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Project acronym **PRIVILEGED**

Project title

**Determining the Ethical and Legal Interests in Privacy and Data Protection for  
Research Involving the Use of Genetic Databases and Bio-banks**

Co-ordinating Action

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## **PROJECT RECOMMENDATIONS**

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## **Executive Summary**

### **Background**

Medical research using genetic information and biobanking offers extraordinary opportunities for the prevention, diagnosis, and treatment of disease. Equally, achieving these social and individual benefits carries risks to individuals' fundamental rights and freedoms, especially their privacy. Unless the research is undertaken in a robustly regulated manner, ensuring transparency and the appropriate safeguarding of rights, there is a risk to individuals and to public trust and confidence in medical research. For Member States, the existing regulations covering this area are contained in a wide range of instruments, in particular the European human rights legislation, in the Data Protection Directive (95/46/EC), in the Clinical Trials Directive (2000/20/EC), in the Helsinki Declaration, and in national legislation relating to medical research, the use of human tissue, and to biobanking. The legislation already seeks to hold in balance two expectations: the autonomy of the individual, and the public interest. Thus, in much of the legislation, but in particular in the data protection Directive, there are two themes at work: self protection by the individual data subject; and, creating duties upon those who process data to safeguard the interests of the individual (duties that are in balance with broader choices in the public interest, and involve regulatory authorities in determining boundaries of individuality).

Whereas medical research has been regulated for many years, and a coherent legal and ethical set of norms have emerged that would suggest that the regulation of this new technological development and biological understanding would produce relatively few novel dilemmas, medical research using genetic information and biobanking places the group or shared nature of medical information about individuals at the heart of the governance debate. The shared or group nature of genetic information means that the harms that concern an individual are also concerns for others who share significant genetic similarity. Those individuals may

react to the risk of those harms in different ways. Further, the identification of those who share significant genetic similarity is equally uncertain. The shared or group nature of this data challenges many of the basic starting points in medical ethics and law; concepts of privacy, property, and, fundamentally, autonomy and freedom, are reopened by this development. PRIVILEGED seeks to identify regulatory choices that can be made to produce more effective protection of fundamental rights and freedoms of all the parties involved.

**The PRIVILEGED project** was funded under by Science in Society in FP6<sup>1</sup>. It was a co-ordinating action<sup>2</sup> bringing together academic lawyers, ethicists, sociologists, medics and biomedical scientists from the Member States, Norway, Iceland, Israel, Japan and Taiwan. The project had three stages:

1. A literature review of the understanding of biobanking and genetic information, and of privacy in the different countries, particularly examining the available literature indicating the public opinions held about privacy interests in genetic information used in medical research and in biobanking;
2. An examination of the existing law in place at the European and national levels, particularly data protection law, to ask how privacy interests are protected, and to assess how far that protection accorded with the findings of stage one; and,
3. An identification and consideration of particularly difficult areas in the law (the areas identified were the access to data by relatives, and access to the data by other third parties particularly considering issues of property in the data, issues of

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<sup>1</sup> Project number 36775 (Co-ordinating Action under FP6-2005-Science and Society-14): *Determining the Ethical and Legal Interests in Privacy and Data Protection for Research Involving the use of Genetic Databases and Bio-banks: PRIVILEGED*. <http://www.privilegedproject.eu/> (last accessed 23 July 2010).

<sup>2</sup> A 'Co-ordination Action' is an EC Research Framework instrument designed to bring a consortium of experts in a particular field together to develop their existing ideas. It does not fund new, empirical research, rather it provides a forum for developing new ideas from collective discussion of existing work and perspectives.

consent, the operation of the research exemption, and the relationship between the sample and data contained in the sample) and the presentation of recommendations for regulation in the area.

## **PRIVILEGED RECOMMENDATIONS**

In pursuing these three elements of the project, we have found that:

- a. The existing legislation was created to cover a number of applications other than medical research using genetic information and biobanking (and this is particularly the case in relation to data protection);
- b. The approach adopted is broadly focused around an individual-centric model (but not consistently so);
- c. A number of different expectations and sensitivities are shown by citizens when they discuss their expectations about medical research using genetic information and biobanking;
- d. Public trust and confidence is of vital importance in the effective development of this area of medical research, and a single concept approach, or a predominantly single concept approach, does not foster wide and effective inclusion of those who take different positions in relation to privacy (especially different but still mainstream positions);
- e. There is discretion, particularly in relation to the research exemption in 95/46/EC, allowing different positions between Member States on the basis that the particular change from the individual norm are allowable because they are made with 'sufficient' or 'appropriate' safeguards in national legislation.

