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² The home page of the website should contain the generic European flag and the FP7 logo which are available in electronic format at the Europa website (logo of the European flag: http://europa.eu/abc/symbols/emblem/index_en.htm; logo of the 7th FP: http://ec.europa.eu/research/fp7/index_en.cfm?pg=logos). The area of activity of the project should also be mentioned.
4.1 Final publishable summary report

Executive summary

The Tiss.EU project analysed the impact of current EU legislation and guidelines on biomedical research which is based on the procurement, storage and transfer of human tissues and cells in and across the European Union. The project evaluated the consequences of current EU legislation and related guidelines, as well as the way they are implemented at a national level, on translational research activities. It identified regulation deficits and inconsistencies, and created an evidence base for the revision of legislation, where necessary.

In the three years of its duration, the project hosted nine international workshops and three International Status Conferences that gathered information on the ethical and legal regulation of human tissue research and biobanking in the 27 Member States plus Switzerland. The results of these events have been published in form of country reports at the project’s website which is freely available to interested scientists as well as the wider public. The reports will also be released in print. In the course of the project an on-line database has been established that entails legal documents, ethical guidelines as well as scientific articles on human tissue and biobank research. In addition, during the project a network of experts has been established that provides a platform for further discussions and expertise in this particular field.

Besides the country reports, the Tiss.EU project dealt more particularly with four Focal Themes relevant to this field: (A) Procurement, storage and transfer of tissues and cells for non-clinical research purposes, (B) Rights, interests and entitlements, (C) Anonymization and Pseudonymization as means of privacy protection, (D) Biobanks. Although these fields are regulated rather heterogeneously across the EU Member States, several convergences can be observed. In particular, there is evidence that existing EU Directives, e.g. Data Protection Directive 1995/46/EC or the Human Tissue Directive 2004/23/EC have a considerable impact on the national level. This is also true for the Council of Europe’s Recommendation 2006(4) on research on biological materials of human origin. For example, its distinction between identifiable and non-identifiable materials tends to hold sway in several countries’ legislations or guidelines.

The information gathered at the workshops and conferences have been integrated into a final recommendation document dealing with the most important issues from the four Focal Themes as well as related topics. The recommendation document addresses not only scientists in this field, but is also meant for policy makers at the national or European level. For reaching a wider audience the document is foreseen to be published in an internationally renowned journal in the near future. From a general point of view it can be concluded that the ethical and legal regulation of human tissue and biobank research is far from being subject to a cross-national homogeneous approach. However, our analyses revealed considerable convergences in several fields which might also be explained by the impact of existing EU documents pertinent to this field.
Summary description of project context and objectives

The Tiss.EU project analysed the impact of current EU legislation and guidelines on biomedical research which is based on the procurement, storage and transfer of human tissues and cells in and across the European Union. National differences in the regulation of the handling of these tissues and cells, however, represent a serious barrier for biomedical research in the Member States and associated countries. EU legislation has dealt with these topics but covers mainly clinical application. An EU biobanking Directive is still missing which might pose an obstacle to translational research involving human samples. The project evaluated the consequences of current EU legislation and related guidelines, as well as the way they are implemented at a national level, on translational research activities. It identified regulation deficits and inconsistencies, and created an evidence base for the revision of legislation, where necessary.

Activities and results of the whole project period (April 2008 – March 2011)

The Tiss.EU consortium started its work in April 2008. A first important step was made by the launch of the Tiss.EU website still the same month (www.tisseu.org). The website works as an information portal and a starting point for research on the topic of human tissue research. Accordingly, all partners received a partner-login that also allows for internal exchange and communication. In addition, the website makes all events within the project and its related topics visible to both, partners and other potentially interested researchers.

