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ETHICAL AND LEGAL ASPECTS OF HUMAN TISSUE AND BIOBANK RESEARCH IN EUROPE: REPORT OF THE TISS.EU PROJECT AND ITS RESULTS

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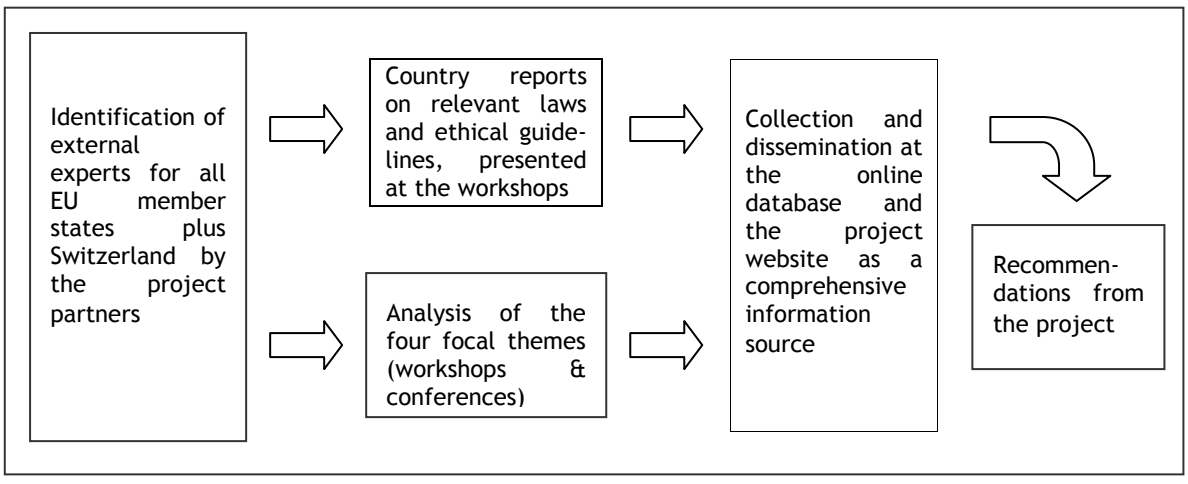
1. Structure and aims of the Tiss.EU project

The Tiss.EU project[1], funded by the European Commission in the 7th Framework Programme, focuses on questions of ethical and legal regulation regarding human tissue research. The absence of a comprehensive EU regulation on human tissue and biobank research poses a serious threat to biomedical research across borders in the European Union and associated countries. The regulations that do exist are for the most part confined to clinical applications of human tissues and cells. It is the aim of the Tiss.EU project to survey and compare EU (and Swiss) regulations in the field in order to identify their shortcomings, in order to create an evidence base for the possible European harmonisation of ethical and legal regulations governing human tissue research.

Between April 2008 and March 2011, the Tiss.EU project conducted nine workshops in as many different EU countries, and three conferences drawing together international experts in the field of human tissue research. A summary of results of the project will be available in the near future.

One of the main goals of the Tiss.EU project is to make its findings widely accessible to the public. For this purpose, it has launched a project website[2] to provide a free-of-charge and readily available platform for academics, researchers and other interested parties. The website includes a large online database of relevant international documents, as well as reports resulting from the project workshops and conferences. A network of experts can also be easily reached through the links on the portal.

The Tiss.EU project has a two-tiered organisational structure. First, the coordinating institution and nine academic partners located in different EU Member States form the consortium. Each of the partners is responsible for a country group of two to five EU countries, which are invited to report on the ethical and legal situation with regard to human tissue research in their respective countries.