## **Recommendations**

1. The laws regulating the use of genetic information and biobanks in relation to medical research, particularly the laws regulating the protection of personal data, contain sufficient discretion and are sufficiently open textured, to allow for a number of routes to be constructed through them by Member States. The number of possible routes could accommodate the majority of the range of privacy expectations expressed as interests in the theory of privacy and in the available attitude surveys. From this:

Individual Member States may find a specific law on medical research or on biobanking necessary to connect generally expressed legal principles with the practical issues of research and biobanking, but the regulation of privacy in medical research using genetic information and biobanking should resonate with the general principles of privacy, and should sit within the general privacy canon. Further, it is not desirable to open the data protection directive to redraft it and its principles; rather the existing law should be interpreted to accommodate the challenges of clarifying the use of genetic information and biobanking through the existing discretion available to Member States; and,

It is clear that there are a number of pathways available for the interpretation of the available discretion. There is no obvious or right choice of pathway. Rather, the choice is a matter of political will and negotiation at a governmental level. Any number of choices can be devised, the responsibility of making the choice is one for the democratic process.

The understanding of the data protection directive in relation to the following require specific attention:

## ***Information Provision and Informed Consent***

2. We recommend that it be made clear that the requirement for 'specific', 'unambiguous' and 'explicit' consent does not preclude the possibility of legitimately seeking the kinds of broad consent that are associated with biobank research ie. consent for types of research use e.g. medical research supported by a Research Ethics Committee, rather than for specific individual research projects.
3. We recommend that, if the ambition is to regulate access to a biobank resource consistent with the public interest, access to biobanks should not be *exclusively* determined by the terms of a 'broad consent' without accompanying safeguards sufficient to protect the individual.
4. We recommend that it be made clear that the obligation to provide information is on-going and further relevant information should be made available to research participants as this becomes practicable. Later availability of more detailed relevant information should not, however, undermine the validity of a consent previously given (so long as that information is not inconsistent with that which was provided at the time consent was obtained). Facilitating practicable access to current, and more detailed, information should, however, enable a research participant to exercise any valid right to withdraw ongoing consent.
5. We recommend that the advantages of introducing a requirement to make information available to groups beyond individual data subjects (e.g. in relation to information capable of affecting groups) should be considered. There appears to be no current responsibility within European law for communication with a potentially affected group for the purposes of (even) informed decision-making by data controllers. It might, however, be more consistent with the existing data protection regime to understand such a requirement as independent of any

requirement to obtain consent rather than as being fundamental to any notion of group consent.

***Research, Access and Best Interests: identifying the limits in the name of privacy protection***

6. We recommend that access to biobanks should be supplementally regulated by concerns motivated by the long term public interest in the research. Independent expert review of access decisions may be an effective way to support this ambition. Public consultation, and transparency, are also likely to be important means of ensuring, so far as possible, that decisions on access maintain public trust.

***Genetic Data and Family Members***

7. We do not recommend adopting a 'result' orientated approach to determining who is a 'data subject' for the purposes of the data protection directive (95/46/EC) or bringing relatives within the scope of data subject in particular.

8. We recommend that solutions outside of data protection law be explored that enable the proband's relatives to benefit (if possible) from genetic testing performed within the respective family group. Model solutions already exist within national laws (for example in Hungary) and agreement over terms should be pursued in order that the conditions may be made transparent as soon as possible.

***Research Exemption***

9. We recommend that the *Research Exemption* be termed the *Parallel Research Track* and suitably encouraged as a positive, equal route for Member States to construct using similar approaches to the safeguards.

10. We recommend that Article 6(1)(b) should be read broadly, resolving the difficulties of interpretation in Article 10, and allowing for a change in purpose for processing if the new purpose is compatible with the original, notified purpose.

11. We recommend that the broad consent with the safeguards of robust prior checking by a data protection authority based on proportionality of risk, data security measures, and an opt-out register offers a more proportional regime to balance the community of rights in biobanking.

