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CODING AND CONSENT: MORAL CHALLENGES OF THE DATABASE PROJECT IN ICELAND

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ABSTRACT

A major moral problem in relation to the deCODE genetics database project in Iceland is that the heavy emphasis placed on technical security of healthcare information has precluded discussion about the issue of consent for participation in the database. On the other hand, critics who have emphasised the issue of consent have most often demanded that informed consent for participation in research be obtained. While I think that individual consent is of major significance, I argue that this demand for informed consent is neither suitable nor desirable in this case. I distinguish between three aspects of the database and show that different types of consent are appropriate for each. In particular, I describe the idea of a written authorisation based on general information about the database as an alternative to informed consent and presumed consent in database research.

INTRODUCTION

In the spring of 1998, a bill was introduced in the Icelandic parliament authorising the construction of a central database with medical information about the entire population.[1] In order to

[1] Much has been written about the history of this project and the controversial issues. See, for example: K. Stefánsson. 2000. The Icelandic Health Care Database: A Tool to Create Knowledge, a Social Debate, and a Bioethical and Privacy Challenge; T. Zoëga & B. Andersen. The Icelandic Health Sector Database: deCODE and the 'New' Ethics for Genetic Research; and S. Gudmundsson. The Icelandic Health Case – Current Status and Controversies. All in *Who Owns Our Genes?* Proceedings of an International Conference. Nordic Council of Ministers: 23–73. See also: R. Chadwick. The Icelandic Database – Do

finance the construction of the database, the license to operate it would be open to competition.[2] In the following months this small nation (approximately 290 thousand inhabitants) was shaken with fierce debates about the project. The bill was passed in December 1998, and in January 2000 the genetic research company Íslensk erfdagreining (or deCODE genetics Inc. as it is called in English) was given an exclusive license to operate the database for 12 years.

In this paper I will attempt to map and analyse what I take to be the major moral components of this issue. After explaining what the database is, I will discuss the moral questions regarding privacy and consent. I critically evaluate the arguments that have been presented for the policy of presumed consent and find them unconvincing. I then focus on the question of whether the requirement of obtaining informed consent for participation in research is applicable in this case. I will argue for a negative answer to this question and spell out an alternative way to obtain consent for participation in database research. This alternative, which I call an informed authorisation, is to strike a balance between protecting the interests of the participants in the database and paving the way for this new type of genetic research.

THE DATABASE

To start with, it is necessary to understand what the database is. Unclarity about this basic matter has made the issue opaque and confusing. In the law we find the following definition: 'Health sector database: A collection of data containing information on health and other related information, recorded in a standardised fashion on a single centralised database, intended for processing and as a source of information.'[3] In accordance with the law, I will refer to this 'centralised database of personally non-identifiable health data'[4] that will be processed from medical records, as the Health sector database or HSD. But the Act also authorises the licensee to connect data from the HSD to data from two other databases. The first is a database with genealogical data that have

Modern Times need Modern Sagas? *BMJ* 1991; 319: 441–444; H.T. Greely. Iceland's Plan for Genomics Research: Facts and Implications. *Jurismetrics* 2000; 40: 153–191; and H. Rose. 2001. *The Commodification of Bioinformation: The Icelandic Health Sector Database*. The Wellcome Trust.

[2] This was a mere formality. The idea initially came from deCODE Genetics Inc. and there never was a serious contender.

[3] Act on a Health Sector Database no. 139/1998, Art. 3.

[4] Act on a Health Sector Database no. 139/1998, Art. 1.

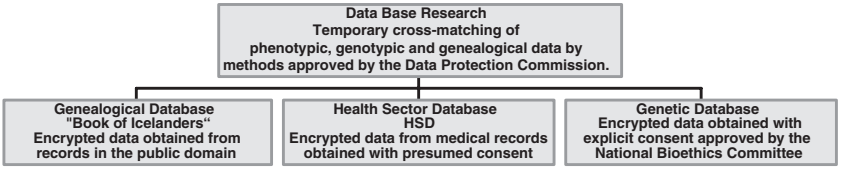

Figure 1: A Diagram of the Icelandic Central Database Complex

been processed from public genealogical records. The second is a database of genetic information that has been processed from biological samples obtained for research by physicians co-operating with deCODE. The genealogical database and the genetic database are not covered by the Health Sector Database Act but by other legislation.[5]

In effect, therefore, the Icelandic central database is a cluster of three databases with information that can be (temporarily) interconnected on certain conditions for research purposes. One of the confusing issues in the debate is that people mean different things when they mention the database. Often, 'the database' refers only to HSD,[6] but sometimes it refers to the complex of the three databases.[7] Sometimes, especially in the international

[5] The genetic database is covered by the Act on Biobanks no. 110/2000, the Patients' Rights Act no. 74/1997, the Data Protection Act no. 77/2000 and other legislation. The genealogical database is covered by the Data Protection Act.

[6] This is most obvious from the Act itself. A clear example of this use is a pamphlet put out by the Icelandic National Directorate of Health, and sent to every household in Iceland, intended to inform the population about the HSD. The question 'What is a centralised database?' is answered: 'A centralised database is a collection of selected health data, derived from medical records and stored in computerised form in one location. The data will be coded, and protection [sic!] by access limitations. They are not traceable to individuals (i.e., not personally identifiable), except by expending considerable funds and manpower, and subject to revocation of the operating licence, fines and imprisonment.' Centralised Health Sector Database. Questions and Answers. May 1999: 3. Later it is explained that 'the database may be linked to a database of genealogical data.' There is no mention of a database of genetic data. Instead, this doubly misleading clause: 'Genetic data derived from biological samples previously donated for purposes of scientific study will not be entered into the database, except with the consent of the individual concerned (informed consent).'

