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'Iceland Inc.'?: On the ethics of commercial population genomics

Jon F. Merz
University of Pennsylvania, merz@mail.med.upenn.edu

Glenn E. McGee
University of Pennsylvania

Pamela Sankar
University of Pennsylvania

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Keywords
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Authors: Jon F. Merz*¶

Glenn E. McGee*

Pamela Sankar*

* Center for Bioethics, University of Pennsylvania

¶ Address correspondence to: Center for Bioethics, University of Pennsylvania, 3401 Market Street, Suite 320, Philadelphia, PA 19104-3308; ph: 215-573-8107, fax: 215-573-4931; email: merz@mail.med.upenn.edu

Abstract

A detailed analysis of the Icelandic commercial population-wide genomics database project of deCODE Genetics was performed for the purpose of providing ethics insights into public/private efforts to develop genetic databases. This analysis examines the moral differences between the general case of governmental collection of medical data for public health purposes and the centralized collection planned in Iceland. Both the process of developing the database and its design vary in significant ways from typical government data collection and analysis activities. Because of these differences, the database may serve the interests of deCODE more than it serves the interests of the public, undermining the claim that presumed consent for this data collection and its proprietary use is ethical. We believe that there is an evolving consensus that informed consent of participants must be secured for population-based genetics databases and research. The Iceland model provides an informative counterexample that holds key ethics lessons for similar ventures.

Key words: population studies; genetics; ethics; privacy; genetic epidemiology; commerce.

In mid-December, 1998, the Icelandic government passed the highly controversial Act on a Health Sector Database (HSD Act) (Government of Iceland, 1998). The HSD Act authorized the Ministry of Health and Social Security to contract to construct a national computerized medical record database (HSD). The HSD Act was proposed and promoted by deCODE Genetics, a US company operating in Iceland through its wholly owned subsidiary Islensk Erfdagreining. A little more than a year after enactment of the law, an exclusive license was granted to deCODE to compile and operate the HSD.

The HSD Act allows deCODE to use the HSD as part of a comprehensive genetics research database involving the Icelandic population. This database, called the "Genealogy Genotype Phenotype Resource," or GGPR, will involve the linkage of three smaller databases: 1) a genetics database, 2) a genealogical database, and 3) the HSD (Gulcher & Stefansson 1998). The first two databases will contain deCODE's proprietary data. The license gives deCODE exclusive commercial rights to link the HSD into the GGPR and use it to conduct approved research for itself and for fee-paying clients.

deCODE's proposal to build the HSD and use it in its GGPR has been one of the most thoroughly debated and analyzed biotechnology ventures in history. A primary source of the controversy has been the failure of the project to require consent from citizens whose medical records are being compiled and used in deCODE's research. Within Iceland, various versions of the bill were extensively debated in the Althingi (the Icelandic Parliament), scores of town meetings were held, and hundreds of newspaper articles and radio and television shows addressed the topic (Gulcher & Stefansson, 1999; Pálsson & Hardardóttir, 2002; Pálsson & Rabinow, 2001; Philipkoski, 1999). Numerous foreign journalists and researchers visited Iceland to get a first-hand look at the project, and many more have written accounts from afar

(Andersen & Arnason, 1999; Billings, 1999; Chadwick, 1999; Greely, 2000; Greely & King, 1998).

While others have raised many ethical concerns about the GGPR project, we believe that they have not addressed all of the morally relevant details. In large part, many of these details have been missed in part because the project has undergone numerous changes in the last 3 years as it moved from conception towards implementation, and in part perhaps because the details have been obscured by incomplete information and the fever pitch of the controversy. The GGPR project has, for example, repeatedly been confused with deCODE's on-going gene discovery research performed under a US $200 million contract with the Swiss pharmaceutical firm Hoffmann-LaRoche, under which agreement any drugs developed will be offered to the Icelandic population for free (Dorey, 1998). Many, but certainly not all, of the details have been clarified as the project has progressed.