12. We further recommend that much greater energy should be put into public participation in the planning and execution of research.

### ***Regulating Research Using Samples: Clinical Samples or Data Protection***

We find that neither the data protection regime nor the clinical trial model provide a complete and appropriate legal framework for regulating biobanks involved in tissue research. Even if the two models are combined, this would not result in sufficient regulation taking into account the specific features of tissue research, and do not recommend such an approach.

We find that both of these relatively well developed regimes that regulate medical research across the EU i.e the data protection model and the clinical trial model have elements that are very relevant to the collection and use of tissue for research purposes and that can be instrumental to achieve the required protection.

We find that despite the utility of these existing systems the differences between tissue and data and between clinical trials and database research means that even if the two models were to be combined, this would not result in sufficient regulation taking into account the specific features of tissue research using biobanks.

13. We recommend additional and more specific protection, particularly that national law-makers should have the necessary discretion to decide how best to realise this but we prefer that approach that elaborates a comprehensive regime for tissue research (a 'third' model) that takes specific account of six elements:

- that physical interventions are typically needed to procure human tissue and should be subject to safeguards comparable to the ones laid down in legislation concerning research with human subjects (including written informed consent and ethical review);
- even if tissue is already available (e.g. surplus to treatment) and there is no bodily interference in obtaining it, informed consent is warranted;
- the information provided (to inform consent) should depend on the context, but should include: possible inconveniences linked to the removal of the sample; technical information on the biobank and how it operates; foreseeable uses of the tissue; and the location of analysis, storage or archival of the tissue. Research participants should express an opinion on whether they wish to receive any information (including any that is obtained incidentally) that is relevant to their present or future health. This choice should be accompanied by information on the potential consequences of the decision for the private and family life of the individual;
- Consent to research use of tissue is not sufficient to protect individual interests. The initial, and often necessarily broad, consent of research subject should be supplemented by additional ethical review of both biobanks themselves and specific research projects that include analysis of tissues, with a special view towards protecting participants from 'informational harm';

- Issues of ownership should be put beyond doubt. Legislators should clarify how these ownership rights are limited to adjust for the legitimate interests of participants, or qualified by rights developed to protect them.
- The law should ensure that in the case of competing claims on scarce tissue, biological samples that have been stored for research purposes can, as far as reasonably possible, be reclaimed by research participants if necessary for their own diagnosis or treatment (unless patients have explicitly waived their right to re-use the tissue for their own medical treatment).

### *Anonymisation*

14. Anonymisation is seen as a major safeguard in medical research. However, in medical research using biobanking and genetic information, the great value in the information comes from linking the information to patient histories and updating those histories over time. Thus, data in the hands of the biobank is unlikely to be deidentified. It is likely that a safeguard for the donor will be that the data transferred to individual researchers will be de-identified. The data is gathered as personal data, and remains personal data in the hands of the biobank. We recommend that Member States make it clear in national law that anonymisation, the de-identification of data, is a processing of data under the Directive.

## **IMPACT OF THE PRIVILEGED PROJECT**

The PRIVILEGED project concerned the ethical and legal governance of Medical Research using Genetic Information and Biobanking, and in particular, the effectiveness of that governance in protecting rights to privacy especially as it is protected through data protection legislation.

The major impact of the project has been in informing the governance debate, bringing information and critical analysis in three major areas of major concern to governance:

1. The understanding of privacy in relation to biobanking, particularly including the concerns expressed by citizens in various studies published in the literature;
2. A country by country analysis of the relevant laws in relation to European requirements;
3. The identification and critical discussion of major unresolved issues in the current legal regime, with suggestions for solutions.

The PRIVILEGED project, as a Co-ordination Action gathered together existing information. Its original contributions were through novel analysis and consideration of inter-disciplinary materials, in undertaking a thorough and detailed analysis of the existing domestic regulation of medical research using genetic information and biobanking, and in reflecting on these resources in contributing to the international discussion about effective protection of fundamental rights and freedoms of individuals and groups in biobank governance.

