Are There Any Recipes for Making a Good Law on Biobanks?

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Dilemma

What should be the main focus of regulation?

- Freedom of research (e.g. OECD Guidelines)
- General rights and dignity-based (CoE Recommendation, 2006)
- Property issues in samples, ownership and intellectual property (WIPO, UNESCO 1997 Declaration)
- Informational privacy
- Data protection (UNESCO 2003 Declaration, Hungarian Bill, EU)
- Partnership between sample donors and researchers

The Nature of Regulation

The nature of regulation depends on whether the biobank is regulated as

- as an institution
- as a process
- as an extension of biomedical research
- as an investment

Conceptualizing Biobanks

Two extreme positions

1. The biobank is: body in bank
2. The biobank is: a simple research tool

Legal Attitudes to Biobanks

- **Property law-oriented**

  (tissues, ownership, patentability)
- **Personal rights-oriented**

  (prohibition of discrimination, confidentiality rules, protecting information, privacy rules)
- **Genetic data as a special kind of data**

  (data protection norms, recognition of the symbolic meaning of the genetic data, elaborate norms on data communication

Basic Conditions for Regulation

- The appropriate nature and scope of regulation cannot be decided on without knowing a good deal about the facts, the scientific background, including the practical effects of various regulatory strategies.

Step 1: Mapping biobanks

Different kinds of biobanks may need different types of regulation:

- Lots of local biobanks and virtual network of biobanks (Germany, Hungary)
- Central, National Biobank Projects, (UK. Biobank, Estonia, Latvia)
- Disease specific databanks

Does it require a new legal paradigm?

- Article 4 of the International Declaration on Genetic Data
- Human genetic data have a special status because:
- (i) they can be predictive of genetic dispositions concerning individuals;
- (ii) they may have a significant impact on the family, including offspring, extending over generations, and in some instances on the whole group to which the person concerned belongs,

Special status (cont.)

- (iii) they may contain information the significance of which is not necessarily known at the time of the collection of the biological samples;
- (iv) they may have cultural significance for persons or groups.

- Genetic exceptionalism or special guarantees?

Needs to Which Regulation Responds Well

- Collective action problems, co-ordination questions (resulting from inadequate information)
- Asymmetry of information
- Aims to avoid *ex ante* choices, *ex post* harm or dissatisfaction

Biobanks – a new paradigm for biomedical research

Traditional research with biological specimens generally involves:

- (1) a single researcher or an established group of researchers;
- (2) obtaining and using the samples in defined ways to research in discrete areas; and
- (3) obtaining informed consent from each research subject to use his or her sample and, where appropriate, an authorization to obtain, use, and disclose the subject's health information.

Specificity of Biobanks

By contrast, in biobanks:

- (1) the individual or entity obtaining the sample may not be engaged in research, but may be only a broker or intermediary supplying specimens to other researchers;
- (2) the purpose of a biobank is to develop a repository that can be used for many research protocols, often in numerous scientific areas;

Specificity of Biobanks

- (3) a biobank contemplates future research activities, including research by investigators who cannot be specified at the time of the sample collection; and
- (4) research using biobanks seeks to move beyond the one study/one informed consent model to a format of obtaining general consent to participate in the research activities of the biobank.

(Mark Rothstein, 2005)

Legislative Triad of Biobanks

Sample	**Data**	**Product**
Law on Biomedical research	Data protection law	Property law IP Law

Data and Samples: Terminology Inflation

Anonymous
Anonymized
Anonymously coded
Unidentified
De-identified
De-linked
Permanently de-linked
Not traceable
Irretrievably unlinked to an identifiable person (UNESCO)
Completely anonymized
Traceable
Coded

Identifiably linked
Pseudonymized
Unlinked
Encoded
Encrypted
Identified (NBAC)
Directly identified (Clayton et al 1995)
Fully identifiable
Confidential (NHS Confidentiality Strategy)
Linked to an identifiable person (UNESCO)
Identifiable

DNA Banks: Duplication of Legal Norms

Sample

- Property
- Access
- Destruction
- Retention

Data

- Privacy
- Information
- Anonymization
- Coding

Step 2: Scope of the Law

- Omnibus approach (law encompasses both public and private biobanks)
- All-inclusive approach (use of genetic data in all fields: Insurance, health, research)
- Sectoral approach (piece meal lawmaking)
- General data protection law+ professional guidelines

Legislative illustrations

- Portuguese law
- Spanish law
- Swedish law
- Estonian law
- Hungarian law

Portugal (Data protection oriented)