In the course of the 36 months of the Tiss.EU project three very successful International Status Conferences were held in Göttingen. Whilst for the launch conference a broad topical frame was chosen by inviting contributions on “Ethical and Legal Aspects of Research with Human Tissue in Europe”, the second Status Conference focused on the more specific issue of “Privacy, Confidentiality and Personality Rights in Biobanking and Genetic Research with Human Tissue”, whilst the Final International Conference on “The Future of Biobanking in Europe: Searching for answers to the Ethical and Legal Challenges of Human Tissue Research” aimed at drawing conclusions from the three years of work. The first conference was especially important to forge links with experts in the field of human tissue research all-over Europe. These contacts were strengthened and extended at the Second and Third Status Conference as well as the nine international workshops accomplished within the course of 36 months.

In line with the programme of work, between April 2008 and March 2011 nine international workshops in Hannover, Budapest, Paris, Padova, Leiden, Stockholm, Dublin, Birmingham and Vilnius have been accomplished in order to examine the regulations on human tissue research in the different countries. Due to the workshops’ focus on specific country groups information on all 27 European Member States plus Switzerland have been gathered (see reports at the Tiss.EU website).

The compilation of country reports was accompanied by the establishment of a project-tailored database that includes central normative documents as well as soft law regulating human tissue research in the European countries. The database is available free-of-charge to the scientific community and the general public and will be maintained beyond the project’s duration. For the systematization of entries, a differentiation between normative and non-normative documents was chosen. As a result of two training sessions at the workshops in Budapest and Paris, all beneficiaries are familiar with the database’s structure and
functioning. Until the end of the project the database lists about 700 documents for the regulation of human tissue research in all 27 EU Member States plus Switzerland. The database is available at the project’s website.

Whilst the database gathers all different kinds of documents relevant to the field of human tissue research, in addition, the most important legal documents from an international point of view are compiled at the Tiss.EU website for download. The provision of these documents can be explained by the fact that in the absence of any particular human tissue research regulation many countries, especially from the Eastern European area, derive legal guidance from international statutory in this field.

From the very beginning of the Tiss.EU project the establishing of a European-wide network of experts in the field of human tissue research was started. In particular, all speakers at workshops and conferences have been invited to join the network by indicating their fields of expertise and disciplinary background alongside with their contact data. At the end of the project, more than 150 scientists have entered the network which provides a valuable platform for further exchange on the project’s topics. The network can be accessed via the project’s website. In addition, the Tiss.EU project established contacts with other EU-funded projects dealing with human tissue research and/or biobanking. This contact was strengthened by the coordinator’s participation in a network meeting held in Brussels, November 2008. Since it is the Tiss.EU project’s aim to collect ethical and legal guidelines that regulate human tissue research, the representatives of different biobanking projects have been asked to submit information on their respective regulative frameworks to the coordinator of the Tiss.EU project.

The cooperation with other biobanking projects was deepened at the Second International Status Conference of the Tiss.EU project which was organized with inputs from the EU-funded projects GeneBanC and PRIVILEGE; vice versa, a representative from the Tiss.EU project participated in the final conference of the GeneBanC project in Leuven, May 2009. For the organization of the Final Conference the project benefited from already established contacts, but did also establish new ones, especially to clinicians and operators of biobanks.

In the course of the Tiss.EU project several initiatives for the dissemination of scientific results have been undertaken by the partners. Besides individual publications in the national and international context (a detailed list is provided in section 4.2 of this report as well as in the two periodic reports of the Tiss.EU project), also several joint publications have been produced. As a result of the First International Status Conference a book on “Human Tissue Research - A discussion of the Ethical and Legal Challenges from a European Perspective” was published at Oxford University Press in the beginning of 2011. In addition, a book on “Biobanks and Tissue Research: The Public, the Patient and the Regulation” is forthcoming in August 2011 at Springer publishing house. The reader entails articles by all partners of the project plus some additional experts in the field of human tissue research. In addition, a symposium comprising articles on the Focal Themes of the project is foreseen to be published in the Journal of Medical Ethics. To this purpose the respective two or three partners who work on the same focal theme have submitted a joint article that is currently under review. Finally, a reader including all project reports in an updated and edited version will be forthcoming in 2011 at Goettingen University Press.
The following section lists the most important objectives of the project according to Annex I and accounts for their realization:

1) **Firstly**, it is the major goal of the Tiss.EU project to carry out high-quality, interdisciplinary analysis on European health policy to assess the impact of EU legislation and normative documents on research which is based on the procurement, storage and transfer of human tissues and cells. (Month 36)

   For the realization of this goal, nine international workshops and three International Status Conferences were held in the course of the three years of the Tiss.EU project’s duration. At these meetings experts from the field of human tissue and biobank research provided for an analysis of current national and European regulations of human tissue research. In this vein, important information for the final evaluation how these existing regulations impact on research were be obtained.