[7] This complex has no official name. The Act on a Health Sector Database no. 139/1998, Art. 10 simply states: 'The licensee shall develop methods and protocols that meet the requirements of the Data Protection Commission in order to insure confidentiality in connecting data from the health-sector database, from a database of genealogical data, and from database of genetic data.' Moreover, the act permits that the HSD be connected 'with other databases than those specified here.' The Government regulation on a Health Sector Database

press, the entire database is even reduced to a biobank or a genetic database, usually in relation to the remark that Icelanders have sold their genome to a private company.[8] This deceptive picture has been effectively used by critics to discredit this controversial project.

While it is correct, useful and important to distinguish between the three databases, it is clear that the threefold complex is regarded as of major research interest for the licensee: as two major spokesmen of deCODE write, 'One of the principal advantages of this data base is the ability to cross-reference phenotypic information with a large amount of genotypic and genealogical data.'[9]

THE ISSUE OF PRIVACY

The moral issue of privacy is closely related to respect for persons and their liberty: 'the right to privacy protects liberty by delineating a zone of private life within which the individual is free to choose and act.'[10] In this context, the right to privacy could be seen as the rightful control of individuals over access to information about themselves. In the debate about the Icelandic database project, however, the single issue that caught the most attention was the worry that individuals could be identified by the information in the HSD.[11] The emphasis has mainly been on two kinds of technical issues. The first is a legal technicality about personal identifiability. The HSD Act states that a person is identifiable 'if he can be identified, directly or indirectly.'[12] This clause has

No. 32/2000, Art. 32 states: 'The Licensee shall establish rules of procedure and work processes which meet the conditions of the Data Protection Commission in order to insure privacy protection in the cross-referencing of data from the Health Sector Database, a genealogical database, and a database containing genetic data.'

[8] To take only one typical example of this pervasive misunderstanding: R. Lewontin writes that the HSD project implies 'selling of Icelandic DNA.' People are not Commodities. *New York Times* 23 January, 1999. I have frequently heard scientists and politicians describe the Icelandic database in this way, for example at parliamentary hearings about biobanks in Uppsala 16 September, 1999, and in Copenhagen 2 October, 2002.

[9] J. Gulcher & K. Stefánsson. The Icelandic Healthcare Database and Informed Consent. *NEJM* 2000; 342: 1827.

[10] T.L. Beauchamp & J. Childress. 1989. *Principles of Biomedical Ethics*. Oxford. Oxford University Press: 318.

[11] This was the main concern of professionals and politicians; it is not clear whether the common Icelander was much concerned with this question.

[12] The Act on a Health Sector Database no. 139/1998, Art. 3: '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

been interpreted in accordance with a Recommendation of the European Council of Ministers: 'An individual shall not be regarded as "identifiable" if identification requires an unreasonable amount of time and manpower.'[13] In light of this, data in the HSD have been regarded as unidentifiable because of the sophisticated coding techniques employed.[14] This stipulative definition of unidentifiability is debatable and relatively weak. Unidentifiable data in this sense must not be confused with anonymous and anonymised data that 'have been irreversibly stripped of all identifiers and are impossible to link to their sources.'[15] On this standard, information in the HSD is not anonymous; they are more correctly described as 'unidentified for research purposes, but can be linked to their sources through the use of a code.'[16] This is important because the unidentifiability of information has been used as one of the main arguments for not obtaining explicit consent for entering information into the HSD. But unidentifiability in the sense used in the Act on a Health Sector Database is by itself not strong enough for waiving individual consent.

Secondly, it is relative to decoding techniques at each time how safe the coding devices are. Since there will never be an absolute protection of privacy of coded data, the risk of identification is always there. Moreover, it can be argued that when healthcare data are connected to genealogical and to genetic information, there is a considerable risk in a small society that individuals can be identified, even though the data obtainable for research and inquiries from the HSD will only be in statistical form and never about fewer than a group of ten.[17] There are also instances in the process where the data are not coded and the only protection is the confidentiality of the staff working with the information.

specific to his physical, physiological, mental, economic, cultural or social identity.' This is in accordance with the European Data Protection Directive (95/46).

[13] Recommendation No. R (97) 5 (50).

[14] The Data Protection Commission's definitions of technology, security and organisation terms, which the Licensee must fulfil in relation to the preparation and operation of the HSD, is found at: http://www.personuvernd.is/english

[15] The American Society of Human Genetics Report. Statement on Informed Consent for Genetic Research. *Am. J. Hum. Genet.* 1996; 59: 472. Similar definition is in: E.W. Clayton et al. Informed Consent for Genetic Research on Stored Tissue Samples. *JAMA* 1995; 274: 1787.

[16] ASHG Report. *Am. J. Hum. Genet.* 1996; 59: 472.

[17] Cf. E. Arnason. Personal Identifiability in the Icelandic Health Sector Database. *The Journal of Information, Law and Technology* 2002; 2. http://elj.warwick.ac.uk/jilt/02-2/arnason.html (accessed on 27 November, 2002).

