

Is It Time to Move Away from the Classical Standard of Informed Consent in Biobanks?

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Developments such as the sequencing of the human genome have sparked a demand for genetic and genomic research. As a consequence, there is a trend both nationally and internationally towards the development of large-scale human biobanks. The word biobank can be defined as the “organized collections of biological samples and the data associated with them.”¹ There are different forms of biobanks “according to the type of samples that are stored and the domain in which they are collected.”² The concept of biobanking is not new: many collections have been in existence for decades, but none have been on a massive national scale until the Icelandic DeCode initiative.³ Since then, various countries have attempted to establish their own national data banks.⁴

The scientific utility of these large scale biobanks is their ability to link DNA information with individual medical, genealogical and lifestyle data, helping to elucidate the role of gene/environment interaction in disease development. In addition, they are becoming an integral research tool in the field of pharmacogenetics.

The establishment of new biobanks and the growth of existing ones have stimulated a plethora of guidelines to deal with the challenges confronted by these repositories. For example, the World Medical Association produced the Declaration on Ethical Considerations Regarding Health Databases in 2002 and the International Declaration on Human Genetic Data in October (2003).⁵ These guidelines differ in important areas such as standards for collecting data and processing samples and in their ethical composition. This hinders international cooperation.

Why are international regulations of biobanks so different? The collection and storage of biological samples raise a number of scientific, ethical, policy and social issues associated with the scale and operation of large DNA biobanks (e.g. privacy, confidentiality and access), particularly regarding issues of informed consent. How to deal with informed consent is one reason for the lack of consensus among international guidelines. An important characteristic of a vast majority of large-scale biobanks is that biological samples and data are collected for multiple future uses and not just for a single research project. Prospective research studies of DNA samples are often difficult and

¹ Anne Cambon-Thomsen, *The Social and Ethical Issues of Post-Genomic Human Biobanks*, 5 NATURE GENET. 866 (2004).

² *Id.*

³ Melvin G. McInnis, *The Assent of a Nation: Genetics and Iceland*, 55 CLIN. GENET. 234 (1999).

⁴ Such initiatives have taken the form of national efforts aim at collecting biological samples and associated health information on large populations (e.g. UK Biobank, the Estonian Genome Project).

⁵ Bernice S. Elger & Arthur L. Caplan, *Consent and Anonymization in Research Involving Biobanks*, 7 Eur. Molecular Biology Org. Rep. 661, 662 (2006).

nearly impossible to foresee, thus precluding participants from giving informed consent.⁶ The uncertainty of the nature of future research projects raises a critical ethical question for biobanks: should the same rules regarding informed consent apply to research involving large-scale biobanks as apply to other research?

The doctrine of informed consent in the context of research is influenced by the Nuremberg code of 1947 and the vast ethics literature that has developed since that time. Informed consent allows research participants to permit the use of their biological samples and associated data.⁷ The principle of informed consent requires researchers to provide as a baseline minimum information about “all potential risks”⁸ and material information “on the nature of the research protocol.”⁹ Protecting the autonomy of research subjects through a consent process is an important issue in clinical research, so few would argue against a robust consent procedure. However, there is a concern that strict adherence to the classical standard of informed consent will limit population genetic research.¹⁰

European guidelines incorporate broad consent for secondary undetermined prospective research using biobanks, if two conditions are met: 1) an ethics committee must approve future research protocols; and 2) participants must have the right to “opt out” their samples. The United States, among other jurisdictions, allow the use of stored biological samples without consent as long as the samples are classified as non-identifiable.¹¹

A common recommendation to deal with consent issues seems to be the use of a form of “blanket consent,” where research participants are able to consent once about the future use of their biological samples.¹² Another strategy suggested is the use of “presumed consent,”¹³ while others advocate for a new legal/ethical framework such as an “authorization” model which includes: a) permission for unforeseen research; b) re-contact of research subjects; c) the right to withdrawal; d) setting time limits on the use of samples; e) availability of information or materials to third parties; f) information on implications for groups; and g) information on commercial uses. The establishment of

⁶ Mark Rothstein, *The Role of IRBs in Research Involving Commercial Biobanks*, 30 J. LAW MED. ETHICS 105 (2002).

⁷ Robert M. Sade, *Research on Stored Biological Samples Is Still Research*, 162 ARCH. INTERN. MED. 1439 (2002).

⁸ Jacquelyn Ann K. Kegley, *Challenges to Informed Consent*, 5 Eur. Molecular Biology Org.Rep. 832, 835 (2004).

⁹ *Id.*

¹⁰ *Id.* The UK Human Genetics Commission on 2002 concluded: “[t]he difficulties involved in tracing and securing re-consent for different forms of medical research may make obtaining fresh consent impractical and would seriously limit the usefulness of large-scale population databases.”

¹¹ See Elger & Caplan, *supra* note 5, at 663.

¹² See Kegley, *supra* note 8, at 835 (suggested by the 2001 UNESCO Report on Collection, Treatment, Storage and Use of Genetic Data).

¹³ Dave Wendler and Ezekiel Emanuel, *The Debate over Research on Stored Biological Samples: What Do Sources Think?* 162 ARCH. INTERN. MED. 1457 (2002). The study found that because only 29% of the survey participants would want to re-consent, Wendler and Emanuel suggest “using presumed consent with opt-out.”

such a model requires additional safeguards and a “socially constituted,” “legally mandated oversight body.”¹⁴

In reviewing new developments of population genetics databases, there seems to be a gradual move toward allowing broad consent for future secondary research together with the right for subject to withdraw and a requirement for ethics committee approval. I am not sure that this model allows for sufficient expression of participants’ personal values and autonomy. One thing is clear, however: the classical view of informed consent needs to be revised and a new ethical/legal framework established.

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¹⁴ Henry T. Greely, *Breaking the Stalemate: A Regulating Framework for Unforeseen Research Uses of Human Tissue Samples and Health Information*, 34 WAKE FOREST L. REV. 737 (1999).