2) **Secondly**, the Tiss.EU project aims to create a web-based comprehensive information source which facilitates progress in relation to the debate on the treatment of human tissues and cells and to foster the provision of easy, comparative access to the data gathered. (Month 36)

   After the database has been established in the first period of the project all partners continuously entered bibliographical data of documents and articles on human tissue and biobank research regulation in their respective countries. The database is available at the project’s website and will be maintained for the scientific community also in future.

3) **Thirdly**, in the course of the Tiss.EU project an information exchange network will be set up which connects ethicists, lawyers, patient representatives, physicians, policy makers, non-governmental institutions, scientists and institutions for the procurement and storage of human tissues and cells. (Month 36)

   A network of experts in the field of human tissue research was set up from the very beginning of the project. Speakers at conferences and workshops were asked to join the network and to allow for the publication of their contact data at the Tiss.EU project’s website. At the end of the project about 150 scientists from all European Member States plus Switzerland have joined the network.

4) **Fourthly**, the Tiss.EU project wants to provide for an overview of international conventions, primary and secondary legislation, case law, professional codes of conduct, ethical guidelines, case reports, consultation documents and academic literature relevant in the EU member states. (Month 36)

   For the achievement of this goal the database was continuously updated. In addition, an up-to-date compilation of international documents dealing with human tissue research is available for download at the Tiss.EU project’s website.

5) **As a fifth** goal, the Tiss.EU project aims to assess the ethical and legal situation across the European Union in the four focal themes: (A) the procurement, storage and transfer of tissues and cells for non-clinical research purposes (Month 18, 26, 30), (B) rights, interests and entitlements involved (Month 9, 21), (C) anonymization and pseudonymization as means of privacy protection (Month 12, 24), and (D)
biobanking (Month 15, 27) under special consideration of diverging ethical and legal traditions in different countries, especially the accession countries.

In the course of the project period, nine workshops on each of the named Focal Themes took place. The results are made available by reports at the project’s website. In addition, the partners authored several publications on issues related to the focal themes. Besides individual articles and books, the consortium worked also on several joint publications. Whilst the reader is already published, another reader as well as a journal symposium and a book including all reports of the project will be forthcoming.

6) Finally, the Tiss.EU project aims to develop a proposal for the harmonisation and convergence of the described areas in the EU and to provide information and recommendations for future EU policy decisions. (Month 36)

During the whole reporting period information for the final recommendation document have been gathered at workshops and conferences. On this basis, the partners agreed to release a joint final document on the most important ethical and legal issues in the field of human tissue and biobank research. Regarding the form of publication, the consortium will publish a joint article in an internationally renowned journal.

Description of the main S&T results/foregrounds

Due to the Tiss.EU project’s two-layer structure, conclusions can be derived from both, the analyses of the European Member States’ regulation on human tissue research and the more theoretical examination of the aforementioned four focal themes. Although these issues are far from consensual assessment, several convergences can be observed.

