

WHAT SHOULD WE LEARN FROM THE ANALYSIS OF BIOBANK CONSENT DOCUMENTS?

Jurate Lekstutiene
Lithuanian Bioethics Committee

Background

Biobanks have been recognized as a key research infrastructure in reaching the ambitious goals of the personalized, predictive and preventive medicine.

However, developments in the field of biobanking also raise important ethical and human rights concerns, one of which is how individuals donating biological samples and sensitive health related data should be informed about their participation in biobanks.

Materials

14 consent documents from biobanks in 11 European countries: Austria, Belgium, Estonia, Germany, Italy, Latvia, Luxemburg, the Netherlands, Norway, Portugal, and the United Kingdom.

Types of Biobanks

Population biobanks (Latvia, Estonia, UK biobank)

Disease biobanks (Rotterdam, Luxembourg, Oslo, Cambridge, Brussels, Munich, Milano, Padova, Lisbon)

Mixed' biobanks comprising both population and disease collections of human biological material and data (Graz, Oxford)

Aims

To explore how donors are informed about their participation in biobanks.

To suggest what the most important thematic issues of information are to be given to the biobank donors and how this information should be presented in the biobank consent documents in the context of respect to donor's autonomy paradigm.

To protect the donor's interests, the biobank should:

Employ some form of explicit rather than presumed consent (exception for residual material)

Define the scope of future research in a reasonable detail

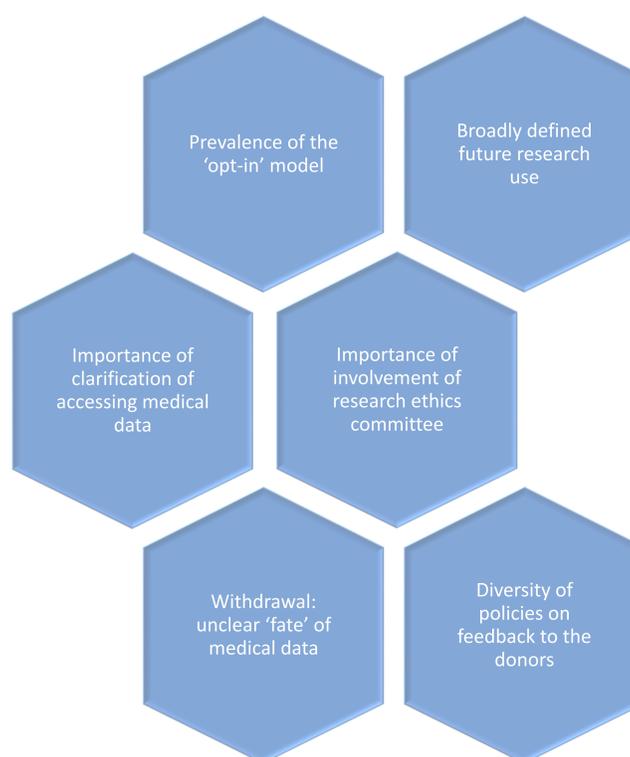
Explain a possibility for the biobank to access personal medical data in the future

Offer different options of feedback regarding findings discovered in the course of research along with appropriate personal counselling

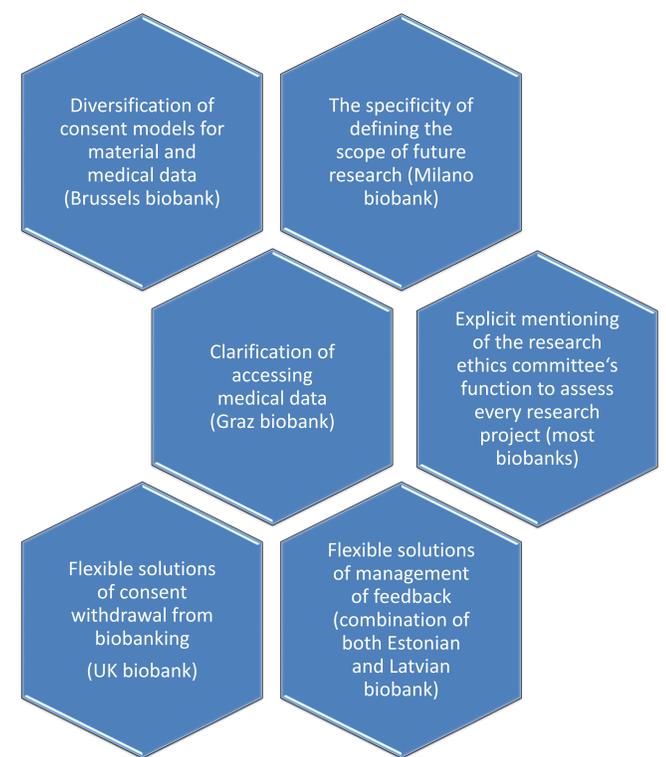
Explain the consequences of and offer different options for disposal of biological material and medical data in the case of withdrawal

Ensure research ethics committee's review for every research project which involves biobanked samples and medical data

Trends



Good practice examples



Discussion

The analysis of consent documents reflects the heterogeneity of biobank consent document policies applied in different European countries. However, it also shows some trends how ethically relevant issues characterizing biobanks are described in consent documents and their different level of compliance with the donor's autonomy centered approach.

This analysis does not imply the bottom line of how biobanking system should be organized in any given country which is establishing biobanks or updating biobanking regulations, as this will also depend on differing social and cultural environments amongst the countries. However, we suggested some examples of good practices to balance the interests of the donors with those of the researchers and future patients.

Reference: Serepkaite, Jurate, Valuckiene, Zivile, and Eugenijus Gefenas. "Mirroring' the Ethics of Biobanking: What Analysis of Consent Documents Can Tell Us?" *Science and Engineering Ethics* 20(4):1079-1093. Accessed November 24, 2014. doi: 10.1007/s11948-013-9481-0.

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Contact

Jurate Lekstutiene
Vilnius University
Lithuanian Bioethics Committee
Email: jurate.lekstutiene@gmail.com
Websites: <http://www.mies.mf.vu.lt/en/>;
<http://bioetika.sam.lt/index.php?3221858831>
Phone: +370 60130685