The Finnish Act on Biobanks and the EU Regulatory Landscape of Biobank Research: Need for Harmonization?

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TALK OVERVIEW

- Analyse the Finnish Act on biobanks with a focus on ethical and legal issues
- Consider biobank research ELSI within the EU regulatory landscape:
  - Proposal for General Data Protection Regulation
  - Convention on Human Rights and Biomedicine
  - Recommendation on the Use of Human Biological Materials for Research
- Conflicting elements—Need for harmonization (?)
28 Member States → A wide variety of acts on biobanks
(state laws, EU recommendations, EU directives, EU regulations ......)
Regs in force on a EU level:

- Convention for the protection of human rights and dignity of human beings with regard to the application of biology and medicine (1997)
BIOBANK LAWS IN EUROPE: EXAMPLES

- Danish legislation of biobanks (several acts)
- Swedish Act on biobanks
- **Finnish Act on biobanks**
- Spanish Law on biobanks
- France Law on biobanks
- Portuguese Law on biobanks
THE FINNISH ACT ON BIOBANKS: OVERVIEW (1)

- Finnish Act on Biobanks → (688/2012) or “Biobank Act” came into force on Sept., 1, 2013
- English translation is unofficial and legally valid only in Finnish and Swedish
Biobank Act covers all the activities of (new or converted) biobanks for research purposes.

Clinical trials and «one-time» research protocols fall into the Medical Research Act (488/1999).

Unless otherwise provided in the Biobank Act or in other laws, the Personal Data Act (523/1999) – which ratified the EU Directive 46/1995 on the protection of personal data – covers the processing of personal information.
Biobank Act Objectives (section 1):

- support research with use of HBMs
- promote openness in the use of HBMs
- secure the protection of privacy and self-determination when processing HBMs
Biobank Act Scope (sect. 2)

Regulating:

- establishment of a biobank
- supervision of storage and processing of samples
- rights of registered (= identifiable) individuals
a biobank is a unit maintained by an operator engaging in biobanking activities (sect. 3)

a biobank may be established by a private person or a public institution with:

- necessary financial and operational means
- legal and research-related conditions for maintaining a biobank
- a positive statement of the National Medical Research Ethics Committee
THE FINNISH ACT ON BIOBANKS: OVERVIEW (6)

- duty of a biobank is to provide service for biobank research (sect. 5)

  - biobank research is = research utilising a) samples contained in a biobank or b) associated information with the purpose of (sect.3):
    - promoting health
    - understanding the mechanisms of disease
    - developing products and treatments used in health care and medical care
FINNISH ACT ON BIOBANKS AND ELSI

Putting the “informed” in informed consent

PRIVACY
Unless otherwise stipulated in an agreement on transfer of samples (sect. 7):

- the biobank **owns** the samples in its possession
- the owner shall appoint a **custodian** for the biobank with the following functions:
  - performing quality control
  - ensuring the protection of privacy
  - realizing the right of access to information
A biobank’s right to process sample is based on consent, unless otherwise provided (sect.11);

A person may consent to (sect.11):

- storage of samples - taken or to be taken - in a biobank
- use of samples for biobank research
- use of personal information
- linking of registered data and other processing of information related to him/her
Consent shall be prior, volunteer, free, written, informed (sect. 11)

The donor must be provided with sufficient clarification of (sect. 11):

- nature of biobank research
- any possible drawbacks
- purpose of collecting and storing samples
- owner of samples and biobank storing them
- opportunity to impose restrictions on or to cancel consent without negative consequences
Underage Persons (sect. 11):

- the consent is signed by the person who has the custody of the child
- If an underage person, according to his/her level of development, is capable to understand the significance and nature of biobank research $\rightarrow$ his/her written consent is also required
A person has the right to, at any point (sect. 12):

- cancel the consent or
- change it or
- prohibit the use of samples for research purposes or
- impose restrictions for their use when samples are furnished with an identifier

In all cases, a notification in writing must be submitted to the custodian of the biobank
Processing of old samples (sect. 13)

- Health care or other units, research and higher education institutes may transfer samples collected and analysed for clinical or research purposes prior to the entry into force of this Act to a biobank, based on:
  - positive statement of a regional ethics committee and
  - consent of the concerned person
CONSENT AND OLD SAMPLES (2)

Before the transfer (sect. 13):

- Identifiable individuals → must be notified of a change of purposes as concerns the samples and associated information;
- notification must state that samples and related info may be used for biobank research and
- a description of the nature of biobank research and
- instructions for providing consent and exercising the rights to prohibit or limit the use of samples/info must be attached to the notification
If obtaining the contact information of an identifiable individual is not possible, although reasonable efforts, due to:

- age or large number of samples or
- for other similar reasons

the notification must be published in an official paper or in a public communication network
Deceased persons: the transfer of samples or info to a biobank may not be performed if there is reason to assume that the person, when alive, would object to the use of samples for research.

