingly that company was deCODE genetics Inc. These negotiations resulted in an agreement in January 2000 between deCODE and the Ministry of Health, and the granting of the operation license to deCODE. According to the agreement, deCODE would pay an annual license fee of 70 million Icelandic króna, approximately 800,000 EUR. It would also pay 6% of its profits each year, up to a maximum equivalent to the annual license fee. The first payment was to cover the costs incurred by the database, such as the costs of the monitoring institutions. The second payment was to be used for the health care system and for research, and can be considered as benefit sharing.

\textsuperscript{22} Ibid.
\textsuperscript{23} Guðni Th. Jóhannesson, \textit{Kári í jöutmóð}, p. 171 (see an unnumbered page between pp. 124 and 125 for a reproduction of the second page of the fax).
Many physicians were reluctant to co-operate with deCODE and give the company access to the medical records of their patients. It was clear that deCODE would not be able to access medical records unless physicians entrusted with the records would give their permission to process them for the database. On 30 November 1998, two letters signed by 44 general practitioners and 108 specialists, respectively, were sent to the Parliament. The letters asked the Parliament not to pass the HSD Bill, and said that the signatories would not grant access to medical records of their patients, except on patients’ written request. The Icelandic Medical Association was also opposed to the Bill, and the subsequent Act, and received support from the World Medical Association regarding its concern about the ethical issues, in particular that of consent and the common requirement of allowing research participants to withdraw their participation. The Icelandic Medical Association came to an agreement with deCODE that participants in the database could withdraw, not only by having their medical information no longer entered into the database, but also by having existing information deleted from the database. The issue of consent was still in the way, but it was the Supreme Court that put an end to the database plans. The decision of the Icelandic Supreme Court in 2003 in the case of Gudmundsdóttir v. the State of Iceland (No. 151/2003), found the HSD Act in violation of the provisions on privacy of the Icelandic Constitution. Although deCODE was by then clearly losing interest, or the financial ability, to construct the HSD, it was this Supreme Court decision that made it all but official that the database would not be constructed.

Although the HSD has not been constructed, deCODE has continued its research in the genetics of common diseases and has already started clinical trials on drugs. The company did reach many of the milestones of the 1998 agreement with Roche and continues to co-operate with Roche in research and drug development. Its research does make use of the Icelandic population, but without a centralized database of health information.

IV Ethical Issues

The most significant ethical issues in the Icelandic database case are privacy and consent. A third significant issue, which was not much debated in Iceland, but which was addressed in two of the negotiations discussed above, is benefit sharing. Other ethical issues were also debated in Iceland, for example freedom of research (which the HSD Act was seen to limit), commercialization of medical information and the possibility of genetic discrimination.

IV.i Privacy

The issue that probably received most attention in Iceland is privacy. Information from medical records is confidential and it was from the beginning debated whether privacy and confidentiality could be guaranteed. This issue is closely linked to the issue of consent, in particular the decision not to require informed consent, but to presume consent, for being included in the Health Sector Database. To justify applying the principle of presumed consent, privacy was to be ensured by technical means. This included making all personal data anonymous or, more accurately stated, non-personally identifiable.

The definition of “personally identifiable” turned out to be a complicated matter. In the Act on a Health Sector Database, ‘personally identifiable’ is defined according to Article 2 of a European Union directive entitled “Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data”:
‘Personal data’ shall mean any information relating to an identified or identifiable natural person (‘data subject’); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.

A draft of the Database Act, which Kári Stefánsson faxed to the Ministry of Health in July 1997, contained a different definition, based on Recommendation No. R (97) 5, of the European Council’s Committee of Ministers on the Protection of Medical Data (1997):

The expression ‘personal data’ covers any information relating to an identified or identifiable individual. An individual shall not be regarded as ‘identifiable’ if identification requires an unreasonable amount of time and manpower.

The second definition, from Recommendation No. R (97) 5, was used for the first two drafts of the Bill, but following severe criticism from the Data Protection Commission it was replaced in the third and last draft by the one from Directive 95/46/EC. During the controversy over the Health Sector Database Bill, deCODE insisted on using the second definition in the media. That was perhaps not surprising, since the technologies did not disconnect personal identification from data, but only coded it. According to the Directive, such data are personally identifiable and, hence, not anonymous. According to the Recommendation on the other hand, coded data may be considered non-personally identifiable, if identification required an unreasonable amount of time and manpower. The Act, however, did use the first and more restrictive definition from the Directive.

deCODE was to guarantee the security of health data by using complex encryption technologies. The data would be encrypted when transferred from a health care institution to the Identity Encryption Service, which would then again encrypt personal identifiers and send the data on to the company, which would encrypt the data once again. One of the three steps in this encryption procedure is supposed to be one-way, making it in principle impossible to trace the data back to the individual patient.