It is unrealistic to expect that disputes about the identifiability of healthcare data will be settled. Although the data are not unidentifiable in the strict sense,[18] it is not unreasonable to expect that they can be kept coded and confidential. Moreover, there are important arguments for retaining links to samples. Irreversibly unlinking them not only precludes the possibility of cross-referencing data, but also makes it impossible to contact the source of the sample in cases where that could be of benefit to him or her and possibly to relatives. Linkability can also increase individual control over data. It could be argued, therefore, that there is an ethical presumption in favour of linkability with emphasis on strong measures of confidentiality and privacy, coupled with means of obtaining individual consent.

Security of information of the kind that goes into the Icelandic database is a crucial issue. My criticism is aimed at the way in which the emphasis on coding has been used to exclude the question of consent. There is a tendency to focus either on coding or consent. An emphasis on consent should certainly not ignore the need for the security of the data,[19] and sophisticated coding is not always a good reason for waiving consent. If consent were obtained from individuals for entering the HSD, this would be one of the factors for their deliberation about whether to participate or not. Instead, they are told that because the information will be so well protected their consent will be presumed. Strong encryption has thus not only been used to protect the data but also to paternalistically override the autonomy of the Icelandic people.

Technical secrecy cannot, either, replace the trust between patients and professionals. It should be up to the individual participants to decide whether they trust researchers and other staff to deal with important medical information about themselves in a responsible way. It is also an important issue of trust for the individual to delegate decisions about storage and use of their personal data to ethical committees and other supervisory institutions. Due to the exclusive emphasis on the technical aspects of coding and secrecy in the HSD debate, the moral issue of privacy

[18] For discussion of this issue, see: A. Meyer & A.C. Zeller. The Icelandic Health Sector Database and the Right to Privacy. *Human Rights and Law Journal* 2000; 21: 404.

[19] Jane Kaye correctly emphasises this in: Genetic Research on the UK Population – Do new Principles need to be Developed? *Trends in Molecular Medicine* 2001; 7: 529.

that is intimately linked with individual consent and trust has been neglected.

THE QUESTION OF CONSENT

It complicates the issue of consent for participation in the database that there are different requirements for the three databases explained above. For the HSD there is a blanket presumed consent for placing information from medical records on the database and an opt-out policy.[20] The law states that a patient may at any time request that any existing or future information about him or her will not be placed or stored in the database. According to a special agreement between deCODE and the Icelandic Medical Association, participants in the database will also have the right to withdraw their information when they so wish.[21] For the genealogical database, which is processed and encrypted (in computerised sequence codes) from a publicly accessible collection called the 'Book of Icelanders', there is no consent obtained or presumed and no opting out policy either. And for the genetic database, which is being built up by deCODE, there is an explicit written consent. The consent policy for each of these databases is problematic. I will first briefly discuss the consent for the genealogical database and then focus on the consent for the genetic database and for the HSD.

To start with the genealogical base, which is the simplest case, people are not asked whether they would like to participate in this database since in Iceland genealogical records are public material. But this is by no means unproblematic. It is one thing to be presented in a family tree that is accessible to curious members of the public, and quite another thing to have these genealogical data be subjected to scientific research where they can be connected to healthcare information and genetic data. It could be argued that those individuals who do not opt out of the HSD are thereby also consenting to their presence in the genealogical database in a coded form. But then the reverse

[20] The initial proposal did not require any form of individual consent for the inclusion of medical information in the HSD, but this was later changed to the 'opt out' mechanism because of international and domestic pressure.

[21] This agreement, which was signed on 27 August, 2001, was part of an effort to settle deep disagreement between the two parties about the HSD. http://www.icemed.is/frettir/yfirlysingLI-IE.htm (accessed 15 November, 2002). But this important agreement has no legal standing.

should also apply, that individuals who opt out of the HSD are thereby refusing to be in the genealogical database. Although it would be more of symbolic than substantial significance, they should have the right to be sheared from their family tree before the genealogical data are processed into the database.

As for the genetic database, I said that an explicit consent is obtained from participants in genetic research. In co-operation with contracted physicians, deCODE genetics has collected blood from thousands of people in relation to several research projects of diseases in families.[22] Participants in this research have been given options to sign either of two consent forms, '1A' and '1B.' The A option authorises the researchers to use the sample for a particular research that is described and then to destroy the sample. This 'restricted' option meets in principle the requirements of informed consent, but these samples will only be stored in a genetic databank as long as is necessary for the specified research. Consent form B authorises the researchers to use the sample for the particular research described in the protocol *and* to use it for further research of the same kind, provided that it will be permitted by the Data Protection Commission and the National Bioethics Committee. By signing the B form, participants also consent to having their DNA extracted from the blood sample that will be coded and stored (presumably in a genetic databank). This genetic material may be used for any research that has been approved by the Data Protection Commission and the National Bioethics Committee.

The National Bioethics Committee decides in each case whether new consent shall be obtained.[23] According to their criteria, the committee will permit additional research without obtaining new consent from those who signed the B form, provided that the initial research has been adequately performed and the additional research:

[22] On the deCODE homepage, under the heading of 'Science and Research' / 'The deCODE Population Approach' / 'Unique Resources', it says that the company has collected 'DNA samples and detailed disease data from approximately 80.000 volunteer participants in more than 50 disease projects.' http://www.decode.com/ (accessed 9 December, 2002). These samples have been collected with either A or B consent.

[23] The criteria of the Icelandic National Bioethics Committee 'on informed consent for participation in genetics research and/or research which is based on the use of biosamples' were accepted by the committee in October 2000. They are published in Icelandic on the website: http://www.visindasidanefnd.is/ (accessed 18 November, 2002).