Results from Focal Theme (A): Procurement, storage and transfer of tissues and cells for non-clinical research purposes

The issues of this Focal Theme have been intensively discussed at the workshops in Padova, Dublin and Vilnius. The European Member States show different levels of development concerning the issues within this Focal theme and the related legislation. For example, the UK has a discrete Act on human tissue and other reference Acts on this issue, whereas countries like Malta or the Eastern European countries mainly refer to EU legislation for tackling this topic. From an ethical point of view, regarding the procurement and transfer of tissues and cells for non-clinical research purposes the autonomy of sample donors and protection of their privacy is crucial. However, discussions on the donors’ consent are predominantly focused on themes of procurement and use of biological material for research purposes whereas less attention is given to issues pertaining to storage and transfer. Furthermore, the type of consent (open, specific, broad) that is required for the procurement, storage and transfer of human tissues and cells is a matter of discussion. In particular, it has to be asked whether all three stages can be covered by the same type of consent or whether more specified procedures are inevitable. Given the peculiarities of human tissue and biobank
research, a trend towards less strict interpretations of informed consent is pertinent in this field. For example, some countries are about revising their requirements for specific informed consent (e.g. Sweden). Other countries like Estonia, Latvia or Switzerland switched over to broad or open consent that makes samples and data available for future research projects with only few restrictions. Another issue arises from secondary research purposes exceeding the donor’s original consent. Some countries allow for exemptions in this regard as well, for instance if the obtainment of secondary consent is too burdensome compared to the value and low risk of the research (e.g. Portugal, Spain) or if the research has been approved by a Research Ethics Committee (e.g. Denmark, Lithuania). In summary, harmonization in this fields appears extraordinarily difficult for the reason that regulations on the procurement, storage and transfer of human tissue are not only divergent between countries but differ even at the level of institutions. However, the existing commonalities might pave the way for an intensified exchange and adoption of existing national approaches and models. In this regard, several issues remain to be addressed in future:

- What kind of consent is appropriate regarding the procurement, storage and transfer of human tissues and cells?
- Under which conditions can the obtainment of secondary consent regarded as dispensable?
- Do donors always need to be granted a right of withdrawal?
- What is the role of RECs in this context? How can their power and remit be strengthened in favour of a stringent model of human tissue research regulation?

Results from Focal Theme (B): Rights, interests and entitlements in human tissues and cells

Human tissue research gives raise to several questions regarding the legal status of human bodily materials. The two workshops (in Hannover and Leiden) on this focal theme revealed that almost all European and national regulations perceive the human body as a res extra commercium. This position is backed by the European documents’ provision that the “human body and its parts shall not, as such, give rise to financial gain” (see e.g. Oviedo Convention or the CoE’s Recommendation 2006(4), art. 21). However, in view of the potential applications of human tissues the no-property principle is by no means self-evident. As separated body parts can be technically processed, they turn into tradable medical products. In Belgium human material after its removal even becomes a “good” with a price (Royal decree 14 October) which is owned by the not-for-profit bank for human material. Other countries (e.g. Germany, Switzerland) feature a de-facto property right as “the natural fruit of an object still belongs to the object after the separation from this object” (Bianca Dörr, Hannover Workshop). Thus, human tissue applications raise fundamental questions regarding the legal status of separates bodily materials. In particular, the following aspects call for clarification by a future European regulation:

- If separated human tissue is not the property of the donor, may researchers, institutions or biobanks rightfully claim a right of ownership on single samples or whole collections respectively?
• If, according to the Lockean theory of acquisition, the processing of human tissue may turn it into the property of the processor, the questions arises how much a material needs to be transformed for being regarded a product?

• Human tissue research also raises particular questions of justice: Whilst donors on the one hand have no rights in their samples and may not receive any financial rewards for their donation, researchers or research institutions on the other hand may derive profits from samples. Taking the different stakeholders (i.e. donors, researchers, companies) in the sphere of human tissue research into account, their interests need to be balanced by providing fair shares to all actors involved.

More generally speaking, a future European regulation on human tissue research needs to be clear on the question whether property is even the adequate framework for grasping the specific relationship between donors, separated bodily materials and researchers. As a matter of fact, more nuanced accounts, such as the bundle theory of rights have been proposed. Whilst property rights, according to this account, are perceived as “socially constructed bundles of separable social relations” (Björkmann 2007: 222), human biological materials should not be regulated across the board by the same category of rights; rather a more nuanced perception of bodily materials and respective rights of protection is pertinent. In addition, property issues might become displaced by more urgent questions regarding donors’ rights and entitlements, such as questions of control on samples and data, feedback of incidental health findings or benefit-sharing.

