Signe Mezinska

ETHICAL ISSUES OF RESEARCH ON HUMAN BIOLOGICAL MATERIALS: LATVIAN CASE

THE 3RD MEETING OF THE BALTIC RESEARCH ETHICS COMMITTEES
MAY 13-14, 2011 VILNIUS

Stakeholders

- What institutions, groups and persons are interested in the protection of rights of donors of biological material in Latvia?
- What institutions, groups and persons are responsible for the protection of rights of donors of biological material in Latvia?

Stakeholders

- donor
- researcher
- State Agency of Medicines
- RECs
- Ministry of Health
- Central Medical Ethics Committee

Legal acts specifically dealing with research on human biological materials

Oviedo Convention
(in force since 01.06.2010)

The Additional Protocol concerning Biomedical Research (not ratified)

The Law "On the Protection of the Body of Deceased Human Beings and the Use of Human Tissues and Organs in Medicine"

Cabinet Regulations no. 208 "Procedures for Banking, Storage and Utilisation of Human Tissues and Organs"

The Human Genome Research Law

The Sexual and Reproductive Health Law

Other documents indirectly dealing with research on human biological materials

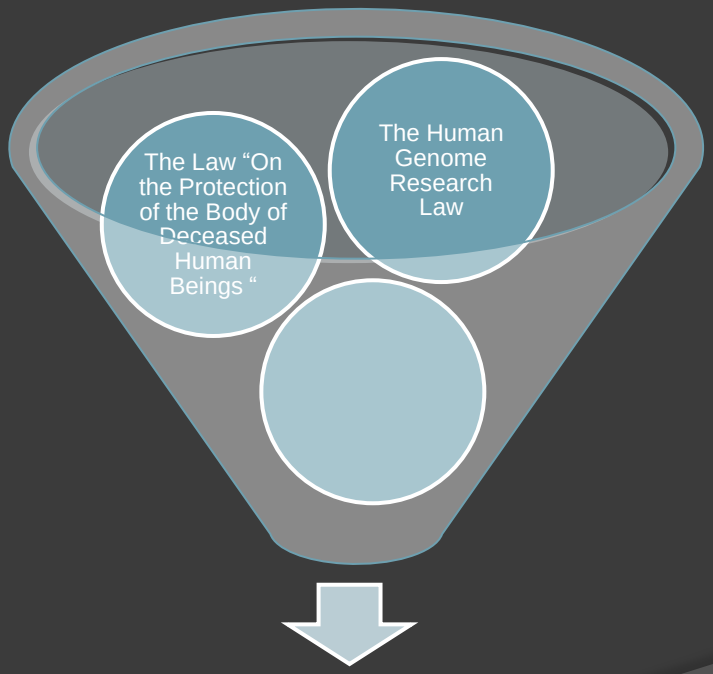
The Law “On the Rights of Patients”

Personal Data Protection Law

Criminal Code

Need for a coherent regulation

- Is there a need for a coherent policy and regulation regarding biobanks in Latvia?



Law on Biobanks?

Research on human tissues and cells that are obtained for specifically defined research purposes

- Generally regulated by the law “On Protection of the Body of a Deceased Human and Utilisation of Human Tissues and Organs in Medicine”

On the Protection of the Body of Deceased Human Beings and the Use of Human Tissues and Organs in Medicine

Scope of the law:

- "*The purpose of this Law is to protect the body of a deceased human being from undignified and illegal actions with it. This Law prescribes the procedures by which the tissues and organs of living or deceased human beings may be used for scientific researches and study purposes, transplantation, manufacture of medicinal preparations and bioprothesis.* " Section 1

On the Protection of the Body of Deceased Human Beings and the Use of Human Tissues and Organs in Medicine

> *"Any institution or organisation is prohibited to deal with pathological-anatomical examination, anatomical studies of the body of a deceased human being, removal and further use of tissues and organs of a living or deceased human being without the permission of the Minister of Health."*
>
> *On the Protection of the Body of Deceased Human Beings and the Use of Human Tissues and Organs in Medicine, Section 17*

Problems

- The law basically applies to organ transplantation and pathological-anatomical and forensic examination and therefore has many shortcomings regarding regulation of research on human tissue
- Scientific research is explicitly mentioned only in the section on removal of tissues and organs from deceased human beings
- The law states that "*only tissues with the capacity to restore may be taken from a living donor*" [Section 13], and it is not clear how this norm applies to the research.