- is scientifically/medically grounded;
- poses no risk to the participants;
- is such that it would not have affected the participants' decision to participate; and
- is a natural continuation of the initial research and/or deals with the same or related research question.[24]

It is questionable whether this 'wider' option B meets the requirements of informed consent in all cases. It depends on the information and understanding the participants have about this 'additional research' at the time the consent is obtained. But even granting that genetic information is collected on the genetic database with informed (B type) consent, that does *not* imply informed consent for the intended database research (i.e., the cross-matching of genetic, genealogical and disease information).[25] The B consent will not be sufficient for the new type of database research that could not be specified at the time of collection. In fact, database research of this type requires a still broader consent ('C'!) which would not meet the requirements of informed consent.[26] Such a policy is not, however, permitted by Icelandic law, which requires informed consent for participation in scientific research.[27] Moreover, database research that includes all three types of information cannot be performed except by permission from a separate Interdisciplinary Ethics Committee which regulates every inquiry from the HSD.[28]

It remains to be seen, therefore, what the actual consent policy for database research will be. It will mainly depend upon three things. The first is the regulations of the Data Protection Com-

[24] My summary.

[25] This can be quite misleading. For example, G. Palsson and K. Hardardottir (in: For Whom the Cell Tolls. Debates about Biomedicine. *Current Anthropology* 2002; 43: 271–301, at 275) say that blood samples for the genetic database will be 'obtained with informed consent.' The reader is likely to wrongly assume that this implies informed consent for the use of genetic data in database research.

[26] This is acknowledged by J. Gulcher and K. Stefánsson (*op. cit.* note 9, p. 1828) who say that genetic data are obtained 'with individual consent': 'An unresolved issue is whether deCODE will be allowed to ask for broad consent from participants to correlate any information in the database with data on variance in their genomes (genotypic data). "Broad consent" as applied here indicates consent in which the potential subjects cannot be informed in the same detail required by informed consent.'

[27] The Patients' Rights Act (no. 74/1997), Art. 10.

[28] Act on a Health Sector Database no. 139/1998, Art. 12.

mission concerning conditions for the connections of the healthcare data and genetic data.[29] These regulations are still in the works. Secondly, the Icelandic parliament will have to take up this issue again if the law on Patients' Rights needs to be changed before the use of genetic data for database research can be permitted. The third is the enactment of the Icelandic law on biological samples. This act permits research on biological samples that have been collected for clinical tests without obtaining explicit individual consent.[30] According to the law, deCODE genetics could negotiate an agreement with already existing biobanks to carry out research on biological samples which have been collected for clinical tests, provided that the Data Protection Commission and the National Bioethics Committee give their permission.[31] The only control for individuals over their biological samples is the right to restrict their use for research or to withdraw from research.[32] This right is altogether ineffective, however, unless the population is well informed about the policy. The Icelandic population sorely stands in need of such education.

I will return to the question of consent for participation in genetic database research in the last two sections of the paper.

[29] It must be stressed that although deCODE has already constructed extensive genealogical and genetic databases, no central database has yet been constructed in Iceland and some crucial regulations are still in the works. The specifications for the database are attached to the license agreement which can be obtained at the Icelandic Ministry of Health homepage: http://www.ministryofhealth.is

[30] Act on Biobanks no. 110/2000. For a critical discussion of this Act, see: D.E. Winickoff. Biosamples, Genomics and Human Rights: Context and Content of Iceland's Biobanks Act. *Journal of BioLaw and Business* 2000; 4: 11–17.

[31] Act on Biobanks no. 110/2000, Art. 7, para. 3: 'If biological samples have been collected for the purpose of clinical tests or treatment, the consent of the patient may be assumed for the storage of the biological sample in a biobank for use as provided in art. 9. provided that general information on this is provided by a health care professional or health institution.' Art. 9 para. 3: '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.'

[32] Act on Biobanks no. 110/2000, Art. 7, para. 4.: '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 . . .'

CONSENT FOR PARTICIPATION IN HSD

The health sector database provides for an interesting and controversial issue of consent. This is partly because the objectives of HSD have not been clearly explained and partly because its relation to the other databases is not entirely clear.

The presumed consent fleshed out in the opting out policy has been supported with four main arguments. The first argument has to do with the usefulness of the database. If explicit consent would be required, it would obstruct the gathering of information and the scientific quality of the database would be diminished. Although this might be correct, which I doubt, such an argument does not weigh heavily in the discourse of research ethics: 'There is legal and ethical presumption in favor of obtaining informed consent even though it means that much medical care is based on research that relies on biased samples because potential subjects could choose not to participate.'[33] The appeal to patients' benefit in the argument (the scientific quality of the database is presumably linked to its possible benefits for people) cannot be legitimately used to outweigh the requirement of respect for autonomy unless it is coupled with other important considerations.

The remaining arguments are meant to provide those other important considerations. We do not need to explicitly obtain individual consent, it is argued,[34] because the data are securely coded. Since there is no personally identifiable information in the database, the requirement of respect for persons, their explicit consent can legitimately be waived. I have already tackled this argument in my discussion of the issue of privacy above where I argued (i) that the information in the database is identifiable, and (ii) that technical secrecy must not be confused with, and hence cannot replace, the requirement of consent. While technical secrecy protects important interests of individuals, obtaining consent shows respect for their moral status.

The third argument is based on the notion of 'community consent.'[35] The idea seems to be that because of the extensive debate that took place in Iceland about HSD and the overwhelming support for it shown in Gallup polls, it is fair to collect data under the presumption of consent.[36] This could be

[33] E.W. Clayton et al. Informed Consent for Genetic Research on Stored Tissue Samples. *JAMA* 1995; 274: 1789.