As the Data Protection Commission pointed out however, there are three major problems with regard to the proposed encryption procedure:

1. No encryption system is 100% secure.
2. As Iceland is a small country, information can easily be personally identifiable in indirect ways, even if it contains only a few facts about the patient, and even if these facts are not directly personally identifiable.
3. An encryption system is never more secure than the people who operate it; and, the more valuable the database, the more likely it is that someone will attempt to gain illegal access to it.\footnote{This point was illustrated by an incidence in 2006, where five former deCODE employees, now working for a competitor, were sued by deCODE for, among other things, stealing information about trade secrets, standardized research methods and procedures, financial contracts, software and data owned by deCODE. The company claimed that none of the cases included personally identifiable information about participants in research. The lawsuit was settled in June 2007. See deCODE, ‘Íslensk erfðagreining höfðar mál gegn fimm fyrrverandi starfsmönnum og bandarískum samkeppnisaðila vegna stuldar á vísindaniðurstöðum og viðskiptaleyndarmálum’, deCODE press release, 26 September 2006, at \url{http://www.decode.is/frettir/2006/2006_09_26.php} accessed 2 July 2007; deCODE, ‘deCODE Files Suit to Defend Intellectual Property’, deCODE press release, 26}
A fourth problem is that, in actual fact, the encryption methods are not one-way. And they could not be. If they were, it would be impossible both to link health data to genetic and genealogical data, and to add further information about a patient. A decoding key is necessary to link information concerning an individual when it is derived from a variety of sources or has been entered at different times. This key was supposed to be with a third party, the Data Protection Commission, but so far as the law is concerned it does not matter who has they key, what matters is that one exists.\(^\text{25}\)

The decision of the Icelandic Supreme Court in 2003 in the case of *Gudmundsdóttir v. the State of Iceland* (No. 151/2003), ignored the existence of a decoding key, but focused on another devastating problem. The data would clearly be personally identifiable, because of the richness of the data (it was to include age group (within a five year bracket), town or municipality of residence, education, marital status and of course all sorts of health information). So, despite a sufficiently strong encryption system, one-way coding and other technical measures, the data would be personally identifiable simply because it would be rich enough to pick out specific individuals, even in the absence of names, addresses, exact birth dates or identity numbers.

Privacy is also an issue for the genealogical database and the genetic database. Privacy is an issue for the genealogical database because it is based on official records of paternity, which genetic research may show to be false in specific cases. deCODE promised not to correct the genealogical database in light of genetic research, but this obviously goes against the instincts and interests of the researchers.

The genetic database contains samples from over 100,000 Icelanders, or more than one third of the nation. The privacy of genetic information is particularly problematic because it does not only concern the person from whom the information is obtained, but also close relatives. This led the Icelandic Supreme Court to decide in 2003 in the case of *Gudmundsdóttir v. the State of Iceland* (No. 151/2003), mentioned above, that the daughter of a deceased man could prevent his health information from being entered into the HSD. In the Reykjavik District Court, the case had been dismissed on the grounds that the daughter, Ragnheiður Guðmundsdóttir, did not have legal standing because the data were about her father, not herself.\(^\text{26}\) The Supreme Court granted Ms. Guðmundsdóttir legal standing on the basis that genetic data do not concern only the individual who is the source of them, genetic data also concern close relatives, in particular the individual’s children. Therefore, Ms. Guðmundsdóttir was granted legal standing and her personal interest in preventing her deceased father’s information from being entered into the HSD was acknowledged. In addition, her right to prevent the same was acknowledged, with the argument that the Act on a HSD did not sufficiently ensure that the data would be non-personally identifiable. Referring to the 1st paragraph of article 73 of the Icelandic Constitution, which states that “everyone shall enjoy freedom from interference with privacy, home, and family life”,\(^\text{27}\) the judgment stated that the constitutional guarantee of the right to privacy could not be replaced with monitoring of the establishment and operations of the database. In other words, the HSD Act violated the provisions on privacy in the Icelandic Constitution (art. 71, paragraph 1). The Supreme Court’s decision made the HSD Act untenable, but there have been no signs of Parliament revising the Act, nor of deCODE asking for a


\(^{25}\) Potts, ‘At Least Give the Natives Glass Beads’.

\(^{26}\) Ms. Guðmundsdóttir was a minor, the suit was filed on her behalf by her mother.