With partial salary and travel support from deCODE, joined by a colleague trained in pharmacology and health policy, the authors paid visits to Iceland in June (JFM & PS) and October 1999 (JFM, GEM & PS) and interviewed or held group discussions with nearly 50 people, including the principals and several employees of deCODE, members of the Althingi, government officials, health care providers, members of Mannvernd (a group opposed to the database), staff at the Icelandic Cancer Society, members of the general public, and other academic researchers. This interview study was performed to understand and describe the GGPR project and its development and assess the ethical issues raised by the project. It was approved by the University of Pennsylvania Committee on Studies Involving Human Beings and the Icelandic Bioethics Committee. Verbal consent was secured from all interviewees; because of the size of the country and the public visibility of some of our respondents, we told subjects

that we could not ensure confidentiality but would not use their names or other identifying information in any publications. We also reviewed the license (Government of Iceland, 2000-1), contract (Government of Iceland, 2000-2), accompanying data security plan (Admiral Management Services Limited, 2000), and regulations issued by the Ministry of Health and Social Security (Iceland Ministry of Health and Social Security, 2000), as well as the substantial literature that has appeared over the last 3 years addressing the ethics of the project.

Here, we present a detailed description of the GGPR project and examine the moral differences between the general case of governmental collection of medical data for public health purposes and the centralized collection under an exclusive commercial arrangement planned in Iceland. The issues addressed here are becoming more important, as numerous countries and biotechnology firms around the globe consider similar ventures and look to Iceland as a possible model to be followed (Abbott, 1999-1; Abbott, 2001; Burton, 2002; Cyranoski, 2000; Dorey, 2000; Duncan, 1999; Frank, 1999; Frank, 2001; Hagmann, 2000; Hollon, 2001; Lähteenmaki, 2000; Meldolesi, 2000; Rosell, 1999).

We find that both the process of developing the database and its design vary in significant ways from typical government data collection and analysis activities. Because of these differences, we believe the database – if ever constructed – is likely to serve the interests of deCODE more than it serves the interests of the public. We believe that the primacy of the commercial purpose of the database undermines the claim that presumed consent for this data collection and its proprietary use is ethical. Furthermore, we identify questions that raise ethical concerns that may only be answered as the project is implemented. Overall, the Iceland model provides useful insights into the ethical issues raised by commercial population genetics databases.

The HSD and GGPR Project

Under the terms of the license, deCODE will fully fund development and implementation of: 1) a system of computerized medical records in clinics and hospitals located throughout Iceland; and 2) the centralized collection of data and operation of the HSD. deCODE will pay all related expenses incurred by the government, plus an annual inflation-indexed payment of 70 million Krónur (currently about US $800,000, or $3/Icelandic citizen), plus 6% of its annual pre-tax profits up to an additional 70 million Krónur (Government of Iceland, 2000-2). Putting these sums in context, they amount to less than 0.5% of Iceland's public expenditures on health, which totaled about 40 billion Krónur in 1998, 48 billion in 1999, and 51 billion in 2000 (Iceland National Economic Institute, 2000; Gudjonsdottir, 2002).

In return, deCODE will be allowed to link the HSD to its proprietary genealogy and genetics databases for a period of 12 years (with the possibility of renewal). All data entered into the GGPR databases will be encrypted by the government's Personal Data Protection Authority to protect subject privacy (Gulcher, Kristjansson, Gudbjartsson & Stefansson, 2000; Government of Iceland, 2000-3). A simplistic illustration of the compilation of encrypted data into the HSD and its incorporation into the GGPR is shown in Figure 1. The linking of medical, phenotypic, genealogical, and genetic data contained in these databases will create a unique and powerful tool for conducting sophisticated genetics research, the exclusive use of which may enable deCODE to profit on its investment. The stock market reacted somewhat favorably to the plan, with deCODE collecting US $173 million from its Initial Public Offering in July, 2000, amounting to US $610 per Icelandic citizen (Herper 2000). The stock initially sold for about US $25, much less than the purported speculative trading of the stock in Iceland for as much as $65 (Sigurdsson, 2003). Despite the subsequent decline in its stock price to under US $2, the IPO

provided deCODE with the capital necessary to move forward with the GGPR project. Nonetheless, a September 2002 layoff of about 200 staff and restructuring casts some uncertainty on whether the HSD/GGPR will be completed (deCODE Genetics, 2002).

