Biobanks: Investigating in Regulation

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1. Iceland's DNA

'Attention shoppers: special today – Iceland's DNA,' was the 1998 heading by which the world learned that the Icelandic Parliament voted in favour of an act 'selling' the 'genetic property' of the Icelandic population to deCode Genetics, an private U.S. biotechnology company. In less dramatic terms, the Icelandic Parliament voted in favour of the Act on a Health Sector Database. This Act allows the Government to assign a license for setting up a national health sector database. For the construction of this national database, the licensee can collect the medical data of every Icelander using their medical files. The Icelanders do not have the opportunity to give their informed consent for the collection of their (coded) medical data; they can only opt out of registration in the central database.


Once data are registered in the database, they cannot be removed from it. The data in the database are not anonymous but coded, for the database has to be kept up-to-date and regularly completed with new medical data. See D. Winikoff, "Biosamples, Genomics, and Human Rights: Context and Content of Iceland's Biobanks Act" (2000) 2 Journal of Biolaw and Business, pp. 11-17.
What especially concerned the public and the research community, was the 'sale' by the Icelandic authorities of the 'genetic characteristics' of the Icelandic population to a private company. However, the first goal of the Act was the creation of a national database coupled with a biobank (a collection of human biological materials) for research purposes. The present paper will solely address this specific aspect of the Icelandic regulation, in other terms the use of biobanks for research purposes. The granting of an exclusive license to deCode Genetics for the construction and exploitation of this coupled biobank, will not be treated, nor will be the question of possible property rights on human biological materials.

A biobank can be defined as a collection of human biological materials. The creation of a national database with medical data linked to a biobank and to a genealogical database is of great interest for researchers. The combination of human biological materials containing DNA (which can be genotyped) with medical and genealogical data allows very valuable research on the genetic nature of certain

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4 This is thought to be harmful to scientific research in general and to scientific progress. The genetic property of a population must not be sold, it is a common good that should be accessible to all researchers and not subject to exclusive (paid) access. See for example, J. Crosby, "Iceland: the selling of a nation's genetic code", Star Tribune, 10 February 1999; W. Gibbs, "Natural-born guinea pigs", Scientific American, No. 298, February 1998.

5 Following the British Medical Research Council, we define human biological materials as "all biological material of human origin, including organs, tissues, bodily fluids, teeth, hair and nails, and substances extracted from such material such as DNA or RNA". See Human Tissue and Biological Samples for Use in Research (Medical Research Council, 2001), p. 2.

6 The Icelandic Ministry of Health and Social Security awarded deCode Genetics in 2000 the exclusive license. deCode Genetics has to pay ISK 70 million per year to the Government for this license. The persons whose data and human biological materials are being collected and used are not being paid.

7 In February 1998, deCode signed a contract with the Swiss pharmaceutical company Hoffmann-La Roche, valued at up to USD 200 million over five years. See T. Zoega & B. Andersen, "The Icelandic health sector database: deCode and the 'new' ethics for genetic research", in Who owns our genes? Proceedings of an international conference (Nordic Committee on Bioethics, 1999), p. 37.

8 Biobanks are not only be found in the health sector, there are also forensic and military biobanks for example, National Bioethics Advisory Commission, The use of human biological materials in research: ethical issues and policy guidance. Draft for public comment, s. 1., National Bioethics Advisory Commission, 1998, p. 24. Collections of human biological materials can be very large (pathology collections in university hospitals) or very small (the private storage of tissue samples by a general practitioner), relatively old or very recent. Almost all sorts of human biological materials are being collected and being used for research. When genetic research is being considered, the human biological material will have to contain nucleated cells, but material not containing nucleated cells (serum e.g.) can also be very valuable for research. Often they are stored in an identified (tagged with the identity of the source) or identifiable (coded) way, sometimes they are stored anonymously or are 'anonymized' before being used in research.