Human Rights in Biobanks
In the Conceptual Vacuum

Prof. Judit Sándor
International Seminar on
“Human Rights and New Technologies”

Organized by EUI and Escola de Direito da Fundação Getulio Vargas
Rio de Janeiro, November 23–24, 2009
Questions to Discuss in the Presentation

• Can we interpret human rights at the molecular level?
• What are the connotations of the concept of ‘bank’ in biobanks?
• Which human rights are challenged by the biobanks?
• What are the implications of extending rights in the context of biobanks?
Invention of the Bloodbank

Bernard Fantus (1874-1940) was a Hungarian-American physician. He established the first hospital blood bank in the United States in 1937 at Cook County Hospital in Chicago while he served there as director of the pharmacology and therapeutics department between 1934 and 1940.
From ‘Storage’ to ‘Bank’

- Small-scale refrigerated storage of whole blood was used first in World War I and this was developed in Russia into a larger scale system of blood depots.
- Fantus conducted experiments in blood storage, culminating in the preservation of blood for up to ten days, and he prepared to establish a “Blood Preservation Laboratory” at the hospital. Crucially, however, he changed its name before launch to “Cook County Hospital Blood Bank”. It opened in March 1937.
The Spread of the Concept of ‘Bank’

• Thus, Bernard Fantus invented the name ‘blood bank’ and put this name into circulation, partly through a landmark article titled “The Therapy of the Cook County Hospital,” published in the Journal of the American Medical Association in 1940, 115(7): 527–529. Reprinted in 198,4 251: 647–649.

• After this publication the concept and the name was rapidly adopted by other hospitals.
Early Attempts at Regulation

Council of Europe

• On human tissue banks

• Recommendation No. R(94)1 of the Committee of Ministers to Member States on Human Tissue Banks (Adopted by the Committee of Ministers on March 14, 1994 at the 509th meeting of the Ministers’ Deputies)
International Norms

United Nations System of Organizations

International Norms

World Medical Association

- *Helsinki Declaration*, Article 23 – “Every precaution must be taken to protect the **privacy of research subjects** and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity.”

  *Adopted by the 59th WMA General Assembly,*
  *Seoul, October 2008*
International Norms

OECD and Council of Europe

• OECD – *Best Practice Guidelines for Biological Resource Centres*, with a specific part on biological resources of human origin, 2007.


• Council of Europe – *Recommendation No. Rec(2006)4 on research on biological materials of human origin*, of the Committee of Ministers to Member States, adopted in March 2006 (see next)
Recommendation Rec(2006)4

- Recommendation No. Rec(2006)4 on research on biological materials of human origin (adopted by the Committee of Ministers on March 15, 2006)

Article 1 – Object

Member states should protect the dignity and identity of all human beings and guarantee everyone, *without discrimination*, respect for their integrity, *right to private life* and other rights and *fundamental freedoms* with regard to any research governed by this recommendation.
Regulating Research on Human Beings

• Similarity to the norms of research on human beings:

Article 7 – Prohibition of financial gain

Biological materials should not, as such, give rise to financial gain.

Article 10 – Obtaining biological materials for research

1. Biological materials should be obtained for research in accordance with the provisions of this chapter.

2. Information and consent or authorization to obtain such materials should be as specific as possible
Human Tissues and Human Rights

• Extending human rights in the field of human tissues

Article 13 – Biological materials removed after death

1. Biological materials should not be removed from the body of a deceased person for research activities without appropriate consent or authorization.
Rights Related to Tissues and DNA

• Council of Europe – Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes (ETS No. 203, 2008)

• Note that this Protocol does not apply to genetic tests carried out for research purposes (!)