The National Supervisory Authority for Welfare and Health will determine, upon application, whether or not the conditions are met.
Identifiable individuals have the rights to (chapter 6):

- receive, upon request, information on whether or not samples concerning them are stored in a biobank
- receive, upon request, info concerning their health as determined by analysing a sample

These requests may be charged of a fee which, at maximum, corresponds to the costs related to the info provision (sect. 39)

biobank cost recovering
Any person who intentionally or out of gross negligence compromises:
- the protection of privacy of donors
- and donor rights

shall be sentenced to a fine for a violation of provisions concerning biobanks, unless a more severe penalty is provided elsewhere in law (sect. 43)
Comprehensive: covers either operational and ethical-legal aspects of biobanking activities

Balance the development of biobank research and donor’s rights

Use special terms concerning biobanks such as «biobank’s right», «violation of provisions concerning biobanks»
Consider crucial ELSI such as:

- **Ownership** of samples stored in a biobank
- **Consent** for biobank research from adult and pediatric individuals
- Consent for biobank research with new or old samples
- Right of access to personal data
To date, definition and status of human body is hostly contested on a global level

- **Theory of personal rights**
  Body and its parts are corporeal elements of the personal identity and the individual has the right to decide autonomously the destiny of them

- **Theory of property rights**
  Body parts are «things» and the individual has the right to dispose of them in any way with the only limit to not abuse of them
Ownership of biological materials of human origin is not explicitly considered in the main Regs governing the research with human specimens in Europe.
The prohibition against direct financial gain deriving from the human body and its parts is widely recognised in:

- EU Convention on biomedicine and human rights (art. 21)
- Charter of fundamental rights of EU (art. 3, par. 2)
- EU Recomm on the use of hBMS for research (art. 6)
The Special Case of Portuguese Law
Lei n. 12/2005 states that (art.18):

- «The material stored in a biobank is the **property** of the people from whom it was collected and, after death or incapacity, is the property of their family members»
- The owner has the right to dispose of these materials in any way, with the only limit to not abuse of them
- The owner has also a right to share the benefits resulting from research-industrial work over his/her samples (De Faria, 2009)
The Finnish Biobanks Act supports a broad consent model and attributes to the individual a right to cancel or change the consent or to impose limitations on the use of samples/data for biobank research.
”When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures”
(Conv. Oviedo, Art. 22)

“Before being asked to consent to participate in a research project, the persons concerned shall be specifically informed, according to the nature and purpose of the research of any foreseen potential further uses, including commercial uses, of the research results, data or biological materials”
(Add. Protocol to the Convention of Oviedo, Art 13.)
“Information and consent or authorisation to obtain (biological) materials should be as specific as possible with regard to any foreseen research uses and the choices available in that respect” (Eur. Recomm., art 10)

Where the research use of HBMs become known later, the researcher should contact the donor to obtain a new or renewed consent to that use.
If recontacting donors is not possible because specimens or data have been unlinked anonimised, then samples and associated data may be used under the following conditions:

- a competent authority (usually an ethics commitee) has recognised the scientific interest of the research and its ethical acceptability
- it is not possible to use other HBMs
- there is no evidence that the concerned person has opposed such research use
# Informed consent models in EU

<table>
<thead>
<tr>
<th>Model of informed consent</th>
<th>Definition</th>
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<tr>
<td>Broad consent</td>
<td>Allows the use of biological specimens and related data in immediate research and in future investigations of any kind at any time</td>
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<tr>
<td>Partially restricted consent</td>
<td>Allows the use of biological specimens and related data in specific immediate research and in future investigations directly or indirectly associated with them</td>
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<td>Multi-layered consent</td>
<td>Requires several options to be explained to the research subject in a detailed form</td>
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<tr>
<td>Specific informed consent</td>
<td>Allows the use of biological specimens and related data only in immediate research; forbids any future study that is not foreseen at the time of the original consent</td>
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Table 2 | Definition of informed consent models for biobank-based research according to the characterization used in international ethical and legal documents
The Reform of the EU Data Protection Framework
Building Trust in a Digital and Global World

Tuesday 9 October 2012
09.00 – 18.14
Wednesday 10 October 2012
09.00 – 16.30

Where Are We Going?
Presently, processing of personal data is subject to the EU Directive 95/46/EC- «Data Protection Directive»

On Jan., 25, 2012 → the EU Commission issued a Proposal for a «Regulation of the EU Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data» (General Data Protection Regulation COM (2012) 0011)

The proposal for a new Data Protection Regulation: Introduction (2)

- On March 12, 2014, the EU Parliament voted in favour of the proposal for a EU Data Protection Regulation.