As regards the issue of feedback on health findings, several international documents foresee a right of the donor to decide whether he wants to be informed about potential health-relevant results (e.g. UNESCO International Declaration on Human Genetic Data, Art. 10)3. However, only few countries have made the provision of feedback obligatory (e.g. Baltic States, Belgium, Spain, Hungary, Luxembourg). Thereby the “right to know” is usually supplemented by a “right not to know”. In other Member States the provision of feedback on individual health findings is at least recommended by National Research Ethics Committee it (e.g. Germany, Austria, Switzerland, Slovenia). On the other side of the spectrum are those countries where the legislation remains silent on this issue (e.g. France, most of the Eastern European States). It is striking that the issue of feedback is mainly addressed by Member States featuring discrete human tissue and biobank research acts. In this context, the provision of feedback is regarded as a trust-building means between donors and researchers (e.g. Estonia). However, there are also countries where individual feedback is excluded (e.g. by UK Biobank). Given the importance of the donors’ contribution to biobank research it is quite likely that the issue of individual feedback on health findings will attract increasing attention in future regulations.

From a more general perspective it is obvious that the field of donors’ rights and entitlements features several gaps that create uncertainties not only for donors but also for the institutions that obtain and process human tissues. Uncertainties are particularly evident regarding the cross-border flow of samples.

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3 “When human genetic data, human proteomic data or biological samples are collected for medical and scientific research purposes, the information provided at the time of consent should indicate that the person concerned has the right to decide whether or not to be informed of the results. […]”
and where a non-diagnostic or non-therapeutic application of samples is foreseen. As the value of research biobanks increases the more samples and data can be used, a more harmonized approach towards these latter issues might be desirable.

Results on Focal Theme (C): Anonymization and pseudonymization as means of privacy protection

The analysis of this Focal Theme at the two international workshops in Budapest and Stockholm revealed a highly diversified landscape in terms of both, definitions of anonymization/pseudonymization and respective safeguards for the protection of donors’ privacy. This situation can also be explained by different national and legal traditions. For example, while the Scandinavian countries have a long history in keeping health records and computerised registers on personal information, Germany is rather reluctant towards comprehensive recording measures of individual data. Ambiguities are also looming in European documents. While the European Data Protection Directive (95/46/EC) stipulates several exemptions of privacy protection for the application of health data, it is not completely clear, how far these exemptions might also hold for research. Thus it may not come as a surprise that the Member States differ in whether human tissue samples fall under the definition of data that is provided in the laws implementing the European Data Protection Directive.

Beyond this widely acknowledged terminological and legal heterogeneity in this field, however, it should not be overlooked that the Council of Europe’s Recommendation (2006(4), art.3) has provided for an appealing definition in this matter. By distinguishing between identifiable and non-identifiable materials it avoids looming misconceptions of “anonymity” in the context of human tissue biobanking. While identifiable materials can either be coded, which implies that the code is accessible; the CoE speaks of “linked anonymised materials” if researchers cannot access the code which is under the control of a third party. By defining non-identifiable materials as “unlinked anonymised materials” that “do not allow, with reasonable efforts, the identification of the person concerned,” the CoE accounts for the impracticality of complete anonymisation in the era of genetic research. As a matter of fact, the CoE’s definition is mirrored in several national legislations. Although the need for the protection of the donors’ privacy is widely acknowledged in the European Member States, it is contested whether anonymization is even obtainable, given the possibility of genetic analysis. Moreover, from the researchers’ perspective complete anonymization is not even desirable, given that the value of biobank research increases with the possibility of linking different repositories across national borders. Consequently, in the majority of Member States coding is the preferred means for protecting privacy and personality rights. However, as from the donor’s perspective de-identification might not be a sufficient means, different options for withdrawal, including the destruction of samples, should be offered.