- Data Protection Act: Law no. 67/98, October 26 (presently being reviewed) implementing Directive 95/46/EC;
  - Law no. 12/2005, January 26 (Act on personal genetic information and information regarding health): regulates biobanks and genetic databases;
  - Law no. 5/2008, February 12 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;

Spain
(Biobanks within biomedical research)

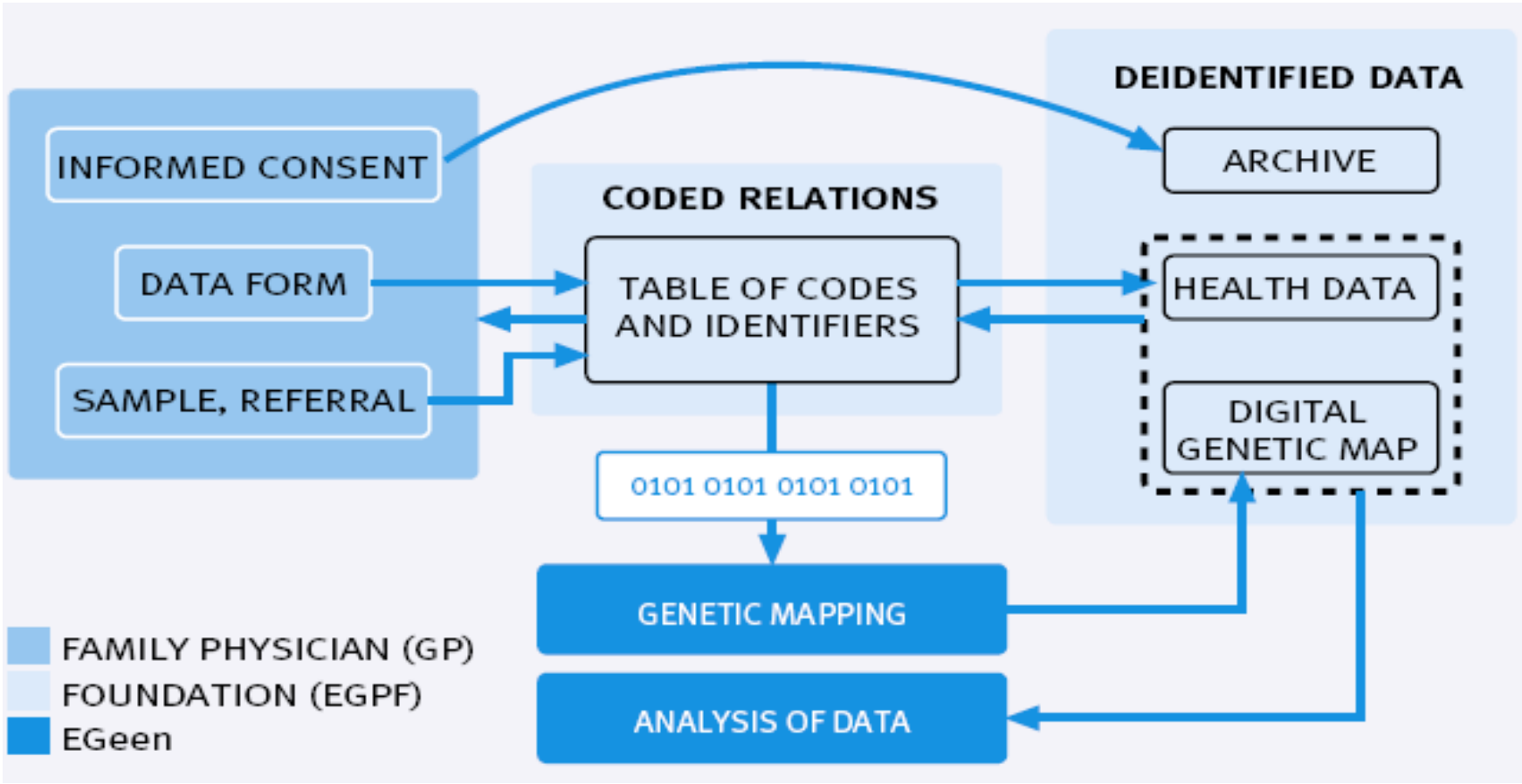
- Data Protection Act: Organic Law 15/1999, of 13 December. (Royal Decree 1720/2007, of 21 December)
- Law 41/2002, on health data protection;
- Law 14/2007, of 3 July, on Biomedical Research (Law on Biomedical Research) including the law on biobanks.