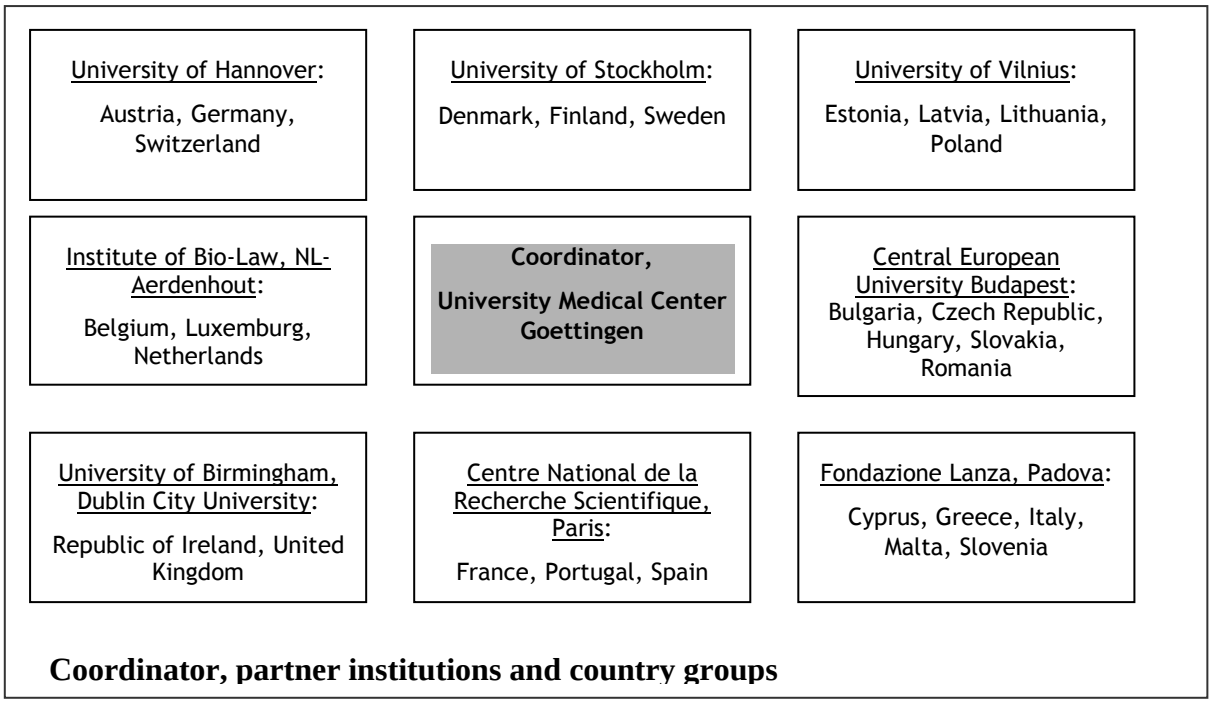


[1] The full title of the Tiss.EU project is: "Evaluation of Legislation and Related Guidelines on the Procurement, Storage and Transfer of Human Tissues and Cells in the European Union - an Evidence-Based Impact Analysis". The project is coordinated by PD Dr Christian Lenk, Prof Dr Claudia Wiesemann (Dept. for Ethics and History of Medicine, University of Goettingen) in cooperation with Dr Nils Hoppe (Centre for Ethics and Law in the Life Sciences, University of Hannover).

[2] See www.tisseu.org (accessed 3 April 2011).

2. Tiss.EU project – Two-Tier Structure

Secondly, the partners are teamed up in groups of two to three to provide a scientific analysis of the crucial ethical and legal issues for human tissue research arising in relation to one of the four focal themes of the project.



Coordinator, partner institutions and country groups

The four focal themes are:

1- Procurement, storage and transfer of tissues and cells for non-clinical research purposes

Scandals in relation to the procurement and storage of human tissue have recently undermined public acceptance and trust in the respective research institutions, suggesting that if potential donors were to withhold their participation in research projects, important biomedical research may run the risk of decline. There is also a large discrepancy between the public perception of tissue storage issues and the views of medical professionals and researchers, pointing to a need for greater transparency. A particular problem is posed by the storage of human tissue that transcends clinical purposes and as such is not related to the treatment of an immediate health threat. In cases as these, issues of consent and anonymisation rise to the fore.

2- Rights, interests and entitlements in human tissues and cells

This focal theme covers questions such as the ownership of tissue removed from the body, and issues related to intellectual property rights, and the freedom of movement within the EU related to goods and services in human tissues and cells.