4For example, the processing of personal data is not prohibited “where processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy” (art. 8.3).
Given the complexity of the issues pertaining to Focal Theme C, it is not surprising that several open questions remain. For just mentioning one point of contention: there is an intensive debate whether it should be allowed to use biobank samples for police investigation or make them available to other state authorities. While at the current stage there are rather few possibilities of using biobank materials for prosecution, some incidents (in Sweden, UK) show that it is at least not excluded that state authorities want to access biobank samples.

In the remaining part, some emerging convergences regarding the issues of anonymisation and pseudonymisation as means of privacy protection will be outlined. For example, most countries of Eastern Europe refer to the Oviedo Convention that seems to be more influential than in other Member States. Secondly, there is a tendency to except anonymised samples and data (i.e. materials that cannot easily be traced back to the source’s identity) from the safeguards that are otherwise applied to sensitive data. For example, a waiver of consent is acceptable provided that research is carried out on anonymised samples (e.g. in Sweden, France, Greece, Spain, Finland, The Netherlands, Ireland, Lithuania, Italy). Thirdly, as regards the processing of coded samples, the separate storage of data and the key code displays the default in the majority of Member States. Moreover, for the transfer of data and samples it is mostly required that the receiving institution or, the receiving country respectively, adhere to the domestic rules of the sender country. In summary, whilst some minimum requirements for a European-wide regulation on this issue already evolved, a number of ethical, legal, technical issues stand out for future clarification.

**Results from Focal Theme (D): Biobanking**

The issues of this Focal Theme were particularly discussed at the two international workshops in Paris and Birmingham. In the context of human tissue research biobanking is of increasing importance. Whilst repositories of biological material have a long-standing tradition in the clinical context with regard to therapeutical application, the progress in genomics and information technologies renders biobanking all the more important for research. Many countries in the European Union, for example UK, Sweden or Estonia, have established population-based sample- and data collections for the examination of widespread diseases. Since biobanks allow for long-time and follow-up studies of mostly healthy people, they may provide for a better understanding regarding the interaction between environmental and genetic factors in the causation of diseases.

Although the importance of biobank-related research is widely acknowledged, the regulations of biobanking vary across the European Member States. So far four general regulative models can be distinguished. Firstly, some countries, such as Sweden or Spain have enacted particular Acts on biobanking. Secondly, there are states that adopted a somewhat wider framework encompassing human tissue research or research with humans in general. Whilst the former is true for the UK, the latter option refers to Switzerland that is about adopting the Act on research in human beings (Humanforschungsgesetz). As another option that falls within the same category, biobank-related research is sometimes regulated by more general provisions on public health or biomedical research. An example of this can be found in Portugal which relies on the Personal Genetic and Health Information Act (2005). Besides the enactment of
specific laws on biobanking or more generally on human (tissue) research and public health matters, some countries established ethical frameworks for the operation of particular large-scale population biobank projects. This is true for the UK (UK Biobank) or Estonia (Estonian Genome Project, EGP). However, these frameworks do not cover any other types of biobanks which might be a problem if other biobanking activities remain unregulated then. For example in the Baltic States, in cases where research “does not fall within the remit of the national genome projects, there is either a lack of regulations or regulations are not sufficiently specific in relation to different types of biomedical research” (see Workshop Report Vilnius, p.7). Finally, in the absence of any regulation, neither on biobanking nor human tissue research, some countries derive their rules for research in human tissues from general European guidelines and statutes, such as the European Bioethics Convention (Oviedo Convention).

Beyond this regulative diversity on biobanking, some common standards paving the way towards a future harmonization can be observed. In particular, there is a wide ranging consensus that the donor’s consent – although to a different extent (blanket, broad or specific) - is indispensable. Thereby a tendency towards a broader consent can be observed. In addition, the donors’ right to withdraw from participation is another common feature that is granted by the current guidelines/legislations on biobanking in the European arena.