In particular:

- The analysis of the available literature on the perception of privacy in genetic information and related issues indicated a wide range of positions held by individuals in societies; that whilst there was some country-based difference in the distribution of these ideas, the same range of ideas was seen in all countries; the legal regulation of biobanks could not be effective in relating to the concerns of individuals if it only addressed a small number of the range of expressed positions.
- The existing European and domestic law addresses only a small proportion of the range of expressions of privacy and the expressed interests relating to privacy in genetic information; some of the traditional preoccupations of the law are at variance with the expressed concerns of citizens and with the scientific and medical communities.
- Of the unresolved challenges in the law, the following are of particular concern:
  - the 'group' nature of genetic information and the tension created by the individually focussed legal regimes;

- the difficulty of using ‘informed consent’ in the biobanking arena particularly in relation to ‘secondary processing’<sup>3</sup>, and the adequacy of other forms of consent as safeguards for fundamental rights and freedoms;
- balancing the need to facilitate medical research in society whilst respecting individual rights, and the difficulty of identifying competing rights holders;
- the difficulty of competing regulatory regimes and requirements (both between jurisdictions and within jurisdictions) in the same substantive area; the relationship between regulation through personal data and through other regimes, particularly those relating to data protection, to samples and to property rights; and,
- the question of ensuring legitimate access to research materials whilst respecting privacy concerns.

The discussion of these issues, through the initial project findings and reviews by the consortium members, informs the international debate, with reasoned suggestions to inform the political process in developing new, more effective governance regimes, where effectiveness is seen in terms of developing and maintaining high levels of trust and confidence in medical research using genetic information and biobanking.

The overwhelming sense from the project was that there are a number of solutions available to resolve the areas of tension. The data protection regime, through the Directive 95/46/EC, with some revisions and an interpretative consensus, could address the concerns and provide a single regulatory regime; equally, a combination of approaches, particularly between data protection and the tissue protection regulations could provide a coherent legal framework after revision and harmonisation; a *sui generis* biobank regime could be created which, with careful attention to its linkages to existing requirements for data and tissue, could provide a specifically tailored regulatory system. Each of these regimes or arrangements could be developed quickly to meet the range of public and research community concerns about the regulation of medical research using genetic information and biobanking. However, at the heart of the reforms is now a need for political debate and choice. Underpinning the choice of regimes is the question, ‘what sort of social balance do we wish to strike between active and passive citizenship?’

The next stage of the work in this area is to raise this issue at the international, European and national levels for political decisions about which option should be taken. Primarily, the choice is about how far individuals require protection of their rights from the State, and how far they can be expected to defend their rights for themselves. The discussions in PRIVILEGED have shown that this is not resolved by academic argument; the matter requires a political choice in democratic society.

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<sup>3</sup> ‘Secondary Processing’, i.e. opportunities for processing the data not foreseen at the point of the collection of the data (where ‘Primary Processing’ is processing the data for the purposes foreseen at the point of the collection of the data).

## **PRIVILEGED RECOMMENDATIONS - Full Report**

### **Introduction**

PRIVILEGED was funded by the EC under the Framework 6 programme for the Science and Society department from January 2007 to December 2009. It brought together academic health lawyers and ethicists, sociologists, medical researchers and doctors from across the Member States of the EU, from Iceland and Norway, and from Israel, Japan and Taiwan, to answer the question: 'Is the current legal protection afforded to genetic data adequate to protect the privacy interests engaged by research using biobanks and genetic databases?'

Of course, 'adequate' is a loaded term. PRIVILEGED approached its definition in two ways: first, it undertook a literature review of the reported research where individual citizens have been asked about their attitudes towards use of genetic data; second, it examined the laws that are already in place at a national, European and international level. It took this approach thinking of the perspective of the European legislator, who asks, 'Is it necessary to ensure a Europe-wide protection of the use of genetic data in research, and especially in relation to research biobanks?' For PRIVILEGED, that question hangs in part on what the citizens' expectations are, as far as they have been explored<sup>4</sup>. It equally hangs on the standards that are accepted in general and specific laws in the area. On the basis of the analysis of these two approaches to the question - the first two stages of the work - we were able to draw a number of preliminary conclusions, but we also identified five key areas for detailed analysis in the third and final stage of the project. These five areas were addressed by sub-groups of the whole consortium, and the conclusions of the groups are presented below.