\(^{27}\) The Icelandic Constitution is available in official English translation at: [http://government.is/constitution/](http://government.is/constitution/) (accessed 2 July 2007).
revision of the Act. This strongly indicates that deCODE is no longer interested in creating the Health Sector Database.

**IV.ii Consent**

A second issue which was much debated in relation to the *Health Sector Database Act* is consent. The principle for gathering medical information for the Health Sector Database is that of “presumed consent”. If you do not send in a specific form asking not to be included in the health sector database, your consent is presumed and information will be collected from your medical records. The argument for allowing presumed consent (or rather opting-out) instead of requiring informed consent is that, first, the data will be anonymous or non-personally identifiable and thus comparable to data for epidemiological research which does not require consent; second, technical measures taken to ensure privacy, together with monitoring institutions, reduce the need for informed consent; and, third, informed consent cannot be given in any case since no one knows what sort of research will be conducted using the database in the future. The objection to the first is that the proposed combination of medical, genetic and genealogical data for research in medical genetics is not at all comparable to regular epidemiological research. On the contrary, this combination of data and the extent of the database render both the data and the research much more sensitive, and the participants more vulnerable to disclosure of private information, than is the case in epidemiological research. The objection to the second is that the requirement for informed consent for participation in scientific research cannot be cancelled or replaced by technical procedures, regulations and monitoring institutions. The objection to the third is that it is possible, albeit cumbersome, to require informed consent for participation in database research, as was the case in UmanGenomics’ database in Umeå, Sweden.

There is at least one further argument against resorting to “presumed consent”. It does not protect those who are most vulnerable, such as many of the sick and the elderly, those with cognitive impairments, drug addicts and others who are unable, unwilling or simply unlikely to actively protect their interests.

Genealogical data is considered public and does not require consent of any kind. Genetic data for scientific research will require informed consent, with the notable exception that biosamples taken for diagnosis or treatment can be stored and used for research without informed consent (unless the “donor” explicitly forbids it).

There were claims that the Icelandic population had given “community consent” or “democratic consent” to the database project. This was based on the sheer amount of debate, measured in the number of newspaper articles and programmes on TV and radio on one hand and on

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the democratic process of making legislation on the other hand.\textsuperscript{30} Bare quantity of discussion cannot however amount to democratic consent, the qualitative level of the debate is important, in particular that it is informed, free and rational. This was not necessarily the case in the debates in Iceland. As for the democratic process, it is correct that democratically elected members of parliament debated the HSD Bill and the majority voted for the Bill to become law. But there is much more to democracy than voting for representatives for the legislature every four years. The parliamentary process is only democratic in name when a Bill, such as the HSD Bill, is drafted by the company which is most affected by it and is then forced through the Parliament, ignoring both the arguments of the opposition and the expert advice of those asked to comment on the Bill, as well as criticism in society from doctors, scientists, academics and others concerned.

\textit{IV.iii Benefit sharing}

Benefit sharing was barely an issue at all in the debates and discussions in Iceland surrounding the HSD Act, but two specific benefit sharing agreements were negotiated: between deCODE and Roche for free pharmaceutical and diagnostic products for the Icelandic population; and between deCODE and the Ministry of Health as part of the Operation License, where deCODE was to pay 6\% of profits annually (with a relatively low maximum of approximately EUR 800,000).

The promise of free drugs was criticized, for instance by one of deCODE’s founders (he left the company and became one of its main critics), physician Ernir Snorronson, who wrote a letter to the parliamentary committee on health, as the HSD Bill was debated in Parliament, arguing that free medications would harm patients’ health, as older, well-known drugs will be replaced by free medications fresh from clinical trials and with little-known side effects (some side effects may first emerge once a drug is on the market and in wide use). Ernir Snorronson suggested that Roche wanted to use the Icelandic population for testing drugs for efficacy and side effects.\textsuperscript{31} Jórunn Eyfjörð of the Icelandic Cancer Society’s research lab, in an interview with \textit{Science}, called the promise of free drugs “a joke. ... How many drugs do you think are going to be developed, and how many people will really benefit from that?”\textsuperscript{32} Jamaica Potts tries to answer a part of that question:

Schizophrenia afflicts up to 1\% of a population, so approximately 2850 Icelanders may benefit if a new drug is developed. A recent innovative treatment for this disease uses a drug called Ziprasidone, which costs $8.12 a day for the average patient. […] If the drug developed by deCODE can fetch the same market price of around $8 per day, each Icelander using the medicine would require $2920 worth of medicine per year. Free medicines would thus save Icelanders or the Icelandic government up to $8.3 million if every schizophrenic took the new

\begin{footnotesize}


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medication. Such an example shows the potential upswing available to Iceland should such a drug ever become available.\textsuperscript{33}

The Icelandic population was expected to enjoy various other indirect benefits as a result of deCODE’s operations in Iceland and the database in particular. These included economic benefits, jobs created in the biotechnology sector, improved research environment for genetics and medicine in Iceland and attracting talented Icelandic scientists from abroad back home to Iceland. And Icelanders expected of course to have access to the medications coming out of the research through the national health service.

