

### Box: Iceland's Health Records Database

A plan to construct a central database of health records in Iceland has garnered recent international attention both for its great promise for human genetics research and the ethical questions that it raises. The database, which will contain “non-personally identifiable health data” derived from the medical records of Icelandic citizens, was authorized by recent legislation passed in Iceland's Parliament amid much debate in Iceland and internationally.<sup>1 2</sup> Like human biological materials stored in the United States, the centralized bank of health records is regarded as a potentially extremely valuable research resource. It also raises similar ethical questions: “What constitutes personally identifiable information?” “How can privacy be protected in the course of research?” “How should research involving patient data be conducted in an ethically acceptable manner?”

The plan to build the database was conceived by Decode Genetics, an Icelandic company that will work with health institutions to amass health records, genealogical records, and genetic information from DNA samples. The new legislation permits Decode to have a 12-year license to construct, operate, and profit from the database, during which time it will use the vast amounts of patient information to conduct research into the origin and nature of various diseases.<sup>3</sup>

Several factors make Iceland a unique place to do genetics research and its health-records database a particularly valuable tool for researchers. First, Iceland's relatively homogeneous gene pool facilitates research into disease-causing mutations, which are easier to detect in a population with low genetic diversity. In addition, Iceland maintains thorough health and genealogical records which, when combined with data that can be

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<sup>1</sup> Act on a Health Sector Database no. 139/1998. 123<sup>rd</sup> Parliament, Iceland. 17 December 1998.

<sup>2</sup> Act on a Health Sector Database no. 139/1998. 123<sup>rd</sup> Parliament, Iceland. 17 December 1998.

“Personal data: all data on a personally identified or personally identifiable individual. An individual shall be counted as personally identifiable if he can be identified, directly or indirectly, especially by reference to an identity number, or one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.”

obtained from biological samples, make the centralized database an even more powerful resource.<sup>4</sup> As an official of Iceland's Ministry of Health and Social Security comments, "This situation imposes on us an ethical obligation and gives us a unique opportunity to promote medical sciences."<sup>5</sup>

However, some observers have noted that the database raises serious ethical questions. Discussion has centered on three issues: consent, privacy, and commercialization of the database.<sup>6,7,8</sup> To begin with, Iceland's new law allows information to be submitted to the database without a patient's consent – all that is required is the consent of health institutions holding the medical records. Patients may "opt out" by informing the Director General of Public Health of their wish that existing information on them or that which may be collected in the future not be entered onto the database. Some have questioned whether this plan of presumed consent is appropriate, particularly in light of the potentially sensitive nature of the information.<sup>9,10,11</sup>

Privacy is another concern. Some worry that the factors that make the database so scientifically useful – a country with a small, homogeneous population, that keeps detailed health and genealogical records – might also create a situation where personal identification can be deduced from "non-personally identifiable data." For example, the new legislation permits Decode to process data on the health database, and connect it with genealogical and "genetic data," which could include data obtained from biological samples. Although the law stipulates that linking databases is allowed "provided that data are processed and connected in such a way that they cannot be linked to identifiable individuals" some experts have questioned how such requirements will work in

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<sup>3</sup> Lyall, Sarah. "A Country Unveils Its Gene Pool and Debate Flares." The New York Times. February 16, 1999

<sup>4</sup> Enserink, Martin. Opponents Criticize Iceland's Database. Science 1998 282: 859

<sup>5</sup> Haraldsdottir, Ragnheidur. Iceland's Central Database of Health Records. Science 1999 283: 487.

<sup>6</sup> Lewontin, R.C. People Are Not Commodities. The New York Times. Section A19. January 23, 1999.

<sup>7</sup> See Lyall

<sup>8</sup> Enserink, Martin. Iceland OKs Private Health Databank. Science 1999 283: 13.

<sup>9</sup> See Lewontin

<sup>10</sup> See Lyall

<sup>11</sup> Schwartz, John. For Sale in Iceland: A Nation's Genetic Code; Deal With Research Firm Highlights Conflicting Views on Progress, Privacy and Ethics. The Washington Post. Section A(01). January 12, 1999.

practice.<sup>12</sup> At least one privacy expert who evaluated the database says that identification would be easy to deduce.<sup>13 14</sup>

Finally, observers have questioned whether the plan to allow one company to own and operate the database is the right thing for science and the people of Iceland. Although the law permits free access to Iceland's Ministry of Health, it permits access to the database by other entities only as long as such access does not affect Decode's commercial interests - it remains unclear what in practice will be the scope of access to the data.<sup>15</sup> The issue of access set aside, the question remains in many critics' minds, what are the ethical implications of commercializing a population's health data?

A number of issues about the construction and operation of the database are still unsettled. How will existing European laws and standards regarding confidentiality of data apply to information obtained from the database? In light of opposition by the Icelandic Medical Association, what will be the extent of cooperation from health practitioners? In many ways, Iceland's health records database foreshadows the future of genetics research and the types of ethical questions that will need to be addressed.

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<sup>12</sup> Act on a Health Sector Database no. 139/1998. 123<sup>rd</sup> Parliament, Iceland. 17 December 1998.

<sup>13</sup> Berger, Abi. Private company wins rights to Icelandic gene database. *British Medical Journal* 1999; 318:11.

<sup>14</sup> See Schwartz

<sup>15</sup> Haraldsdottir, Ragnheidur. Icelandic Gene Database Will Uphold Patients' Rights. *British Medical Journal* 1999; 318:806