[34] Icelandic politicians have been particularly keen on this argument.

[35] See, for example: Gulcher & Stefánsson, *op. cit.* note 9, pp. 1827–1830.

[36] Gulcher and Stefánsson even define presumed consent in this context as 'the consent of society to use health care information according to the norms

true under ideal dialogical conditions of fully competent and informed people. But members of marginalised groups (e.g., mentally ill, poor, illiterate, children), the protection of whom should be the primary concern of research regulation, are likely to be exactly those people who have not participated in or even followed the national debate over this issue, however intensive and extensive that debate may have been.

Moreover, quantitative facts about extensive debate and overwhelming majority opinion must not be confused with the qualitative notion of consent to participation in research, which implies an understanding of the issue consented to.[37] Community consent has to meet both procedural and substantive criteria. The procedural requirements have to do with the time allowed for the debate, the unhindered access of the public to relevant information about the case, and so on. The substantive requirements have to do with the subject matter of the debate, whether the public was well informed about the relevant issues and the principles needed to assess them. It seems to me, if the debate would be scrutinised, that it would fail on both accounts. Much of the HSD debate was uninformed, misleading and prejudicial. The bill was rushed through parliament, informed criticism was largely ignored, and only 13% of the population claimed to have a good grasp of the issue, according to a Gallup poll conducted a month before the law was passed.[38] To a large extent the community debate took place after the bill was passed. Community consultation was minimal and conducted by the prospective licensee. A prior, free, reasoned and informed public dialogue,

of society'. Ibid. p. 1827. As G. Annas correctly points out, 'a community can approve a research project. It cannot legally or ethically require individual members of the community to participate' (Rules for Research on Human Genetic Variation – Lessons from Iceland. *NEJM* 2000; 342: 1831). And as R. Macklin writes: 'When a society's norms and customs diverge from the basic principles of research ethics, researchers are obligated to adhere to the research ethics and not to local or cultural customs' (1999. *Against Relativism.* Oxford. Oxford University Press: 203).

[37] G. Palsson and P. Rabinow state, for example, that the decision about HSD 'was clearly the product of informed democratic consent' (Iceland. The Case of a National Human Genome Project. *Anthropology Today* 1999; 15: 17). The same authors rightly point out, however, that by comparison Icelanders have done quite well and 'the construction of centralized medical databases has gone largely unnoticed' in some other countries: G. Palsson & P. Rabinow. The Icelandic Genome Debate. *TRENDS in Biotechnology* 2001; 19: 169.

[38] The newspaper: *Morgunbladid* 18 November, 1998.

which alone can engender a community consent, never took place.[39]

It is interesting to note that the appeal to the overwhelming support for the HSD in the Icelandic population could clearly be used as an argument for obtaining explicit rather than presumed consent. The argument of substantially decreased coverage, as Henry Greely has pointed out, 'contradicts the premise of the opt-out form of consent, which presumes that people who do not return the opt-out form really do agree to be research subjects.'[40] It is only an educated guess, but I believe that the main reason why many people opted out is that they simply find it wrong not to seek explicit consent from participants in this unique project. If this is correct, participation in the HSD perhaps would have been even more extensive had explicit consent been sought.[41]

The core of the fourth argument for the practice of presumed consent is that since HSD consists of information from medical records, it will mainly be used for epidemiological research and statistical analysis of data useful for public health policy. Presumed consent is the rule in epidemiological research on non-identifiable data routinely collected in the healthcare services.[42] In fact, the argument goes, the opting out policy implies further recognition of individual autonomy than is strictly required for data collected for research of this kind. Even if they are wrongly assumed to be unidentifiable, they are probably more safely protected than any other information in the Icelandic healthcare system.

In response to this argument, I will sort out three points that I deem to be of major importance. The first is that the statement that HSD will be merely suited for standard epidemiological research presumes that it is an isolated base with no connections to the genealogical and the genetic information. This is misleading at best and diverts attention from the database complex that is the main asset of this project. Clearly, if healthcare data are

[39] Cf. V. Árnason & G. Árnason. Community Consent, Democracy and Public Dialogue: The Case of the Icelandic Health Sector Database. *Politeia. Rivista di Etica e Scelte Pubbliche* 2001; 63: 105–116.

[40] H.T. Greely. Iceland's Plan for Genomics Research: Facts and Implications. *Jurismetrics* 2000; 40: 182.

[41] As of 30 June, 2003, 20 426 had opted out of the HSD: http://www.mannvernd.is (accessed 6 September, 2003). An unfortunate effect of the opt-out policy is that a databank with the names of those who opt out is stored at the Icelandic National Director of Health!

[42] Cf. B. Brody. 1998. *The Ethics of Biomedical Research.* Oxford. Oxford University Press: 60.

cross-referenced with genealogical and/or genetic information, there is more than ordinary epidemiology at work.[43] There is something new, interesting and possibly risky going on in this research, which individuals should be explicitly informed about before they decide whether to take part or not.