[insert Figure 1 about here]

The Icelandic government has justified the project by asserting that the distributed computerized medical record system and centralized HSD will help officials better manage the country's health needs, which may be particularly important in light of the recent marked increase in healthcare expenditures. The Ministry of Health and Social Security and the Director General of Public Health also see the HSD as the only way to fulfill a long-standing interest in the computerization of medical records and development of a nationwide data network (referred to as Health Net), programs repeatedly frustrated by inadequate funds. Another oft-cited dividend of the GGPR is the creation of high-technology jobs that may lure home Icelandic scientists working abroad (Kuska, 1998; Mawer, 1999; McInnis, 1999; Palsson & Thorgeirsson, 1999).

Perhaps the most contentious issue raised by the HSD Act is that no consent is required from citizens for the computerization of existing records and information from future health care visits, centralized collection of data, and use of HSD data in the GGPR. Citizens can, however, opt out of the HSD by submitting a form to the Director General of Public Health stating that they wish to have their health care information withheld in totality or selectively by visit or treatment type. These forms are to be made available to patients at health care clinics (although we found no forms in 2 of 3 clinics we visited, suggesting there may be problems inherent in distribution). To date, more than 20,000 Icelanders (about 7% of the population) have opted out (Mannvernd, 2002). On August 27, 2001 an agreement was executed between deCODE, the

Icelandic Medical Association (IMA), and the Director General of Public Health, in which deCODE agreed that a citizen may have his or her data removed from the HSD after it has been collected (Joint Statement, 2001). This agreement, under which the IMA agreed to drop its opposition to the GGPR project, alters the contentious provision of the HSD Act that permits subjects to prohibit only the prospective collection of data (Chadwick, 1999).

Ethics Analysis

A substantial volume of commentary has appeared in the lay and academic press, raising numerous ethical and legal concerns about the GGPR project (Enserink, 1998). Criticisms include but are not limited to the following. First, various writers believe that subjects whose data are included will be inherently identifiable, necessitating informed consent for research use of the GGPR (Annas, 2000; Jónatansson, 2000). Second, some have criticized the project because it includes children and those lacking capacity unless parents or guardians opt-out on their behalf, and families may not prohibit the retrospective collection of information on the dead. A lawsuit challenging this latter issue was filed in Reykjavik District Court against the Director General of Public Health on May 3, 2001 by a minor seeking to prevent data on her deceased father from being included in the HSD (Adalsteinsson, 2001). Third, it has been argued that the grant of exclusive rights to deCODE violates Icelandic Constitution equal protection provisions and European Economic Area (EEA) prohibitions on state creation of monopolies (EFTA Surveillance Authority, 2000), and will stifle academic research as well as commercial competition in Iceland. Fourth is the concern that the research will not be subjected to independent ethics oversight. This concern was highlighted by the government's restructuring of the Icelandic Ethics Committee in the summer of 1999. The 7-member board consisting of ethicists, lawyers, health care providers, and scientists appointed by medical and research

institutions was replaced by a 5-member board appointed by the Director General of Public Health (1) and government Ministers of Health and Social Security (2), Justice (1) and Education and Culture (1) (Iceland Ministry of Health and Social Security, 1999; Abbott, 1999-2). Fifth, various writers have asserted that the project commodifies the Icelandic people by creating a market for and trading in their bodies (Lewontin, 1999; Pálsson & Rabinow, 1999), as well as commodifying bioinformation itself (Rose, 2001). While we agree with the basic thrusts of these criticisms, we believe that there are other crucial attributes of the GGPR project that merit attention.

We begin our analysis with the precept that the ethics of human subjects research must be judged by internationally accepted standards, as reflected in general policies and statements such as the Declaration of Helsinki (World Medical Association, 2000) and CIOMS guidelines (Council for International Organizations of Medical Sciences, 1993). These policies require informed consent for research participation, but generally recognize an exemption for secondary uses of data for research purposes. EU Directive 95/46/EC, with which Iceland must comply as a member of the EEA, requires informed consent for research uses of medical data, but excepts the use of "anonymous" data (European Parliament, 1995). As one commentator recently described, Directive 95/46 and related guidelines (Council of Europe, 1997) differ regarding whether anonymity is to be determined by the likelihood of a subject in fact being identified, or by the technical ability of the researcher to identify an individual in the database (Jónatansson, 2000, at 49-51). We do not attempt to resolve this ambiguity here.