Some further comments are needed about the project's methodology. The overall aim of the project was to produce recommendations to the European Commission about the desirability (or otherwise) of harmonisation of the law across Europe. The project was constructed with this in mind, but saw our place in the process as being to inform the choices that are to be made by the elected representatives; we have no mandate to prescribe a particular approach or response to what we find and identify. Therefore, we present our work in the following spirit: if you wish to produce this effect, to protect these interests and perspectives, then these choices are needed; if you wish to protect these other interests, these are the choices and challenges. The work in stages one and two of the project was conducted through two questionnaires to the members of the

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<sup>4</sup> PRIVILEGED was a co-ordinating action which brings together existing research, rather than undertaking original empirical research,

consortium for individual country by country reports. These were then analysed and discussed in a whole-consortium workshop for each stage. Stage three worked with the consortium being divided into five sub-groups to work on the five identified, key areas and to reflect on the broader conclusions flowing from stages one and two. Again, stage three had a whole-consortium workshop where the five areas were discussed.

## CONCLUSIONS FROM STAGE ONE

### Contested Concepts

Stage one involved a literature survey undertaken by each member in their own jurisdiction. The first thing that became clear through this survey was that the meaning of key terms and concepts remains contested. These contests were, however, manifest in quite different ways: the term 'biobank' is expressly defined in different ways in different places, while the definition of the term 'privacy' is typically assumed rather than explained or defined at all. Considering its different applications, however, it is not at all clear that a consistent, or coherent, concept is being applied. We began then by seeking to determine what, for the purposes of the project, we would understand the terms 'biobank' and 'privacy' to mean.

### **Biobank**

We invited participants to submit definitions of the term 'biobank' that they were aware of in current use. A complete list of the definitions submitted is available on the project website<sup>5</sup>. Asta Cekanauskaite analysed the submitted definitions<sup>6</sup>, and found that while 'biobank' was consistently defined as collections of (human) biological material (samples), within that consistency there were substantive variations in respect of five elements:

- 1) **Association with other data.** Was the sample i) associated with other identifiable personal data, ii) associated with additional non-identifiable data (e.g. anonymised health data) or iii) not associated with additional data at all ie. 'simply' a collection of tissue or genetic data (e.g. human genome project)?
- 2) **Purpose.** Was the purpose solely research or did it have some other primary purpose e.g. organ donation?

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<sup>5</sup> <http://www.privilegedproject.eu/projstages/stage1/introduction/biobank-defs/>

<sup>6</sup> See paper presented at PRIVILEGED workshop 1

3) **Past or Future Samples.** Whether the collection of the samples was **prospective** or **retrospective**?

4) **Scale.** Could a biobank be constituted by a single person's tissue/data or were 'large numbers of people', even populations, necessary?

5) **Period of storage.** Did the collection have to be 'permanently' maintained', could it be 'temporary', indeed could it be defined “with or without a pre-defined period of storage” (Portugal)?

For the purposes of the project, workshop participants took the view that PRIVILEGED should not operate with an arbitrarily restricted definition of the term 'biobank'. There was, however, agreement that as our primary concern was with research uses that might engage privacy interests, our primary case focus should be collections that related to more than one person and which were associated with other data. With that in mind, it was proposed that we operate with a relatively inclusive definition of biobank: 'a collection of biological material from more than one person.' It was recognised that, as well as physical material, a biobank would usually contain information about the architecture of that material and other personal or medical information about the individual from whom the sample was taken.

This definition allowed for the possibility that the collection was either prospective or retrospective in nature, it could be small (ie. only two people), and it could be permanent or of a relatively temporary nature. It was also possible that it did not have research as its primary focus (although we agreed that technical questions about forensic biobanks would be outside the scope of our primary work). What did characterise such a collection, however, was the fact that it was an organised collection of biological material, from more than one person, and that it could, at least potentially, be used for the purposes of research. This was important for the project as, when considering how privacy engages with research using biobanks, we wanted to consider the possibility that privacy might be jeopardised by a *failure* to use a biobank for research purpose.

It was recognised that the term 'Genetic Database' could be said to vary in similar ways to 'biobank'. (Indeed, for some the terms are synonymous.) The project takes the term 'genetic database' to be broader than biobank as it need not contain biological material *per se*. It was recognised, however, that a genetic database will, by definition, contain genetic data and that could be understood, inclusively, to be *any* data derived from an analysis of genetic material. For that reason, and for similar reasons operative when deciding to work with a relatively broad concept of 'biobank', the decision was taken to take the expression 'Biobank or Genetic Database' (**BBGD**) to include:

**'organised collections of biological material, or data derived from the analysis of biological material, taken from more than one person'.**

Privileged is concerned with how the privacy interests engaged by research using BBGDs relates to the public interest in research and how that relationship is currently, and prospectively, mediated by law.