Secondly, it has been argued that individual consent should be required 'because of the commercial nature of the data bank and its for-profit research agenda.'[44] This is an important point that deserves more attention than I have space for in this paper. The Act on HSD implies that healthcare information is handed over to a third party that is not involved in the patient's care.[45] Had the HSD been within the public domain of the Icelandic national healthcare system, a presumption of consent could have been substantiated by an appeal to reciprocity and common benefit. When the information has become a commodity to be exploited by a private company for commercial profit, we are in a very different context that goes far beyond the traditional setting of healthcare research.[46] For whatever reasons, this has not been particularly disturbing to the majority of the Icelandic public who have decided to trust the company.[47] It is preferable, however, to base

[43] This has been well described by J. Kaye and P. Martin: 'In the longer term the company plans to integrate this database of individual genotype profiles with the medical records of almost every Icelandic citizen and publicly available genealogies. These three separate databases will be linked under the administrative structure of the Health Sector Database to allow deCODE to carry out genetic epidemiological research.' J. Kaye & P. Martin. Safeguards for Research using Large Scale DNA Collections. *BMJ* 2000; 321: 1146.

[44] Annas, *op. cit.* note 36, p. 1831.

[45] The new WMA guidelines on health databases declare: 'Patients' consent is needed if the inclusion of their health information on a database implies a disclosure to a third party or would permit access by people other than those involved in the patients' care.' The World Medical Association Declaration on Ethical Considerations regarding Health Databases, Art. 17. http://www.wma.net/e/policy (accessed 15 November, 2002). There is a debate between the Icelandic medical association and deCODE in Iceland as to whether this article applies to the HSD, but they had previously agreed to abide by the WMA statement in the agreement signed 27 August, 2001 (*op. cit.* note 20).

[46] Public and private interests have been unhappily mixed throughout this process. The Icelandic government has been unusually favourable to this particular company, probably in the belief that it would bring great benefits to the Icelandic economy.

[47] Two Icelandic lawyers urged people to opt-out of the HSD and offered to act on their behalf to negotiate payments in return for rejoining. Icelanders showed no interest in this and the idea was stillborn. The newspaper: *Dagur* 23 February, 2000. A German philosopher has argued for a contract model between participants and research companies. Such a contract would imply re-compensation in the case of exploitation and sharing of financial profits. H.M. Sass. A

trust on information rather than ignorance and explicit individual consent would have contributed to more informed decisions in the population.

The third and the weightiest point is that the opting out policy is only suited to competent informed adults. It does not take into account the interests of those – for example the very ill, the demented and mentally handicapped – who are unable to make informed decisions. In fact, presumed consent involves no guarantee that competent people make up their mind at all. To the contrary: healthcare data about people who have never reflected upon this issue for lack of interest or initiative or general negligence of their own interests are likely to end up in the database. Rather than igniting reflective judgement, the presumed consent policy legitimises carelessness and ignorance among citizens about this important issue. This is contrary to the spirit of contemporary research ethics. Although explicit consent does not secure enlightened decisions, it offers people an opportunity for reflecting. One might add that this policy is rather impolite because it says in effect: 'we will lay hold of your information unless you forbid it', rather than the more civil 'we will lay hold of your information if you allow it.'

This is mildly put. The hard critics of the opting out policy have argued that it violates ethical standards in research on human subjects, namely the requirement of informed consent.[48]

THE DEMAND FOR INFORMED CONSENT

If we are to preserve a meaningful notion of informed consent for participation in research, it should only be used about specified research where the participants are informed about the aims and methods of a particular research proposal, the foreseeable risks and possible benefits involved, that personal research data will be kept confidential, and that participants have the right to withdraw from the research at any point.[49] These are the

'Contract Model' for Genetic Research and Health Care for Individuals and Families. *Eubios. Journal of Asian and International Bioethics* 2001; 11: 130–132.

[48] See, for example: Greely, *op. cit.* note 1, p. 182.

[49] Cf. World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, Article 22. Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964. Amended by the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000. WMA Website: http://www.wma.net (accessed 28 October, 2002).

ingredients of informed consent.[50] There is no such thing as 'general informed consent.' The more general the consent is, the less informed it becomes. It is misleading to use the notion of informed consent for participation in research that is unforeseen and has not been specified in a research protocol. It is, however, another and an open question whether it is wise to require informed consent for all secondary research purposes.

If we presuppose this standard meaning of informed consent, it seems to me that it is impossible to obtain it from those who intend to participate in HSD. But as critics all too often overlook, this fact is not sufficient to denounce the database project.[51] Let's consider two options for obtaining informed consent. The first option is to obtain informed consent from participants *before* their healthcare information is placed in the database. But at this point no specific research plans exist, so it is impossible to explain any of the ingredients of informed consent to the prospective participants. There are no specific objectives to be explained, no determinate risks or benefits to be assessed. Informed consent for research before entering the database would, therefore, be empty and senseless. The only specific ingredient that would be possible to explain is the right to withdraw information from the database at any time, that is to say if the aforementioned agreement between deCODE and the Icelandic Medical Association will be put into practice.

The second option would be to obtain informed consent from individual participants for each particular research *after* entering the database. But because of the heavy emphasis on coding and privacy this would be extremely complicated and cumbersome. Not only would it jeopardise individual privacy but also, according to many scientists, severely limit the research possibilities that the HSD is intended to provide.[52] If these scientists are

[50] Moreover, informed consent requires time for dialogue about the research. This is very difficult to facilitate in genetic epidemiological research. The idea of community consultation is more appropriate in that setting.