Subjects in the GGPR are likely to be identifiable directly or inferentially due to the richness of the data (Anderson, 1999; Sweeney, 1997), deCODE admits that subjects could be readily identified by decryption if authorized by the government (Gulcher & Stefansson, 2000),

and deCODE has the technical ability to statistically match the encrypted GGPR data with its identified genealogy and genetics data. deCODE asserts, however, that identifying individuals is specifically prohibited by the HSD Act, and its (currently) illegal nature makes it unlikely. It seems quite clear that there can be no assurance that subjects will not be identified, since they are inherently identifiable. While we believe this identifiability itself requires informed consent for use in the GGPR, we assert that there are other characteristics of the GGPR project that further undermine the ethics of presumed consent.

A second precept underlying this analysis is that the state has the right – and duty – to collect data for public health surveillance of communicable diseases, drug safety, and the like (World Health Organization, 2002). Further, any state that provides nationwide health care, as has Iceland since early in the 20th century, has the right to collect medical information for monitoring and improving health care access, services and utilization. As a matter of practice, these data are normally available for secondary epidemiological, outcomes, and health policy research purposes, albeit with adequate protection of subjects' identities (Lowrance, 2000; Bayer & Fairchild, 2000). These data collection and use activities typically proceed with neither consent nor even notice to patients (Merz, 2001; Merz, Sankar & Yoo, 1998).

In Iceland, surveillance data – in identifiable form – has been systematically collected by the Director General of Public Health in 13 registries, encompassing all hospital discharges, cancer diagnoses, abortions, heart disease, communicable diseases, and other conditions. These data are generally used for monitoring health in the population. It is important to note that these registries have also been used in research in the past. For example, since the 1950s, the Icelandic Cancer Society has managed the cancer registry under a contract with the government, and has used it in genetics research involving linkage with a genealogy database maintained at the

University of Iceland (Pálsson, 2002). One such project was the collaborative study that helped identify the second breast and ovarian cancer gene BRCA2 (Tavtigian, Simard, Rommens, Couch, Shattuck-Eidens, Neuhausen, et al., 1996).

The question remains, then, whether the HSD and GGPR project are different in some morally significant way from these other government activities and uses of government data. Examination of the GGPR project reveals that the primary purpose of the centralized collection of data in the HSD is to serve the commercial interests of deCODE. There are 4 attributes of the project that reveal this primacy.

First, data will be gathered and entered into the HSD retrospectively, reaching back about 15 years, and comprehensive data will be collected on deceased citizens with no opportunity for familial refusal. While a government and its public health agencies might be interested in the retrospective collection of medical data, we know of no cases in which a government performed such a massive data collection effort. Thus, but for the commercial interest, it is unlikely that this retrospective collection would take place; it simply wouldn't be worth it to the government.

Second, the specific content of the HSD itself may serve the research needs of deCODE more than the needs of the government. HSD content purportedly will include any data that can be easily coded such as diagnoses and laboratory results, but the specific details about what data will be incorporated will be determined in future negotiations between deCODE and health care institutions.

Third, and most revealingly, the government adopted an opt-out provision in the HSD Act in response to public and international criticisms, allowing citizens to remove themselves from the HSD (but, as discussed below, not necessarily from the GGPR). The claim that the HSD is a legitimate government database that happens to be paid for by a commercial activity

does not stand up to close scrutiny. The opt-out reduces the utility of the HSD to the government, undermining the pretext for its very creation. Indeed, public health surveillance activities independent of the HSD data collection are likely to continue, and it was reported to us by several interviewees that the HSD data will be biased because of the relatively high rate of opting out by psychiatric patients (perhaps spurred by their clinicians). Similar biased refusal patterns have been observed in Minnesota, where a 1996 state law required researchers to attempt to get consent for prospective use of medical records (Yawn, Yawn, Geier, Xia & Jacobsen, 1998; Jacobsen, Xia, Campion, Darby, Plevak, Seltman, et al., 1999).