To become law this Regulation must be adopted by EU Council of Ministers using the «ordinary legislative procedure». The EU Council is expected to meet in June 2014.

European Parliament supports data protection reforms

Why a New Legislation?

- To harmonize rules across Europe and facilitate transfer of personal data between member states (MS)
- To reinforce cooperation on EU and international level
The GDPR Aims (art. 1)

- Protect individuals with regard to the processing of personal data
- Protect fundamental rights and freedoms of natural persons and especially their right to the protection of personal data
GENERAL DATA PROTECTION REGULATION AND SCIENTIFIC RESEARCH
Processing of personal data concerning health which are necessary for scientific research purposes shall be permitted only with (art. 81):

- data subject consent and
- in accordance with conditions of art. 83 of GDPR
Consent shall be (art. 7, recital 25):

- free
- informed
- explicit
- purpose-limited

- data subject shall have the right to withdraw his/her consent at any time (art. 7)
consent (3)

Processing of children personal data (art. 8)

«Children deserve specific protection of their personal data» (recital 29)

- In relation to the offering of goods or services directly to a child → processing of personal data of a child below the age of 13 ys shall be lawful if and to the extent that consent is given/authorised by the child’s parent/legal guardian
- Controller shall make reasonable efforts to verify such consent
A new specified consent for any further processing of personal data

MS laws may provide an exemption from the consent requirement:

- only when the research serves a high public interest, if that research cannot be carried out otherwise
- data in question shall be anonymised or pseudonymised under the highest technical standards

(art. 81, recital 123a)
CONSENT (5)

According to this Regulation, personal data may be processed for scientific research purposes only if (art. 83):

- these purposes cannot be otherwise fulfilled by processing data which are not or not longer identifiable
- identifiable data are kept separately from other information
According to consent of the data subject (art. 83a)

once the initial processing for which they were collected has been completed, personal data may be processed by archive services whose main or mandatory task is to collect, conserve, provide info about .., in particular for scientific research purposes
European Parliament supports data protection reforms

R. Frackowiack, chair of the Medical scientific committee of Science Europe, said this proposal “will cause massive burocratic delays and will seriously affect european competitiveness in medical research”

B. Thomson, policy adviser at Wellcome Trust, said: “We urge European institutions to ensure the LIBE emendments are rejected in the trilogue discussions (the EP, the Council of Ministers and the Ecommission)”

S. Kentner, director of the Brussels Office of the Helmoltz Association of German Research Centers, said: “I agree it is time to rethink data protection broadly, but medical data issues are being dragged into issues with internet security”
GDPR IMPACT ON TRANSBORDER DATA FLOWS
ON A GLOBAL LEVEL (1)

- GDPR aims to reinforce collaboration on a EU and international level

**How?**

- Data transfer may take place when the **EU Commission** has decided that the third country/international organisation in question ensures an adequate level of protection (art. 31)
GDPR IMPACT ON TRANSBORDER DATA FLOWS ON A GLOBAL LEVEL (2)
GDPR IMPACT ON TRANSBORDER DATA FLOWS ACROSS EUROPE

Partially Restricted Consent

Broad Consent

Partially Restricted Consent

Partially Restricted Consent

Broad Consent
TRYING TO SUMMARIZE (1)

- Eu regulatory landscape of biobank research presents great variability:
  - different kind of state regulations
  - different consent requirements
  - different data flows processing
  - different rights to data access
TRYING TO SUMMARIZE (2)

- Need for harmonization across European MS
- Need for collaboration on a global level
HOW TO GET IT?
Could IT help to handle limited-purpose consent?

In the EnCoRe Project, researchers have built a patient-centric IT system using a «dynamic consent approach». The benefit of this interface is that it enables individuals to give informed consent for new types of research in real time.
CONCLUSION (2)

Could patients/families help to understand which ethical approach using for biobank research?

Elena Salvaterra et al.  
“Pediatric Biobanks: opinions, feelings and attitudes of parents towards the specimen donation of their sick children to a hypothetical biobank”  
Pathobiology, 2014- At press

Mamoun Ahram et al.  
“Factors influencing public participation in biobanking”  
EJHG, 2014

LSG Working Papers 2011/2  
October 5, 2011  
Publics and Biobanks in Europe: Explaining Heterogeneity
CONCLUSION (3)

Could education help to balance regulators, scientists and patients/families interests?
The debate is open.
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