[51] This has been characteristic of the arguments of the spokespersons of Mannvernd, the Association of Icelanders for Ethics in Science and Medicine, with respect to consent for participation in the database. Cf. the website: http://www.mannvernd.is/english

[52] In a booklet from deCODE genetics it is stated that the demand for informed consent would make it very difficult to realise the idea of HSD. Gagnagrunnur á heilbrigdissvidi. Spurningar og svör. Íslensk erfdagreining: 20. For worries of this kind, although not about the HSD, see for example: L.J. Melton III. The Threat to Medical-Records Research. *NEJM* 1997; 337: 1466–1469; and A. Buchanan. An Ethical Framework for Biological Samples Policy. A Commis-

right, the possible benefits of database research, which requires different methodology and a more free interplay of information than traditional research, would also be lost. In addition, it might be quite difficult to explain this research each time to members of the public in such a way that their consent would count as informed. For these reasons it is not advisable to obtain informed consent from individuals after their healthcare information have been placed in the database.

If my arguments are sound, it follows that the standard demand for informed consent is not well suited for research on the information in the HSD. The question then is what the implications of this are. The most restrictive one is that if informed consent cannot be obtained from individuals, no research should be allowed on the HSD. In this view, informed consent protects the inalienable rights of research participants and it should never be waived. Another implication would be to say, as Icelandic authorities have done, that since informed consent cannot be obtained, blanket presumed consent will have to suffice. But these are two extremes that certainly do not exhaust the possibilities. There is a viable middle way between informed and presumed consent, as they are generally understood. If we want to be open to these new research possibilities, we need to be ready to find ways other than individual informed consent to secure the participants' interests.

As I argued above, the requirement of informed consent must also be waived in the collection of genetic data for database research. This is certainly nothing unique but rather in line with a trend that has been forming in the recent years. Legal and moral theorists have increasingly admitted that in this new research environment of multifaceted databases 'too much cannot be expected of individual informed consent, a doctrine that was not designed to deal with scenarios of this type and style.'[53] Stubborn demands for individual informed consent might not only impede the advancements of medical research,[54] but also falsely legitimise complex research because 'consent

sioned Paper. Research involving Human Biological Materials: Ethical Issues and Policy Guidance. *National Bioethics Commission* 1999; 2: B19–B20.

[53] R. Chadwick. 2001. Informed Consent and Genetic Research. *Informed Consent in Medical Research.* London. BMJ Books: 210.

[54] L.O. Gostin & J.G. Hodge. Genetic Privacy and the Law: An End to Genetic Exceptionalism. *Jurismetrics* 1999; 40: 21–57. H.T. Greely. Breaking the Stalemate: A Prospective Regulatory Framework for Unforeseen Research Uses of Human Tissue Samples and Health Information. *Wake Forest Law Review* 1999; 34: 737–766.

achieved by overwhelming an agent's cognitive capacities provides no genuine justification.'[55] The principle of informed consent as such is not at stake, but rather the interests that it is intended to protect. The primary harms against which informed consent provides protection (such as non-consensual bodily invasion and disrespectful treatment[56]) need to be analysed in this changed context of consent along with the institutional fabric upon which individuals can place their trust.

This is a formidable task, which I cannot undertake here. I will, in the final section of this paper, describe a way of obtaining consent for participation in the Icelandic database which implies an alternative to the extremes of informed and blanket presumed consent.

AN ALTERNATIVE

In order to avoid confusion of concepts, I will not use the notion of consent in my proposal for an alternative way to obtain consent from individuals for processing their healthcare information into a coded form to be placed in a central database. Instead, I will use the notion of an explicit written *authorisation* for participation in database research based on general knowledge about the database and the research purposes and practices.[57] The idea is quite simple. No healthcare data about living individuals should be placed in the HSD without the written authorisation of the individual or his/her proxy. A proxy authorisation is needed for those who are, for one reason or other, unable to make informed decisions. Parents should authorise the use of healthcare data about

[55] O. O'Neill. Informed Consent and Genetic Information. *Stud. Hist. Phil. Biol. & Biomed. Sci.* 2001; 32: 701. As O'Neill also points out (p. 696), the limits of individual consent are increasing in light of implications of the family in genetic research. See also: Chadwick, *op. cit.* note 53, pp. 203–210.

[56] Buchanan, *op. cit.* note 52, pp. B16–B18.

[57] Henry Greely uses the term 'permission' in his important proposal of a middle way between informed consent and abandoning consent requirements. Greely argues that the 'requirement of informed consent to the use of non-anonymous information or samples prevents much potentially valuable research.' Greely, *op. cit.* note 54, p. 761. It is all the more strange, therefore, that in a more recent paper about the Icelandic HSD he states that the 'presumption should be in favor of individual affirmative, informed consent.' Greely *op. cit.* note 1, p. 182. The idea of authorisation presented here is similar to Greely's proposal but it has been formed in discussions with my colleagues in Iceland in light of the situation there.

their dead children under the age of 18.[58] Coded healthcare data about other deceased individuals, who died before the option of entering the database became viable, can be placed in the database without authorisation.[59]

The authorisation implies that an individual permits in writing that healthcare data will be processed from his/her medical records and moved in a coded form into the HSD. The authorisation also implies that the individual has been informed about, and that he or she claims to have understood, at least the following:

- which information about her/him will be placed into the HSD;
- how privacy will be secured (without going into technical details);
- how the information will be connected to other data;
- who will have access to the information;
- in what context the information will be used and for what purposes;[60]
- how consent for genetic research will be obtained;
- what are the foreseeable risks and benefits of participation;
- how research on the data will be regulated; and
- that the individual has the right to withdraw the healthcare data at any time.