And, fourth, we find it especially significant that citizens were given the option of removing themselves from the HSD instead of from the GGPR. That is, legitimate government objectives would have been fully met if data on all citizens were systematically collected into the HSD. The commercial research use of HSD data by deCODE could have been subjected to an opt-out choice by citizens. Instead, examination of the literature and the justifications asserted for the GGPR project suggest that the HSD and GGPR were logically conflated, perhaps to the point of confusing their separate and different functions. While ultimately an empirical question, we believe that this could serve to reduce the rate of opting out, because citizens might have felt compelled as beneficiaries of the national healthcare system to be included in the HSD. This point was reinforced by the August 2001 agreement between deCODE and the Icelandic Medical Association, in which deCODE agreed to remove all data from the HSD of those who request it (Joint Statement, 2001). It strikes us as strange that a licensee operating a government database could agree to conditions contrary to the enabling legislation, particularly when those conditions further erode the utility of the HSD to the government.

The reasons why 20,000 Icelanders have opted out of the HSD are not known, but we can imagine several. For example, citizens might be concerned about violations of their medical privacy. The retrospective data collection will be performed by an estimated 300 trained medical transcriptionists, who will be assigned to sites throughout the country to access, abstract, and encode hundreds of thousands of medical records. While these transcriptionists may be contractually bound to maintain confidentiality of what they see, this systematic, comprehensive exposure and coding of 15 years of past medical records of nearly all citizens will nonetheless comprise an unparalleled invasion of privacy. In a nation of only 270,000 inhabitants, all of whom use the same medical care system, half of whom live in the capital Reykjavik, and most of whom are related to one another, the likelihood of a transcriptionist encountering information of personal interest is high. Furthermore, as examination of Figure 1 shows, we believe that data on all citizens will be collected, transmitted, encrypted, and only then will the data for those who opt out be removed from final inclusion in the HSD. Thus, opting out will not prevent this fundamental invasion of privacy. Of course, any alternative plan for exclusion from data collection itself would likely violate the confidentiality of those who opt out by revealing their identities to health care providers.

Additionally, citizens who opt out might be expressing their refusals to being included in the GGPR project. Nonetheless, it is all but a certainty that all of these individuals are in fact included in the GGPR because of the incorporation of nearly complete genealogy data on the Icelandic population. Generally, research is permitted with data – such as the Icelandic genealogy – that is public or available from public sources without an individual's consent (US Code of Federal Regulations, 2002). But research should not be permitted on a subject when that individual in fact refuses; that is, if researchers ask – by seeking consent or giving subjects the

ability to refuse – they should be bound by the answer. Paradoxically, the confidentiality risk posed by the GGPR is a function of the richness of the genealogy, which may include up to 800,000 of the 1.2 million or so Icelanders who have ever lived, and not to the inclusion of medical record information. The project only permits adult, competent subjects to refuse to have their medical data included, but does not recognize their fundamental right to refuse participation.

Simply put, if the government were compiling a centralized medical database for its own purposes, that database would look much different than will the HSD, and it would be available much more widely to the Icelandic research community. While consent for legitimate centralized governmental collection and use for public health purposes would globally be deemed unnecessary, the fundamental, exclusive, and principal commercial research purpose of the HSD suggests that failure to secure express permission from citizens to collect and use their data for exclusive commercial research purposes violates international ethical standards.

Future Issues

There are numerous ethically relevant questions raised by the GGPR project that may only be answered as the project is implemented. We believe it is critical for the Icelandic government and deCODE to maintain openness about these issues so the public can continue to assess the social acceptability of the project. Further, we believe empirical study is necessary to fully understand all the ramifications and outcomes of a public-private venture as comprehensive and complex as that undertaken in Iceland.

