Privacy and Consent Concerns in International Genetic Databanks

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Geothermal pools are the favorite social gathering place for Icelanders. This has been true since Vikings soaked in the hundreds of hot springs that dot Iceland's landscape. Journalist Jason Wilson noted that "[i]n fact, the old Icelandic word for these thermal pools – '*laug*' – is so central to the culture that the word for Saturday in Icelandic, *Laugardagur*, literally means 'pool day'."[1] This fascination with pools seems apropos for a country that pioneered the idea of a nationwide pool of genetic information.

But why would a country want to catalog its entire population's genetic makeup? The answer, if one discounts the fringe conspiracy theorists, is health. While genetic therapies have been slow to realize their promise,[2] there have been enormous advances in the etiology of disease.[3] These advances seem poised to usher in an age of gene-level biomedical therapies and preventions that will accomplish what is impossible today. However, in order to reap this cornucopia, researchers must first collect large, detailed databases of the population's genetic information.

In 1997, deCODE genetics, a private commercial company with authority vested in it by the Icelandic government, began compiling the Icelandic Biogenetic Project, a genetic database that included virtually everyone in that small nation.[4] Controversially, deCODE departed from the norm of informed consent for medical research and instead required individuals to 'opt-out' of the database if so desired. The organizers knew that when saddling the population with a positive requirement to be omitted from the study, the database would achieve a far more ample pool of participants from which to derive better statistical force in their experiments.[5] Controversy over consent and privacy ensued, but mostly from outside Iceland.

A quite different approach to large-scale gene databases is the UK Biobank, which is run by a charitable, not-for-profit company (Wellcome Trust) that focuses primarily on academic pursuits while keeping commercial access on a restricted basis a viable option.[6]

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[1] Jason Wilson, *Wash Thoroughly Without a Swimsuit: A Man's Mission to Swim Through Iceland*, THE WASH. POST MAG., Mar. 6, 2005, at W12.
[2] Early attempts at gene therapy have resulted in disappointing successes and deadly failures. *See* J. Couzin and J. Kaiser, *Gene Therapy: As Gelsinger Case Ends, Gene Therapy Suffers Another Blow*, 307 SCIENCE 5712, 1028 (2005).
[3] Daniel Bustillos, *DNA Dilemmas*, 364 THE LANCET 9432, 408 (2004) (book review).
[4] GENETIC DATABASES: SOCIO-ETHICAL ISSUES IN THE COLLECTION AND USE OF DNA 4 (Richard Tutton & Oonagh P. Corrigan eds., 2004).
[5] *Id*. *See also* Jane Kaye & P. Martin, *Safeguards for Research Using Large Scale DNA Collections*, BRIT. MED. J. 321 (2000); *see also* Jane Kaye, *Abandoning Informed Consent: The Case of Genetic Research in Population Collections*, *in* GENETIC DATABASES, *supra* note 4, at 117.
[6] GENETIC DATABASES, *supra* note 4, at 4.

Unlike the paternalism (or perhaps it is better characterized as presumed solidarity?) of the Icelandic Biogenetic Project, the UK Biobank solicits volunteers to study the "interactions between people's genetic makeup, their experience of health and disease, as well as their lifestyles to determine the underlying epidemiological processes involved in the development of common diseases."[7]

In Estonia, the Estonian Genome Project (EGP) adopts features from both of the gene databanks described above. Like the Icelandic Biogenetic Project, the EGP was formed by a legislative act and is closely connected with a commercial spin-off company based in California.[8] However, it is a voluntary, informed consent study like the UK Biobank, and, unlike either of the two preceding banks, the EGP grants rights to the genetic donors to access genetic information so that they might benefit from any future pharmacogenetics that may result from the study.[9]

In Tonga, however, an ambitious and concerted effort to form a national genetic database has so far been unsuccessful.[10] As had been done successfully elsewhere, the Tongan databank would have licensed the genetic information out to a third-party, private, biotech company – in this case the Australian company Autogen. Perhaps surprisingly, largely due to the fact that Autogen would ensure individual informed consent, the very thing that other national databanks had been severely criticized for lacking, the Tongan public *opposed* the initiative.[11] Traditional Tongan culture deeply values extended family networks and a community-based decision-making process that deems individual-based decisions, especially those having an impact on the entire community as a genetic database surely would, as reprehensibly anti-social.[12] Tongan aversion to the database was also partly due to the fact that Tongans are skeptical about technology in general.[13] When the government of this tiny South-Pacific nation enlisted Autogen to "exploit" the natural genetic resources of the island, no doubt there were also reverberations of former and continuing Western imperialism. More than one commentator has wondered whether a more democratically arrived-at initiative that respected the culture's communal decision-making process would have made the Tongan databank successful.[14]

Aside from national genetic databases there are numerous regional databases around the world. In places where there is no national healthcare system, such as America, regional databases specific to local populations are proliferating.[15] There are gene banks in many