• It protects the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the tests to which this Protocol applies in accordance with Article 2.
National Ethics Committee Norms

• Norms adopted by National Ethics Committees

Sweden

France
• Comité Consultatif National d'Ethique, Avis n°77 – *Ethical issues raised by collections of biological material and associated information data: ‘biobanks’ and ‘biolibraries’*, March 2003.
Spain

• Comité de Ética del Instituto de Investigación de Enfermedades Raras (IIER), *Recomendaciones sobre los aspectos éticos de las colecciones de muestras o bancos de materiales humanos con fines de investigación biomédica*, February 2007.
Body Parts with Personhood

- Body parts that bear the marks of “personhood”
- “Our sense of dignity of humanity is fundamentally disturbed by the suggestion that which bears the marks of personhood can somehow be equated with property.” (Suzanne Holland: Contested Commodities at Both Ends of Life, 2001)

- Genetic databases combine both the “corporal” and “informational”, the interplay of which raises certain ethical, legal and social issues. (U.K. House of Lords)
<table>
<thead>
<tr>
<th>Person</th>
<th>Property</th>
<th><em>Sui generis</em> category</th>
</tr>
</thead>
<tbody>
<tr>
<td>International</td>
<td>Graeme Laurie</td>
<td>Bartha Maria Knoppers</td>
</tr>
<tr>
<td>Declarations</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Conceptualizing Biobanks

Two extreme positions

1. The biobank is: body in bank
2. The biobank is: a simple research tool
Special Case of Biobanks

Problems with the heterogeneous terminology:

• Uncertainty about the notions of ‘gene’, ‘genetic data’, and ‘biobank’;
• Biobank is a combination of research and commercial enterprise;
• As a consequence it is dubious whether altruism can be presumed on the side of the gene donor.
# Diversity of Concepts

<table>
<thead>
<tr>
<th>Location</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denmark</td>
<td>An organized structure of human biological material accessible with some criteria, and where the information contained in the sample can be related to people.</td>
</tr>
<tr>
<td>Norway</td>
<td>Collection and keeping of biological samples from one or several individuals of anonymous or non-anonymous origin.</td>
</tr>
<tr>
<td>Hungary</td>
<td>Collection of samples containing genetic samples and related genetic and personal identification data for the purposes of genetic study and research.</td>
</tr>
<tr>
<td>Sweden</td>
<td>Biological material from one or several human beings collected and stored indefinitely or for a specified time and whose origins can be traced to the human or humans from whom it originates.</td>
</tr>
</tbody>
</table>
Diversity of Concepts

- Different kinds of biobanks may need different types of regulation:
- Lots of local biobanks and virtual network of biobanks (Germany, Hungary)
- Central or National Biobank Projects (UK. Biobank, Estonia, Latvia)
- Disease specific databanks
Ethical-Legal Issues at Stake

- Informed consent
- Commercialization
- Ownership
- Privacy
- Access to results, and new therapies
- Benefit sharing
Elements of Property

Gift, Donation, and Participation

- Richard Titmuss used this framework in the case of blood donation
- Gift refers to altruistic donation of a property
Ownership

• Ownership of samples constitutes the other important question in biobank with serious implications on commercialization.

• Ownership in itself constitutes a complex set of questions, such as who is the owner of the biobank, who can get access to the samples whether samples can be used for making profitable invention.

• Many authors emphasize that ownership rights regarding genetic material are controversial.
# Legislative Triad of Biobanks

<table>
<thead>
<tr>
<th>Sample</th>
<th>Data</th>
<th>Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Law on biomedical research</td>
<td>Data protection law</td>
<td>Property law IP Law</td>
</tr>
</tbody>
</table>
Privacy

• The legal concept of the right to privacy provides a theoretical foundation to guarantee various forms of self-determination over the human body.

• However, when the issue of disconnected body parts, human tissues and DNA is raised, the concept of privacy seems to be an insufficient legal category to describe the complex relationship between the donor and the stored human tissue samples that are used for research purposes.
Data-Mining

• **General demographic information** (e.g., race, gender, and age);

• **History of present illness, treatments, and responses** (especially prescribed drugs and adverse reactions);

• **Longitudinal information** (e.g., a timed series of blood tests after tissue collection to test if the disease is progressing); and

• **Clinical outcomes** (e.g., was the treatment successful, is the donor still living).
Public–Private Liaisons