\textit{IV.iv Other issues}

A fourth issue is that of freedom of research: deCODE has been given exclusive rights to the medical information contained in the database. No one can use that information for scientific research without permission from deCODE, and it is explicitly stated that a permission will be given only if the proposed research is not perceived to conflict with deCODE’s business interests. Furthermore, medical doctors who were not willing to grant access to their medical records, or otherwise cooperate with deCODE, feared that they would be effectively excluded from doing research in medical genetics, since it would be practically impossible to conduct such research without relying on the HSD and thereby working with deCODE.

A fifth issue is related to the third: Commercialization and corporate control of medical data. deCODE is a private, American corporation. It was to have rights to sell information from the database to other corporations or institutions (with certain limitations). Many object to the commercialization of what is seen as confidential personal information or a public resource.\textsuperscript{34}

A sixth issue is genetic discrimination. Could health insurance companies use genetic information, gained directly or indirectly from the database, to determine rates or deny a person insurance? At this time the Icelandic health care system is for the most part public, offering universal health care with moderate user fees, but the trend is towards privatization.

\textit{IV.v Remarks on vulnerability}

In the \textit{International Ethical Guidelines for Biomedical Research Involving Human Subjects} of the Council for International Organizations of Medical Sciences (CIOMS), “vulnerable persons” is defined as

\begin{quote}
those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests.\textsuperscript{35}
\end{quote}

\textsuperscript{33} Potts, ‘At Least Give the Natives Glass Beads.

\textsuperscript{34} See for example Hilary Rose, \textit{The Commodification of Bioinformation: The Icelandic Health Sector Database} (London: Wellcome Trust, 2001).

The principle of presumed consent is problematic, because it does not protect vulnerable persons. The participation of vulnerable persons in research requires a special justification, but on the principle of presumed consent, vulnerable persons become by default participants in research like anyone else.

The purpose of informed consent is to ensure that the autonomy of the research participant is respected. He or she will make a deliberate and informed decision to participate (or not participate) in the research. Presumed consent puts the onus on the individual to obtain the information, understand it and make a deliberate decision to participate (or not to participate). In the words of two Icelandic critics of the principle of presumed consent, “a presumed consent policy legitimizes carelessness and ignorance among citizens about research participation rather than igniting reflective judgment or deliberation”. 36

Many vulnerable persons are vulnerable for reasons that also make their medical data more sensitive. For example, persons may be vulnerable, in the sense of the definition above, because of mental illness, cognitive impairments, drug addiction, alcoholism, or severe physical illness. Such persons often have a particularly great interest in protecting their medical data, but are incapable of doing so. Many of these vulnerable persons would not qualify to give informed consent in the first place.

Presumed consent was only an issue for the Health Sector Database (not the genetic and genealogical databases). Data were to be collected from medical records of all Icelanders who did not explicitly opt-out. In order to opt-out, one would have to become aware of the plans to collect and store health data in a centralized database, come to an opinion about them, take the trouble of getting an opt-out form from a health care center or from the internet (still available on the website of the Directorate of Health), fill in the form, sign it and mail it to the Directorate of Health. By 2003, more than 20,000 Icelanders had opted-out, 37 but for many it was too much to bother, even if they were well informed, opposed to the database and fully capable of opting out. 38

Conclusion

The Icelandic case gives rise to more questions than answers. What is the fair price of a genetic resource, when that resource is a human population? Who can decide to commercialize and sell such a resource, and through what process? This case involves deep ethical and political issues, not least regarding how the decision can be made to subject the population to this sort of research and whether the population can be sensibly said to have agreed or consented to the research as a population. Issues of privacy and consent are difficult to solve, because of the scope of the database research and absence of research plans when data are gathered, and also because of the richness of data, which makes them almost inevitably personally-identifiable, at least when they come from a quite clearly defined population like Iceland’s.

It is also evident, that the issues of privacy and informed consent can become major obstacles for the establishment of population-based genetic databases such as the one in Iceland, or UKBiobank, now under construction in the UK.

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36 Kristinsson and Árnason, ‘Informed Consent and Human Genetic Database Research’.
37 See the website of Mannvernd: http://www.mannvernd.is
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