3- Anonymisation and pseudonymisation as means of privacy protection

Standards of pseudonymisation and anonymisation of tissue samples may come under close scrutiny these days, because many biomedical projects include research on the genetic dispositions of patients. This raises important questions touching on the subject of privacy and control of personal data. Who should have access to donors'

health information, for example? There is a risk that donors may be subject to disadvantage or discrimination on the basis of disease dispositions.

4- Biobanking

It is imperative that mutual ethical and legal standards for the extraction, storage and exchange of human cells and tissues be defined, though different standards will have to be applied to biobanks that focus on the research and treatment of specific diseases, and non-specific and national biobanks (such as the UK Biobank). The property problem that arises when tissues and cells are transferred from donors to research projects or national and international institutions also needs to be dealt with, as a joint ethical and legal regulatory framework is still missing.

3. Conclusions from the Tiss.EU project

Due to the two-tier structure of the Tiss.EU project, conclusions can be derived both from analysis of the European Member States' regulation on human tissue research[3] and from the more theoretical examination of the aforementioned four focal themes. Although there is no consensus on these issues, several convergences can be observed.

3.1 Procurement, storage and transfer of tissues and cells for non-clinical research purposes

Harmonisation in this field appears particularly difficult because regulations on the procurement, storage and transfer of human tissue are not only divergent between countries but differ even at the level of institutions. The UK, for example, has a discrete law and other reference Acts on human tissue, whereas countries like Malta rely mainly on EU legislation. Some common practical standards have, however, emerged. In relation to the transfer of data and samples, for example, the receiving institution or country must adhere to the domestic rules of the sending country. In other areas, such as consent procedures for the protection of tissue donor autonomy, standards may vary dramatically. The type of consent that should be required (whether open, specific or broad) is contested, and it is a matter of debate as to whether one type of consent can apply to all three stages – the procurement, storage and transfer of samples. In the context of the peculiarities of human tissue and biobank research, it is pertinent that there has been a trend towards more lenient interpretations of informed consent. Some countries, such as Sweden, are revising their requirements for specific informed consent. Other countries such as Estonia, Latvia and Switzerland have switched to a broad or open form of consent, which makes samples and data available for future research projects, subject to only a few restrictions. Some countries permit exemptions even when the purposes of proposed secondary research exceed the original consent of the donor. This is the case in Portugal and Spain if it is too burdensome, relative to the value and limited risk

[3] For a more detailed analysis, see K Beier and C Lenk, "A Unified European Approach on Tissue Research and Biobanking? A Comparison" in: C Lenk, J Sándor and B Gordijn (eds.), *Biobanks and Tissue Research: The Public, the Patient and the Regulation* (Springer 2011, forthcoming).

associated with the research, to obtain secondary consent; and also in Denmark and Lithuania, if the research has been approved by a Research Ethics Committee.

3.2 Rights, interests and entitlements in human tissues and cells

Human tissue research also raises questions regarding the legal status of human bodily material. In line with European provisions[4] asserting that "the human body and its parts shall not, as such, give raise to financial gain", almost all countries perceive the human body as *res extra commercium*. Consequently, in most Member States tissue donors do not hold proprietary rights in their biological materials. These provisions are however inadequate to meet the challenges in this field. The non-commercialisation principle may no longer apply (in Germany, for example) if human bodily materials are turned into products. Moreover, a closer look reveals various levels of treatment rather than a strict prohibition of commercial practices.[5]

Human tissue research therefore also raises questions of justice. While on the one hand donors have no property rights in their samples and may not receive any remuneration, researchers or companies may on the other hand derive profits from them. The interests of the different stakeholders (including donors, researchers and companies) must therefore be balanced by providing a fair share of the benefits generated by the research to all actors involved. More attention should be paid to indirect benefit-sharing practices, such as allowing participants to help define the research that their samples will be involved in, or by providing them with feedback on incidental health findings. It might also be asked whether a property framework is adequate at all for satisfying the donors' requirement for control over their samples and data. Alternatively, according to the so-called "bundle theory of rights" a more nuanced perception is needed, whereby not all human biological materials are subject to the same rights regime[6]. Furthermore, property issues might be displaced by more urgent questions, such as how researchers can be assured of equal access and efficient usage of human tissues, while at the same time maintaining the donors' privacy.