(Mezinska, S., Olsena, S. (2010) Country Report for TISS.EU project)

Problems

Lack of definitions:

- biobank
- biomedical research
- only clinical trials on medicinal products are defined in the “Pharmaceutical Law” and genetic research is defined in the “Human Genome Research Law”.

(Mezinska, S., Olsena, S. (2010) Country Report for TISS.EU project)

Review by ethics commitee

- Since Latvia has ratified the Oviedo Convention biomedical research projects should in principle be subjected to ethical review.
- The Statutes of the Central Medical Ethics Committee states that the Committee has a right "*to propose the discontinuance of a biomedical study if it's accordance with the norms of medical ethics has not been evaluated*" (Section 3, § 5.5).

Problems

- In general there are no specific national regulations regarding ethical review of biomedical research except clinical drug trials, research on medical devices and research on the Latvian population genetic database.
- The main practical reason to apply for ethical review is participation in international projects or requirements of scientific journals.

(Mezinska, S., Olsena, S. (2010) Country Report for TISS.EU project)

The register of institutions that are allowed to procure, store or transfer tissue and cells

- Accumulation and use of tissues and organs voluntarily donated by people and acquired in a lawful way shall be permissible in accordance with the procedures specified by the Cabinet in the extraction and storage centres of tissues and organs referred to in a special list. [On the Protection of the Body of Deceased Human Beings and the Use of Human Tissues and Organs in Medicine, Section 17]
- Establishments for the procurement and storage of tissues must be evaluated by the Health Statistics and Medical Technologies State Agency [Section 2, § 7].
- The Agency also has to "*establish, maintain and supplement a register of procurement and storage establishments*" [Section 3, § 14].

The register of institutions that are allowed to procure, store or transfer tissue and cells

- It is allowed to bank, store and use human tissues, cells and organs for the following purposes:
  - for making and utilisation of sterile medical grafts;
  - for transplantation;
  - for pathological-anatomical examinations;
  - for scientific research;
  - for implementation of study programs in institutions of higher education.

  [Cabinet Regulations No. 208; Section 1, § 5]
- The regulations do not apply to:
  - blood and blood components; and
  - tissues and cells used as an autologous graft within the same surgical procedure.

Problems

- After the closing of the Health Statistics and Medical Technologies State Agency in 2009 the function of establishing, maintaining and supplementing the register only partly was given over to the State Agency of Medicines.
- In practice the registration and certification is an initiative of the institutions storing human tissue and cells.
- Currently only 6 institutions are included in the register.

(Mezinska, S., Olsena, S. (2010) Country Report for TISS.EU project)

Informed consent

The Personal Data Protection Law is applicable concerning the processing of personal data.

"*The processing of sensitive personal data is prohibited, except in cases where:*

1) the data subject has given his or her written consent for the processing of his or her sensitive personal data" Section 11

Informed consent

Prior to the procurement of tissues or cells representative of the procurement and storage establishment shall inform a donor regarding:

- ”*the purpose and nature of procurement of tissues, cells or organs, the consequences and potential risks of procurement;*
- *the object of the medical treatment and potential benefits of the procurement of tissues, cells or organs;*
- *the potential safeguard measures of the donor;*
- *the form of registration of donor’s data, data protection and observance of confidentiality;*
- *laboratory tests (if any) and the right to receive the results of such tests in a comprehensible way; and*
- *the necessity to receive the mandatory consent of the donor prior to the procurement of tissues, cells or organs.*”

[Cabinet Regulations No. 208; Section 5,§ 28]

Informed consent

- The information has to be provided "*in an appropriate, clear and readily comprehensible manner*" [Cabinet Regulations No. 208; Section 5, § 29].
- The procurement and storage establishment is obliged to receive the written consent of the donor.

Problems and questions

- What is the quality of informed consent procedures?
- The type of the consent for research is not specified (open? renewable?)
- The right to withdraw the consent is not explicitely included in the Cabinet Regulations.
- Possible levels of withdrawal (no further contact? no further use? total withdrawal and samples destroyed?)?
- Should anonymization be an automatically permissible response to requests for withdrawal?