### **Privacy**

The literature on privacy is extensive. A survey of that literature conducted by the project's research co-ordinators identified articles discussing privacy in the journals of many different disciplines. It is perhaps unsurprising that a concept employed within worlds as diverse as law, philosophy, sociology, psychology and even architecture has evolved into a web of overlapping and subtly differentiated ideas and definitions. A multi-disciplinary review of journal articles categorised 72 different privacy definitions (Newell 1995).

It was never the intention that the project should summarise all that has been, or could be said about privacy. We did, however, seek to build a conceptual framework that would usefully describe the spectrum of interests that could plausibly be described as 'privacy interests'. Our survey of relevant literature found that, amongst other variables, fundamentals such as the object and subject of privacy claims are themselves contested: ideas vary about not only what might be described as 'private' activities (or activities capable of invading privacy) but also about what kind of entities might be engaged in such activities i.e. who/what might possess privacy.

A complete summary of these competing (or at least alternate) conceptions of privacy can be found within the chapter, 'Privacy: a contested concept' (PRIVILEGED Coimbra special edition, forthcoming - see website). Identifying some of the alternate ways in which the idea of privacy finds expression within the literature allowed us to construct a meta-concept of privacy: a framework for illustrating the ways in which concepts of privacy vary. (This meta-concept is also more fully explained within the chapter.) This meta-concept allows us to explain how particular interests may, or may not, fall within the spectrum of 'privacy interest' according to how the parameters of the concept of privacy are initially set.

Specifically, we suggested that concepts of privacy invariably presuppose variations of three different kinds. For the purposes of our analysis we labelled these variables (i) the normative; (ii) the (trans)actional and (iii) the relational. We recognised however, that they could be given different names and it was the substance of the ideas that interested us rather than the labels.

It is important to emphasise that the objective pursued through the construction of this framework, and through discussion of the three kinds of variation surrounding use of the term 'privacy', is to illuminate the breadth of possibilities when considering how research using GDBBs might engage privacy interests. Selection of *the* model for conceptualising privacy interests is not our concern. Selection of an underlying concept of privacy is in fact not merely a legal, philosophical, sociological, psychological or even architectural question but rather a moral and a political question that ought to be informed by the insights of all relevant disciplines. Understanding the presuppositions of any conception of privacy, however, is an important step towards finding answers to the question, 'which conception of the concept privacy is to be preferred?'

### **The normative variable**

The project initially traced the philosophical origins of the term 'privacy' as it is ascribed generally to ancient Greek scholars through to key British philosophers such as John Locke and John Stuart Mill. Their understanding of the relationship between the 'private' and the 'public' dimensions of society has undoubtedly helped to shape the Western world's modern-day understanding of the concept. Their understanding of the public-private interface was not, however, value free. Instead, the relationship was defined by political and moral judgements. The normative underpinnings of their conception of the proper division between the public and the private aspects of one's life undoubtedly influence an understanding of the scope and nature of the activities that are today described as 'private'. It may be possible to construct a 'value-free' concept of privacy by associating it with particular functions within human existence and society that are observed as a matter of fact rather than preference (cf. Altman 1975), but, for as long as the functions themselves are valued (and the nature of the functions associated with privacy means that they will be invariably associated with at least instrumental value) the fact (or absence) of privacy in society will possess a normative dimension. This normative dimension either directly determines, or at least helps identify, the range of actions (or actions between people, i.e. transactions) that are recognised as raising 'privacy' issues. The precise range of actions that will raise privacy issues will depend upon how privacy norms develop in a particular social context. For example, categorising the publication of covert photographs as a privacy invasion relies upon not only particular privacy norms but also upon the existence of the relevant technology. The normative variable may found a privacy claim, but the precise content of the claim will, therefore, depend upon many other factors. The variability in the nature and scope of the actions, or transactions between persons, that will be described as capable of giving rise to

privacy issues - constituting the content of any claim to privacy -may be described according to 'the (trans)actional variable'.