The Swedish Act on Biobanks (broad definition of biobanks)

- The Swedish Act on Biobanks (SF 2002:297) defines the concept “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

C1

Estonian Genome Project: Open consent model



C1 Based on the presentation by Ants Nomper
CEU; 13.07.2009

Hungarian Law: Genetics oriented

- 2000–2002 – Health Science Council discusses the challenges after the Human Genome Project
- 2003 – Prime Minister appoints a Human Genetic Commission (so-called “Clone-Committee”)
- Minister for Health also appoints a committee
- 2004 – First draft of the Bill prepared, debates
- 2006–2007 – Debates across the ministerial level
- 2008 April – Parliamentary debate

Hungarian Biobank Projects

- www.biobank.hu
- Member of the pan-European *Biobanking and Biomolecular Resources Research Infrastructure* (BBMRI) FP7-funded program
- National Research Infrastructure Development Roadmap Project
- NEKIFUT 'nationally significant research infrastructure'
- Examples:
- www.schizobank.hu, www.drugdesign.hu

Problems with the Title

- Protection of the genetic data … special rules for biobanks
- Parliamentary Act No XXI of 2008 on the protection of human genetics data and the rules of human genetics studies and researches
- Based on the tradition of strong personal data protection
- 1997 Parliamentary Act (No. XLVII) on the protection of health care and related personal data

Purpose and Scope of the Act

The purpose of the Act is to lay down rules

- on human genetic studies and
- human genetic research,
- the conditions and purposes of the processing of genetic data and rules on biobanks

Step 3 – Definitions

- Biobanks
- Types of biobanks under the scope of the law
- Problematic points: genetic data (no agreement within science)
- Anonymous data is different from coded data
- Coded vs. double coded,
- Genetic sample, specimen, data
- Linking, cross-linking, transfer

Normative Definition of Genetic Data

- *genetic data* means information on the inherited features of a given person concerned which arises from the processing of a genetic sample or health documentation and which refers to risk inherited tendencies, physical or behavioural features of the individual and is appropriate for identifying the individual