Public and private use of biobanks

- Iceland (deCODE Genetics)
- Estonia (EGeen)
- Tonga database (An Australian biotech company)
- Newfoundland-based research (Newfound Genomics)
Regulating Biobanks in Portugal

• An example of a data protection oriented approach

• **Law no. 67 of October 26, 1998 on data protection**: implements Directive 95/46/EC;

• **Law no. 12 of January 26, 2005 on personal genetic information and information regarding health**: regulates biobanks and genetic databases;

• **Law no. 5 of February 12, 2008**: regulates the implementation of a database of DNA profiles, for civil and criminal identification purposes, and it has rules on the safety, storage and management of genetic data, in those situations.
Regulating Biobanks in Spain

• An example of situating biobanks within biomedical research

• *Organic Law 15 of December 13, 1999 on Data protection* (Data Protection Act) (Royal Decree 1720/2007, of 21 December);

• *Law No. 41 of 2002, on Health data protection*;

• *Law No. 14 of July 3, 2007, of 3 July, on Biomedical research* (Biomedical Research Act) including the law on biobanks.
Regulating Biobanks in Sweden

• An example of defining biobanks broadly

• The Swedish Act on Biobanks (SF 2002:297) defines the concept of biobank as “biological material from one or several human beings collected and stored indefinitely or for a specified time and whose origin can be traced to the human or humans from whom it originates.”

Source: http://www.biobanks.se/biobank.htm
Regulating Biobanks in Hungary

a) the encoded genetic sample or data that means genetic sample or data regarding which all the personal identification data relating to the person giving the sample are replaced by a code;

e) pseudonym genetic sample or data means encoded genetic sample or data regarding which the code replacing the personal identification data was provided to the person concerned;

f) anonymized genetic sample or data means genetic sample or data regarding which all the personal identification data relating to the person giving the sample was made incapable of identifying the person.
Contested Fields as a Result of Conceptual Problems

Notion of Genetic Privacy
Data for Health and Criminal Purposes?
Cross-Linking

Case 1 – Anna Lindh’s murder case

- The Swedish authorities requested the help of the FSS to carry out DNA LCN profiling on a knife used in the murder of Swedish Foreign Minister, Anna Lindh, in 2003. The testing on the knife handle was successful and a mixed DNA profile was obtained.

- Part of the profile matched Anna Lindh herself (as she had bled) and the remaining part matched that of suspect Mijailo Mijailović. The national phenylketonuria bank was one of the sources.
Retention of DNA samples

Case 2 – S. and Marper v. The United Kingdom

- The court’s judgment stated that the retention of cellular **samples, fingerprints and DNA profiles** constitutes an infringement of the **right to respect for private life** contrary to Article 8 of the European Convention on Human Rights.
The Conceptual Problem of Anonymity

- In order to protect research participants’ interests, personal data of research subjects are kept confidential.
- Usually coded or even anonymized.
Many Faces of Anonymity

- **Spanish Law No. 14 of 3 July 2007 on Biomedical research**
- **Anonymized** or irreversibly disassociated biological sample is a “sample which can not be associated to an identified or identifiable person as the nexus which had all the information that identifies the subject has been destroyed or because such association requires an unreasonable effort.”
Threats of Discrimination

It is not only genetic data that is collected

- In the case of UK Biobank, a 45-page long questionnaire and medical examination is associated with the study and one of the questions is ethnicity
- As it follows, the potential threats of discrimination cannot be solved alone by anonymization
Biobank Only With Links?

- Biobanks contain blood or cell samples from large numbers of people.
- Genetic information from each sample is linked to the individual’s medical history and lifestyle data.”

- Source: GeneWatch, www.genewatch.org
Dual Assessment of Technology

Challenge to privacy

• Large pool of data can be collected, processed, possibility of cross-linking
• One single individual can no longer control (unless he/she fully abstain from participation)

Privacy enhancement

• Data can be coded and encrypted
• Data processing is possible without human touch
Can Privacy Be Maintained?

- Privacy can no longer be guaranteed in large scale tissue/DNA banks
- Ruth Chadwick: *veracity* instead of *privacy*