First, the government of Iceland has agreed to trade a period of exclusive use of the HSD to deCODE in return for having the company pay for the HSD. While it has proved economically and politically impractical in Iceland, the government could nonetheless have paid

for a centralized medical database, similar to the health records collected in Denmark (Frank, 2000) and in the federal Medicaid and Medicare programs in the US. We believe it would be wrong for the governments in these countries to grant exclusive access for commercial use to public data, regardless of the price. Indeed, a recent proposal of a private firm to use data collected under the US government funded Framingham Heart Study foundered precisely because the National Heart, Lung and Blood Institute refused to grant exclusive access (Rosenberg, 2001; Niiler, 2001). Conversely, the UmanGenomics effort in Sweden involves a grant of exclusive commercial rights (but not exclusive access) to an existing publicly-owned research biobank for which consent was secured from individuals. Recontact and new consent will be secured for individual projects that exceed the scope of the existing consent (Høyer, 2002; Nilsson & Rose, 1999).

Governments may justify granting exclusive rights to public resources if the resource would otherwise go unused or undeveloped. However, simply because there may be commercial value in a government-controlled resource does not in itself mean that that value should be sought or realized if it requires the sacrifice of other important societal values or norms. When justified, the terms of exclusivity should be narrowly drawn to minimize detrimental effects, such as restrictions on academic researchers and competing commercial enterprises. Yet, deCODE seeks exclusivity to be as broad as possible, capturing an interest in any commercial product resulting from research using any deCODE-provided resources (including institution-specific computerized medical records), to enable them to recoup and profit from their investment. The scope of deCODE's commercial exclusivity will emerge only as the HSD is compiled and various institutions throughout Iceland negotiate the terms governing access. A particular concern we heard voiced by physician-researchers was the risk that currently

maintained databases may be rendered obsolete by the medical record system provided by deCODE, thereby reducing researchers' access to digital data unburdened by deCODE's proprietary claims.

Second, we have been unable to determine conclusively whether the government will continue to collect registry data independent of the HSD activity. Continued operation of the registries negates in part the justification for the HSD. Removal of opt-outs from the HSD will diminish the government's surveillance capabilities, which may be used as justification in the future for amending the law and removing the opt-out provision. Further, if the HSD is used for surveillance, this may place the traditional role of the Cancer Society and public health and other researchers' access to registry data in jeopardy.

Third, flags have been raised by the May 2000 enactment of a law on biobanks that could enable deCODE to negotiate access to clinical samples collected or archived at various institutions without express consent (Government of Iceland, 2000-4). This would contradict deCODE's repeated promises to secure informed consent from subjects donating DNA to their genetic database (Kong, Gulcher & Stefansson, 1999; Winickoff, 2000-1; Winickoff, 2000-2). Archives such as the Dungal collection at the University of Iceland hospital, a complete pathology archive containing nearly a half-million samples and dating back about 70 years, could prove highly alluring.

Fourth, an overriding and common theme we heard from our interviewees was that data collection would undermine the trust of patients in their health care providers, which could negatively affect their care; indeed, the primary purpose of medical confidentiality is precisely to promote trust and openness (Annas, 1993). Because of such concerns, the project risks fundamentally altering physician-patient relations; indeed, several interviewees reported

anecdotally that some physicians were coercing patients to opt-out. Other concerns include whether the database will be used to examine physician practices (physicians have not been ensured anonymity), and whether physicians will alter their record keeping practices to protect their patients and, potentially, themselves.

Fifth, in early October 2002, the World Medical Association adopted a policy regarding ethical considerations in constructing and using health databases (World Medical Association, 2002). The August 2001 agreement between deCODE, the IMA, and the Director General of Public Health discussed above also provided that this new policy "shall be looked upon as guidelines for gathering, transferring and processing of information" into the HSD, and that, "[i]f necessary, both deCODE and the Board of the IMA will urge that amendments be made to the [HSD Act] to ensure the law's conformity with these rules." (Joint Statement, 2001). This policy specifies a preference for deidentification of data, that is, irreversible stripping of linking codes, for secondary uses such as research, but also permits use of coded or linked data when the former is not possible. The policy also states that patient consent "is needed if the inclusion of their information on a database involves disclosure to a third party or would permit access by people other than those involved in the patients' care," but here too, consent may be waived by applicable national law that otherwise conforms to the policy statement, or where approval has been granted by an ethics review committee. When no consent is required, the policy requires that patients be provided with detailed information about the potential uses of their information, the storage and potential uses of the data, their rights (if any) to access the data, and their rights to have inaccurate data amended. It remains to be seen if this policy will be relied upon by the IMA in an attempt to get the Icelandic government to make changes to the HSD.