(Mezinska, S., Olsena, S. (2010) Country Report for TISS.EU project)

Left-over

- No legal requirements regarding informed consent for use of medical waste
- *Example: left-over newborn spots are originally banked without parental permission.*
  - *What type of consent should be asked for research?* [1]
  - *Should it depend on the level of identifiable information attached to samples?* [1]
  - *What is importance of public engagement?* [1]

[1] Richer, J.; Ghebremichael, M.S.; Chudley, A.E.; Robinson, W.M. ; Wilfond, B.S.; Solomon, M. Z. (2011) Research use of leftover newborn bloodspots. *Genetics in Medicine*. 13 (4): 305-313

Archived samples

- Access to archived samples is not regulated by the law.
- In practice usually the approval of ethics committee and permission of head of institution is required.
- How to ensure just usage?
- Who should decide?

Problems

- There are at least 17 institutions of pathology service in Latvia (e.g. pathology centers and pathology departments at hospitals) where tissues and cells are collected and stored for diagnostic purposes.
- Tissue samples in these centers are mostly derived from biopsies.
- Only two of these institutions are currently included in the register of tissue procurement and storage establishments.

(Mezinska, S., Olsena, S. (2010) Country Report for TISS.EU project)

Extra biological material

- Biological material that is collected above and beyond what is needed for a clinical or diagnostic procedure, i.e., collecting a few extra amount of blood during a blood draw for diagnostic purpose.
- Research involving collection and use of extra biological material is human subjects research and needs REC review.
- In practice there are violations of informed consent and confidentiality requirements.

Biobank research (human genome research)

- In general – well regulated field of research.
- Problems:
  - quality of informed consent
  - documentation required by REC is specific for clinical research
  - How to inform about the results of the research (hemachromatosis)?

Children as genome research subjects

- “A child’s genome research may be performed only with the written consent of a parent (guardian) and the Orphan’s court (Parish court). The Orphan’s court (Parish court), in deciding this matter regarding a child who is able to formulate his or her opinion shall clarify the opinion of the child and evaluate such opinion taking into account his or her age and maturity.”

Human Genome Research Law, Section 12 (3)

Collection of tissue samples from deceased

- Samples of tissues for scientific research may be taken during pathological-anatomical and forensic examination "*if the deceased has permitted it during his or her life, if the will of the deceased is unknown, as well as if the will of the deceased is unknown and he or she does not have the next of kin*"

  The Law "On the Protection of the Body of Deceased Human Beings and the Use of Human Tissues and Organs in Medicine", Section 9

Collection of tissue samples from deceased

- *“If there is no data in the Population Register regarding a prohibition or permission of a deceased human being to use his or her body, tissues and organs after his or her death, the spouse, parents, adult children, brothers or sisters (hereinafter – the next of kin) have the right to inform a medical treatment institution (tissue and organ extraction centres) regarding the will expressed during his or her life.”*

  The Law “On the Protection of the Body of Deceased Human Beings and the Use of Human Tissues and Organs in Medicine”, Section 4

Questions

- Do physicians or researchers have an obligation to search for the next of kin and ask whether the deceased did not object to such procurement and use of his / her biological material after death?
  - According to law there is no obligation to search for the next of kin. It is also not done in practice.
- Is it possible to procure biological material from the deceased if his / her next of kin did not inform the register about the will of the deceased?
  - Yes, the procurement of BM is possible, because there is no obligation to inform the register.
- If the next of kin does not know the will of the deceased, can he/she object to procurement and use of the biological material of the deceased?
  - Not possible according to the law. Next of kin does not have independent decision power.

Genome research

- Genome research of a deceased person may not be performed if this is against his or her expressed will while alive. If such a will was not expressed, it is prohibited to perform the genome research of the deceased person.

Human Genome Research Law, Section 3 (6)

- In practice there are no genome studies of deceased persons in Latvia

Problems

- Latvian legal acts do not propose a person's right to express specific prohibition to use person's tissue for research purposes after his/her death.
- Only a general permission or prohibition to use person's body, tissues and organs after his/her death may be registered in the Population Register.

(Mezinska, S., Olsena, S. (2010) Country Report for TISS.EU project)

Thank you!

signeme@hotmail.com