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[7] UK Biobank (2005), *at* http://www.ukbiobank.ac.uk (last visited Aug. 17, 2005).
[8] GENETIC DATABASES, *supra* note 4, at 4-5.
[9] *Id*. at 5.
[10] M. A. Austin, S. Harding, & C. McElroy, *Genebanks: A Comparison of Eight Proposed International Genetic Databases*, 6 COMMUNITY GENETICS 1, 37-45 (2003).
[11] GENETIC DATABASES, *supra* note 4, at 5.
[12] Klaus Hoeyer, *Ambiguous Gifts: Public Anxiety, Informed Consent and Biobanks*, *in* GENETIC DATABASES, *supra* note 4, at 106.
[13] *Id*.
[14] *Id*.; Austin et al., *supra* note 10; B. Burton, *Proposed Genetic Database on Tongans Opposed*, 324 BRIT. MED. J. 443 (2002); *and* L. M. Beskow et al., *Informed Consent for Population-Based Research Involving Genetics*, 286 J. AM. MED. ASS'N 18, 2319 (2001).
[15] GENETIC DATABASES, *supra* note 4, at 5.

of the individual States as well as regional databanks in Newfoundland, Spain, Britain and others.[16] These local databanks have been more successful at escaping controversy because they have, on average, tailored their studies to the needs and sensibilities of the local population who will make up the donor pool.[17]

The question remains, however, how larger international genetic databases – databanks that transcend national borders in order to yield better results for medical research by sheer population size – can develop in the fragmented global situation.

How Will Law Play a Part?

The main way in which privacy is protected here and abroad is through law. When faced with the myriad concerns raised by potential loss of privacy in genetic research – issues such as psychological harm, disrespect, discrimination, stigmatization and loss of self-determination – it is understandable that stringent laws and policies will be written to protect participants. But when considering the issues outlined above, it seems that little thought has been given as to what legal, political, ethical and social approaches will be successful in both protecting participants as well as allowing research to flourish in a field that transcends borders and cultures. Unfortunately, there probably cannot be any simple answers to this complex problem. Instead of a model act or international privacy regulation, the solution will most likely involve a multifaceted approach that will include both international oversight checked by local governance and changes in social institutions. It cannot be a comprehensive initiative, nor can it be left totally to each municipality or state to decide. It will have to have a broad international framework within which local flexibility is allowed and encouraged.

Making international genetic privacy policies context specific will allow for research that is uniquely suited – and beneficial – to local communities. This will mean that provincial gene bank initiatives will be responsive to the needs of the participants as well as to the broader public health. This will leave researchers, governments and commercial interests free to tailor genetic databases that will closely mirror the values and interests of local participants while working for the health of the world at large. This will in turn signify that these initiatives will have to be democratically agreed upon if, for example, "presumed consent" is deemed appropriate for a particular locality. In this way communities like Tonga that value interdependent decision-making will still be able to participate and potentially benefit from genetic research while protecting against exploitation. Countries that have little concern for informational privacy (or at least a higher threshold for its violation) will be able to tailor the design of their genetic databases according to their laws and social mores as long as individuals are not harmed.

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[16] *Id*. *See also* Austin et al., *supra* note 10; *and* GENETIC DATABASES, *supra* note 4.

[17] Whenever there has been a problem, it is usually because the outside researchers or commercial interests have exceeded the scope of the participants' consent. This has recently happened on American Indian reservations where consent provisions are more difficult to enforce. *See* Jeff Wheelwright, *Native America's Alleles*, DISCOVER, May 2005, at 64-71.

Much like the United States' federalism model, cultural and national states should be allowed discretion to implement genetic research that will uniquely reflect the wants and needs of their citizens, but subject to international legal safeguards. This is necessary for at least two reasons. First, it is not altogether impossible that exploitation will occur even in democratic states, and this could be curbed by imposing research sanctions much like trade sanctions in other contexts. Prohibiting any local or international benefit from any genetic research where the contributing society's ethical sensibilities were not respected can serve as a powerful deterrent for exploitation of underrepresented minorities (or decisionally impaired participants). Much like the research "embargo" against Nazi research findings that were obtained under unethical circumstances, a modern day embargo against a state could reduce the commercial or societal worth of a genetic database enough to be an effective deterrent to disrespectful or exploitative genetic research. Second, the nature of genetic research makes many of the objects of the research easier to obtain when there is open collaboration between nations and gene banks. In order to facilitate the exchange of information in ways that will be respectful of participants, an international governing body should oversee the international access to genetic information while policing signatories.

A policy that is layered and context-specific is probably a better solution than no international policy or one universal policy. It boasts structural integrity in global exchange and ethics review while allowing the flexibility needed for local conceptions of privacy to be honored. In short, it provides a platform through which unequally situated parties can come together and reap any benefits that genetic research might offer. None of this is to say that implementation of an international policy will be easy or that it will be without problems. What this kind of policy does offer is a superiority to the two obvious alternatives: having no international policy, which will stunt genetic research and protect no one, and having a strict universal policy that will probably reflect only the biomedical cultural imperialism of Western society and its distinctive notions of individuality and informed consent.

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