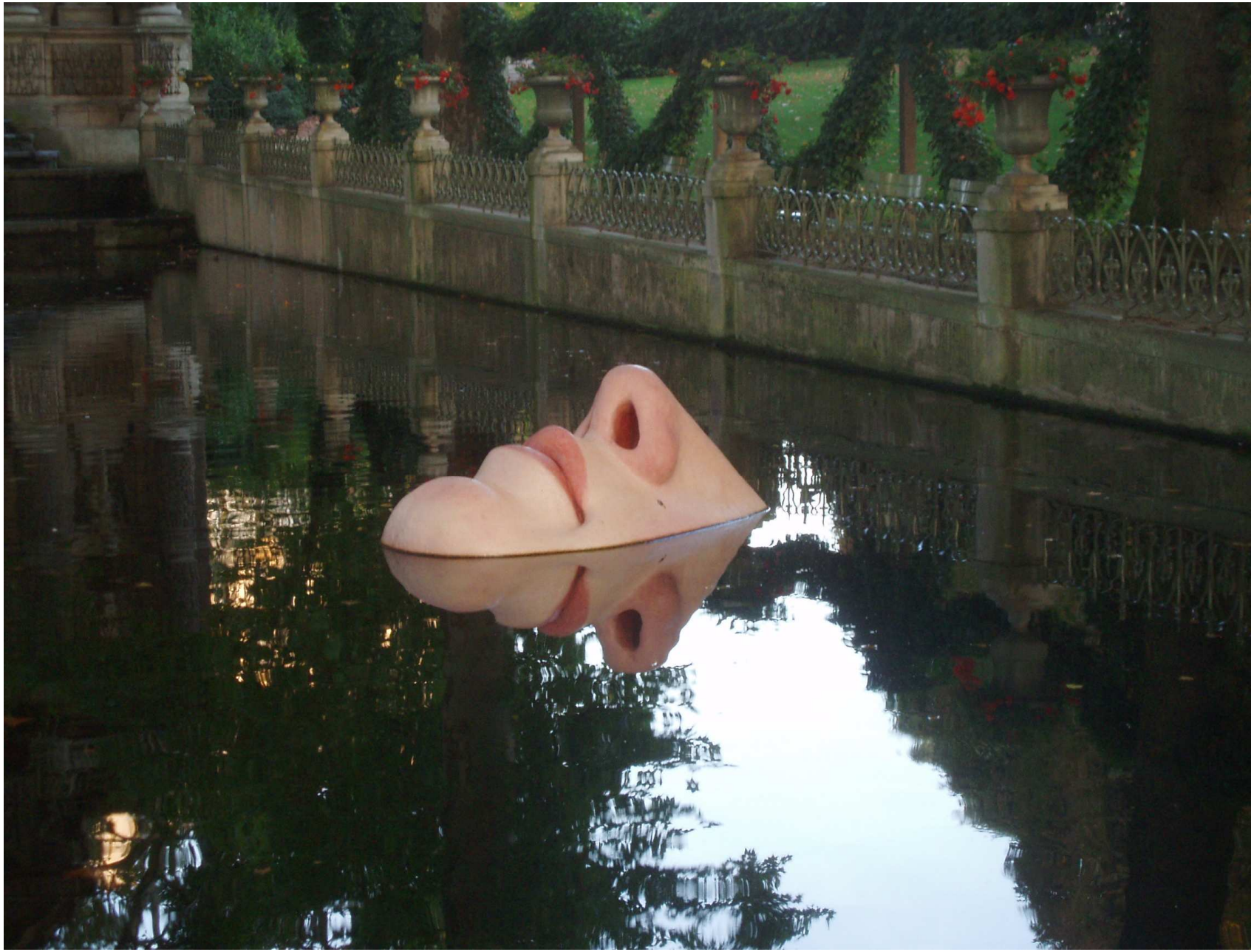
Problems of Anonymity

- Early legal models preferred **anonymity** – now **coded samples** constitute the main rule
- *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;

Article 29
Data Protection Working Party

Anonymous data

"Anonymous data" in the sense of the Directive can be defined as any information relating to a natural person where the person cannot be identified, whether by the data controller or by any other person, *taking account of all the means likely reasonably to be used either by the controller or by any other person* to identify that individual."



Coded Samples

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

“Pseudonym Samples”in the Hungarian law

- *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;

Step 4 –
Mapping Interests, Analysis of Rights

- Identification of rights and interests
- Dignity-Privacy-Liberty
- Right to be informed
- Right to decide (consent)
- Freedom of choice right to withdraw sample/data

Map of Interests in Biobanks

Tissue/ Gene-donors	Scientists	Society	Industry
Data protection	Research benefit	Security (protection against bioterrorism)	Industrial use Potential to develop new biotech products
Health benefit (diagnostic, therapeutic)	Diagnostic tool		
Privacy	Access to biobank networks	Public benefit Public use	

Purpose of Processing Genetic Data

In the HGA

Genetic data may be processed for the purposes of

- *a)* genetic study or
- *b)* human genetic research;
- As a consequence genetic data does not processed for forensic purposes
- Is it sufficient? (Anna Lindh case in Sweden)

From Collection to Biobanks

A *biobank* means a collection of

- samples containing genetic samples and
- related genetic and personal identification data for the purposes of a human genetic study or human genetic research (under the Hungarian Act)

Step 5 – Preparing the First Draft

- Different options can be still kept in the texts
- It is advisable to prepare a parallel Explanatory Note in order to keep the arguments behind certain legal solutions

Analysis of basic rights and correlative duties

- Following the process from sample to data and to product
- Right to Consent (Duty to provide information)
- Right to withdrawal (duty to respect and enforce it)
- Benefit Sharing based on agreement
- Right to feedback based on agreement

Example: Right to Self-Determination

- Before taking a genetic sample, it is necessary to obtain the written consent of the person entitled to disposal based on detailed information, irrespective of the purpose of the treatment of the genetic data.

Withdrawal

The person(s) concerned may withdraw their consent to the treatment of their genetic data being stored together with their personal identification data, code or pseudonym at any time. For a declaration of withdrawal, the person concerned may request that the genetic sample and all the derived genetic data be destroyed.

Adoption of the New Hungarian Law

- The Hungarian Parliament adopted the Bill on the protection of human genetic data, the rules of human genetic tests and researches, and biobanks
- Archived and other collections of human biological samples have to be converted according to the new law on biobanks until October 1, 2009

Global Challenges

- Cultural significance of genes
- Different patent regimes
- Different levels of development and infrastructure in the field of biotechnology
- Transnational practices (need for harmonization of ethical standards)
- Benefit sharing

Advantages of (Good) Regulation

- Predictability
- Channeling information & providing general access to it
- Promote mutual understanding (definitions)
- Answers to international flow of genetic information (avoiding the problems of legal uncertainties and comparisons)
- Less cost (as rules of the game are settled)
- Protection of underrepresented and vulnerable groups, including minors

Step 6 – Public Consultation

- Informed and broad public debate
- If necessary special consultations with minorities
- Channels for feedback
- Analysis of regulative failures
- Assessment of new technologies, hazards, risk and benefits
- (safety challenges, privacy enhancement technologies)

Follow up

- Follow up procedure is still necessary
- Monitoring
- (e.g. The Hungarian law provide deadline for existing tissue collections to be registered as biobanks)
- Law on new technologies often require further adjustment, corrections