Conclusion

In conclusion, we believe that the major ethical concerns posed by the HSD arise because its primary purpose is commercial, and only secondarily does it support legitimate governmental operations. There simply are too many provisions of the overall project that serve deCODE's interests, and not those of the government or individual citizens. It is, for example, technically feasible in the creation and operation of the GGPR that those who have opted out be totally excluded.

The importance – indeed the moral necessity – of informed consent for participation in a research project as complex and nuanced as the deCODE endeavor has been well established. Among those who have studied the GGPR project, no scholar of research ethics has argued in print against informed consent, and it is difficult to see how such an argument could be made. Implicit in deCODE's assertion that it has broad public support for the GGPR project is the claim that informed consent could be secured, but that it would be unnecessarily expensive and time consuming, would decrease participation, and would likely impute greater bias into the database. It is, after all, easier to say nothing than to actively say yes. Nonetheless, other regional or national projects around the world are proceeding with express intent to secure informed consent from subjects (Beskow, Burke, Merz, Barr, Terry, Penchaszadeh, et al., 2001), and this appears to be the emerging consensus ethical approach to performing population genomics (Kaye & Martin, 2000). While it has yet to be followed elsewhere, the Iceland model provides an informative counterexample that must be critically examined by others considering similar ventures.

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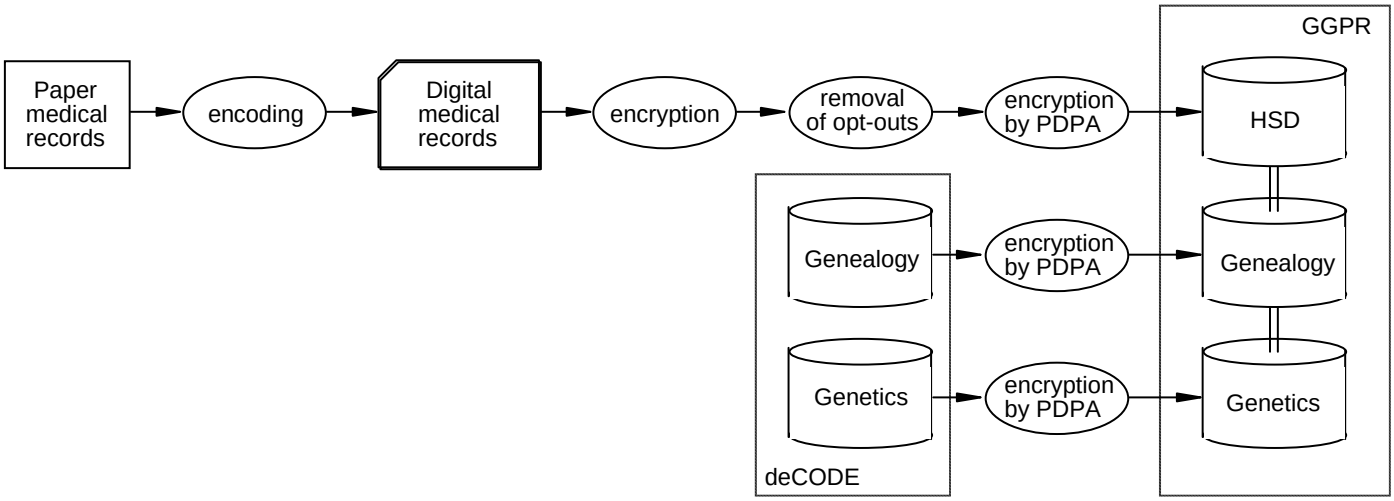

Figure 1 A simplified flow diagram of data into the GGPR. Medical records and deCODE's Genealogy and Genetics databases contain identified information, but all data is passed through multiple levels of encryption overseen by the government's Personal Data Protection Authority (PDPA) before combination in the GGPR.