While thinking about the ethical and legal regulation of biobanks, the shaping of the relation between the biobank and the participants as well as the public in genera should be seen as pivotal. Thereby neither “an exclusive appeal either to individual rights or to public goods will not do all the work in deciding how to regulate biobanks” (see Workshop Report Birmingham, p.14), but rather a context-sensitive and balanced approach is needed. For example, in some contexts it might be justifiable to waive the donor’s right of withdrawal if this might compromise otherwise beneficial research. Similarly, the purpose and aims of biobanks have to be taken into account for deciding on an appropriate normative framework. For example, while disease-based repositories are a rather common phenomenon in medical research, the establishment of population-based genetic databases which include the samples of mainly healthy volunteers raises new questions that might require a new approach.

It has to be noted that the field of biobank research features overlaps with the three aforementioned issues. Since biobanks have to provide rules on the obtainment, storage and processing of human tissue samples as well as on donors’ rights of control and privacy, for a further investigation of the legal landscape in this field, the following aspects may serve as guiding questions:

- What is the scope of the respective regulation on human tissue biobanking?
- What are the requirements for the establishment of a biobank (licensing, acknowledgement by a REC or other national authority)?
- Which type of consent is required in the respective legislation (specific, broad, open)?
• Are there any provisions for secondary use of samples and is there an obligation to re-contact donors in this case?5

• What are the provisions for removal of material from deceased?

• Does the respective framework entail any rules for the provision of benefit sharing or feedback of health-relevant information to donors?

• How is the privacy of the participants in biobank research secured by the respective regulation?

By looking at the findings of the four Focal Themes from a more general perspective, it becomes clear that an outright harmonization of human tissue research will neither be attained nor desirable. Besides the countries’ specific legal and ethical traditions that are likely to abide, there is also a legitimate concern of overregulation that might be an impediment to research. In addition, given the complexity of human tissue and biobank research, any future regulation needs to be context-sensitive, by not only taking the peculiarities of different human tissue applications but also the divergent stakeholder interests into account. Just to give an example: regarding the feedback of health-relevant information to individual donors, one could think of a nuanced step model of disclosure as it has been suggested by Annelien Bredenoord at the Final Tiss.EU Conference in Goettingen (see Final Status Conference Report).

Despite persisting differences in the field of human tissue and biobank research, considerable convergences in the existing regulations and approaches have emerged. This might firstly be explained by the impact of European documents (e.g. particularly in the Eastern European States). Secondly, a cross-national learning process is ongoing. For example, countries that enacted human tissue and biobank research laws more recently have adopted features of already existing frameworks. A third reason for the harmonization in this field is intrinsic to human tissue and biobank research as its value increases if samples can be consolidated with other collections and even transferred abroad. For this being possible, almost all European Member States insist on protection measures that match their domestic provisions of sample and data protection. In the long run, this might lead to additional adjustments - not only amongst country groups, but even across the 27 members of the European Union, plus Switzerland.

The research results carried out by the ten partners in the Tiss.EU project have led to several publications, ranging from reports, over journal articles to books and book editions. All publications are listed in detail in Template A1 below. In addition, the project’s website makes the reports of all project events available to the public. Furthermore all reports of the Tiss.EU project will be published as project proceedings at Goettingen University publishing house in 2011. Finally, the established database is available to all interested scientist but also to policy and law makers for searching relevant documents and scientific literature on respective topics.

5 Whilst the Oviedo Convention requires the informed consent of the donor if the removed material is “stored and used for a purpose other than that for which it was removed” (art. 22), the Council of Europe’s Recommendation 2006(4) does allow for a waiver of secondary consent provided certain conditions are met (cf. art. 22).
Socio-economic impact and the wider societal implications of the project & main dissemination activities and exploitation of results

The accumulation of a large amount of comparable data on the current state of play in all 27 Member States (plus Switzerland) permits the scientific and academic community as well as the policymakers to find common ground and gather an overview of the different attempts at solving the dilemma of procuring, storing and transfer of tissue and cells, particularly for biomedical research in the European Union. The analyses of the deficiencies of current European regulations and the comparison of different legal and ethical approaches to the human body in national jurisdiction paves the way to finding common ground in this field across the European Member States. In addition, by collecting and classifying information in relation to the legal and ethical framework within which normative approaches and academic and scientific debate are carried out, the Tiss.EU project also created a dynamically grown database of material and information, which permits a cross-jurisdictional inquiry that gives researchers a firm footing when addressing questions of entitlements.