This authorisation is in the spirit of informed consent, but it is far more general and open and should, therefore, not be confused with it. This authorisation does not imply a consent to any particular research project. Each research protocol regarding the healthcare data must be assessed by a Research Ethics Committee. In accordance with the ethics of research concerning human subjects, such a committee would only allow exception from informed consent when the research poses none or minimal risk

[58] There could be exceptional cases where a surviving spouse has that function. It could be argued that there should be a way to opt out of the HSD generally on behalf of the dead, but the question who should have that authority can be become very complex.

[59] A legal challenge to this policy has been in the Icelandic courts. Information about this and other lawsuits testing the database act can be found on http://www.mannvernd.is/english

[60] Legitimate purposes are already stated in the Act on a Health Sector Database no. 139/1998, Art. 10: '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.'

to the participants. In this way, a Research Ethics Committee would protect the interests of every participant in the HSD, both living and deceased. However, the most important protection for participants in research is the right to withdraw from the HSD at any time.[61] This is technically possible without violating privacy and it is probably the single most significant device against misuse of information and maintaining trust in the HSD.

There is an additional benefit to the proposal about written authorisation for participation in HSD. One of the consequences of the legislation on the HSD is that medical doctors can be required to hand the medical records of patients who have not opted out of the database over to the licensee for processing information into the database. The licensee negotiates with the politically appointed board of each healthcare institution that has the legal authority to negotiate all transfer of information from medical records.[62] Understandably, the medical profession has reacted strongly to this policy. Not only is their professional autonomy threatened but also their status as guardians of information, which has been created in their confidential interaction with patients. In order to safeguard the trust that is the cornerstone of the professional-patient relationship and to respect the responsibility of healthcare professionals, they should not be required to hand over medical records to third parties without their patients' written authorisation.[63] This is especially important when the third party is not involved in the patient's care. Moreover, if this trust is eroded it may affect the data that will be registered in medical records, both because patients could be less willing to

[61] This point is especially important because Icelandic political authorities have shown that they want to control the ethical review process. In 1999 the Minister of Health suddenly ousted the National Bioethics Committee whose members had been mainly nominated by academic institutes. Such an action is clearly damaging for the construction of trustworthy institutions, which is crucial for database research. Now the committee is nominated exclusively by the government. See, for example: A. Abbott. 'Strengthened' Icelandic Bioethics Committee comes under Fire. *Nature* 1999; 400: 602.

[62] DeCODE has already completed contracts to this effect with some of the smaller healthcare institutions in Iceland. Negotiations between deCODE and the National University Hospital have been going on but as I am preparing this paper for publication (November 2002), deCODE has decided to withdraw from these negotiations.

[63] It has been argued (Palsson & Rabinow, *op. cit.* note 37, p. 170) that this position of the Icelandic Medical Association is based on 'a paternalistic and rigid category of knowledge.' True as this description of physicians often is, it fails in this particular case. Icelandic medical doctors should not be expected to 'follow the will of the majority of the Icelandic public' because their primary obligation is towards every single patient.

unveil information and physicians would be more careful in what the write down, at least in the official records. This would, of course, diminish the quality of the scientific conclusions that will be reached from the HSD.[64]

This idea of a written authorisation could be tailored to fit consent for the use of biological samples in genetic epidemiological research in relation to HSD and the genealogical database. Since participants cannot be informed in advance about the specific aspects of the research normally required for informed consent, they could be asked to sign a written authorisation specifying more general, yet restricted, use of the samples for further research. They would also be informed about purposes of the research, security, access, review procedures, and the right to withdraw at any time and to have the samples destroyed. The main addition for authorisation of coded biosamples for unforeseen research would be about re-contacting sources. In this age of communication and information technology there are several ways to do this, and it could partly be in the hands of ethics committees to decide when there is a reason to re-contact participants (special scrutiny category) who could then opt-out of particular research projects. But the main task is to find effective ways to protect the interests of welfare and autonomy of the participants, which everyone agrees is the main objective of the ethics of research. Forging such a policy is the task of regulatory 'trustworthy institutions' which 'have to offer individuals simple and realistic ways of checking that what they consent to is indeed what happens and what they do not consent to does not happen.'[65]

CONCLUSION

In this paper, I have considered the issues of privacy and consent in the debate about the Icelandic health sector database. I have examined the prevailing arguments for obtaining consent for the different type of databases that are being set up in Iceland. In particular, I have scrutinised the arguments for presuming consent for the transportation of information from medical records into the HSD. I have not found these arguments convincing. I argued that the traditional requirement for informed consent is not well suited for the collection of information into the HSD. I proposed the idea of a written authorisation, based on clear but general information about the right to withdraw and about the use, pro-

[64] Cf. Zoëga & Andersen, *op. cit.* note 1, pp. 33–64.
[65] O'Neill, *op. cit.* note 55, p. 702.

tection and purposes of HSD. This I take to be an alternative to both informed and presumed consent worth considering in the new research environment of multifaceted databases.

Giving up the requirement of informed consent for secondary research purposes that cannot be foreseen at the time of collection[66] certainly does not amount to asking individuals for blanket consent for future uses. Such a consent would give researchers optimal freedom for research but it is 'actually a waiver of consent, which is unacceptable for research.'[67] There is a need to search for an alternative to informed consent and uninformed blanket consent, which would strike a balance between respect for the participants and freedom of research. This task is of vital importance in the new research environment of databases that is now being created, not only in Iceland but also throughout the world.

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[66] Of course, informed consent would still be regarded as essential for medical treatment and participation in most primary research and in experimentation, the scenarios for which it was initially constructed.

[67] Annas, *op. cit.* note 36, p. 1832.

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