3.3 Anonymisation and pseudonymisation as means of privacy protection

The need for the protection of the privacy is widely acknowledged in the European arena. In most countries, the protection of samples and data is regulated by national data protection laws implementing the European Data Protection Directive,[7] which makes several exemptions for the application of *health data* in research. What is contested however is whether these exemptions also apply to *research*. Whether

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[4] See for example the European Convention on Human Rights and Biomedicine (1997, art. 21) or the Council of Europe's Recommendation 2006(4) on research on biological materials of human origin (art. 7).

[5] C Lenk, "Ökonomie der Körperteile: Wie weit reicht das Kommerzialisierungsverbot des menschlichen Körpers?" (The economy of body parts. How far does the no-commercialization principle extend to the human body?) (2010), 21(4) *Berliner Debatte Initial* 9–18.

[6] B Björkman, "Different types—Different rights: Distinguishing between different perspectives on ownership" (2007) 13 *Sci Eng Ethics* (2007) 221–233.

[7] Directive 1995/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (European Data Protection Directive).

anonymisation is even obtainable, given the possibility of genetic analysis, is also open to question. There is however a point of convergence in the definition of "anonymity" by the Council of Europe, which distinguishes between identifiable and non-identifiable materials and so avoids looming misconceptions of "anonymity" in the context of biobanking.[8] In several countries, such as France and Greece, there is a trend toward excluding anonymised samples and data (i.e. materials that are not easily re-traceable) from the measures for protection of sensitive data. Given that re-identification is indispensable for many research projects, the coding of samples is often regarded sufficient as a means of protection of privacy and personality rights. Although some minimum requirements for a European-wide regulation are already shared amongst the Member States, a number of ethical, legal and technical issues remain for future discussion.

3.4 Biobanking

In the context of human tissue research, the banking of samples is of increasing importance. Many countries, including the UK, Sweden and Estonia, have established national biobanks, but the number of local and small-scale biobanks is also increasing. Although the significance of biobank research is widely acknowledged, the regulation of it varies across the Member States. While some countries, such as Sweden and Spain, have enacted discrete laws on biobanking, others address it in a wider legal framework comprising research on human tissue (the UK, for example) or research with humans in general (for exampled the Swiss draft *Humanforschungsgesetz*). Biobanking may alternatively be subject to general provisions on public health or biomedical research (France and Portugal, for example). Other countries have established ethical guidelines for the operation of national biobank projects (e.g. UK Biobank and the Estonian Genome Project). Finally, in the absence of particular regulations, some countries derive their rules from European guidelines and statutes. Despite this regulative diversity, however, some common standards can be observed. For example, participants in biobank research have a right to be informed about the use of their samples and data. Furthermore, the consent of the donor is obligatory in most countries, though requirements might vary as to the extent (blanket, broad or specific) of the consent. The same is true for the donors' right to withdraw from participation. The disclosure of incidental research findings alongside a "right not to know" is also increasingly recognised (e.g. Spain, Portugal and the Baltic States). Given the donors' inevitable contribution to biobank research, there should be disclosure of research results and the establishment of benefit-sharing practices, which are also important means of engendering trust and thus assuring high rates of participation in biobank research.

In a nutshell, given that the value of human tissue and biobank research increases as more repositories are linked and samples and data are transferred across country borders, some harmonisation of rules is indispensable. The Tiss.EU project also revealed, however, that neither a "one-size-fits-all" approach nor harmonisation in all fields is necessary. Although initiatives for a pan-European framework on biobanking (e.g. BBMRI) are an important step forward, further analysis and an enduring

[8] Rec 2006(4), art.3.

European-wide exchange in this field are needed. The established Tiss.EU expert network provides a valuable platform for both.