Due to the involvement and the contact of the project members with a number of national, European and international regulatory and policy-making bodies, these connections support the impact of the project’s findings and will facilitate a purposeful communication of results and recommendations to the relevant administrative and political institutions. The established network of experts regarding ethical and legal issues of human tissue and biobank research provides an important platform for further discussions and expertise in this field. A specific initiative, as a direct result of the TISS.EU project, is the creating of a task force in Padova to analyse the issues of biobanks for research and elaborate ethical guidelines for the legal and ethical issues concerning the biobanking in Padova, inside the Italian and European perspectives.

Additionally, the project website, which entails the results of the country workshops and status conferences, facilitates a broad impact and publicity in the academic community, but also amongst patient groups (which are committed to research projects that include biobanking), policy makers, non-governmental organisations and the general public. As the workshops were open to the academic community and the general public, the visitors of the workshops had the opportunity to be informed about the relevant legislation and ethical guidelines in the field, not only in their part of Europe but with a broader European perspective. The findings of the nine international workshops and three Status Conferences are also communicated via the project website which will be maintained beyond the project’s duration.

At the end of the project exists a number of printed dissemination materials, like posters, flyers and press releases. In the course of the Tiss.EU project one PhD project has been accomplished at the partner institution in Paris in the field of legal science and another project of a PhD student at the Medical University Centre in Goettingen dealing with the issue of feedback on health-relevant information to participants in biobank research is ongoing. In addition, the project has been presented in a range of journals, for example in Germany, UK and Italy. Moreover, the partners of the project have published about 100 articles and 10 books in relation to the project’s topic. Of particular interest is a paper series edited by the Central European University in Budapest which provides an overview to the legal regulation of biobanking in 15 European Member States. In addition, the partner in Padova, Fondazione Lanza, is publishing the proceedings of the workshop in Padova.
As regards joint publications, selected contributions from the first Status Conference have been published as an edited collection at Oxford University Press at the beginning of 2011: “Human Tissue Research – A discussion of the Ethical and Legal Challenges from a European Perspective”. Another manuscript on “Biobanks and Tissue Research: The Public, the Patient and the Regulation” is about being published at Springer publishing house. A third joint publication of the project consortium consists of four articles that were submitted for a journal symposium to the *Journal of Medical Ethics* at the end of 2010. At the current stage the articles have been reviewed and after minor revisions are about being resubmitted. Finally, all reports of the Tiss.EU project will be published as proceedings at the Goettingen University publishing house still in 2011.

The discussion and the results of the status conferences will be of great interest for the European discussion and efforts for a convergence or even harmonisation of rule sets in relation to the procurement, storage and transfer of human tissues and cells. Selected results of the workshops and Status Conferences provide the basis for the compilation of the recommendations document at the end of the project. It is foreseen to be published in an internationally renowned journal in the near future. In addition, Christian Lenk participated in two expertises on human tissue and biobank research - one for the UK Medical Research Council, one for the German national biobanks initiative which is available in Germany. If the EU is preparing policy documents or normative instruments dealing with the procurement, storage and transfer of human tissues and cells, information on these issues could be provided by the Tiss.EU project.

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[http://www.tisseu.org](http://www.tisseu.org)
4.2 Use and dissemination of foreground

Section A (public)

This section includes two templates

- Template A1: List of all scientific (peer reviewed) publications relating to the foreground of the project.

For this section, please see the uploaded version of the Final Report via SESAM.

Section B (Confidential or public: confidential information to be marked clearly)

Part B1

Not applicable to Tiss.EU project

Part B2

Not applicable to Tiss.EU project

4.3 Report on societal implications

For this section, please see the uploaded version of the Final Report via SESAM.