### **The (Trans)actional variable**

The '(trans)actional' variable represents the content of a particular conception of privacy. In 1977, an attempt to provide a consensus definition of privacy led Margulis to propose that

“[P]rivacy, as a whole or in part, represents control over transactions between person (s) and other(s), the ultimate aim of which is to enhance autonomy and/or to minimize vulnerability”<sup>7</sup>

Enhancement and protection of autonomy was viewed by Margulis as a *key function* of privacy and this informed his filtering of relevant 'transactions'. By way of contrast, *control over access* (and not just access to oneself), was highlighted within the definition offered by Altman (1975). Altman chose to define privacy as the 'selective control of access to the self or one's group' (Altman 1975:18). These ideas of 'transaction' and 'access' can be found within the classic description of privacy offered by Westin:

“[P]rivacy is the claim of individuals, groups, or institutions to determine for themselves when, how, and to what extent information about them is communicated to others. Viewed in terms of the relation of the individual to social participation, privacy is the voluntary and temporary withdrawal of a person from the general society through physical or psychological means, either in a state of solitude or small group intimacy or, when among larger groups, in a condition of anonymity or reserve.: (Westin, 1967:7)

Immanent within such concepts there may be normative claims, but, the focus of the work is not to defend the validity of a claim to privacy but rather to describe its scope and nature. The definition of privacy offered by Westin has been extended by others (Margulis 2003b); when seeking to elucidate the different dimensions of privacy evident within recent academic writing, Allen distinguishes between four dimensions: 'informational, decisional, physical and proprietary dimensions of privacy'. (Allen 1997:31)

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<sup>7</sup> Margulis 2003b. Note that Margulis himself later acknowledged that this definition failed to recognise elements relating to access to self (Margulis 2003a)

(1) Informational privacy concerns access to personal information; (2) physical privacy concerns about access to persons and personal spaces; (3) decisional privacy concerns about governmental and other third-party interference with personal choices; and (4) proprietary privacy concerns about the appropriation and ownership of interests in human personality. (Allen 1997:33)

It can be seen both how the activities that may fall within the scope of one's 'private life' may vary. Given the different dimensions of privacy represented within the literature it might be thought difficult to imagine a human activity that could not be subject to a 'privacy claim'. It is for this reason that it is important to recognise that, while the (trans)actional variable is important in its own right, it is the interaction between the normative and (trans)actional components that is key to understanding the breadth of any given conception of privacy.

While it might be difficult to imagine an aspect of life that could not be captured under one of the four headings provided by Allen, it is unlikely that one would claim it follows that *every* aspect of one's life would be considered 'private'. The limits to which a particular concept of privacy will run will depend upon the relationship between what we have called the 'normative' variable, grounding the concept, and what we have called the '(trans)actional' variable, working out the normative variable within a specific social context.

This points to the relatively *contingent* nature of any specific privacy claims: while the need for privacy may be a relative constant, the way in which it manifests can vary tremendously between social contexts (over time). This is an important conclusion for the project for it suggests that the description of those interests engaged by GDBB research as 'privacy interests' will depend upon a conception of privacy that is itself malleable. The concept of privacy operative within the jurisprudence of the European Court of Human Rights and the Charter of Fundamental Freedoms is best understood to be fluid. Even *if* the relevant normative variable was fixed (of which we have some doubt) the way in which that variable plays out in particular (trans)actional claims will change as the social context itself changes.

### **The Relational variable**

'The relational' variable is the third and final key variable underpinning our analyses. The relational variable might be considered as describing the relationship between individuals between whom the norms are evaluated. Once more we stress the importance, not necessarily of the isolated concept but now of the three-dimensional interaction between the 'normative', 'transactional' and 'relational' variables.

As noted above, whatever the normative basis, privacy itself will only ever extend up to a point. One of the relevant factors when establishing the (trans)actional variable may well be the pre-existing *relations* between the actors involved. For example, particular privacy norms might attach to joint endeavours, such as raising children, that leave individuals open to legitimate (when viewed from the perspective of a particular normative basis) interference from some individuals but not others.<sup>8</sup> It is also possible that those involved in the joint endeavours are entitled to privacy vis-à-vis particular transactions *because* of the joint endeavour itself. This gives rise to the possibility of ‘group privacy’. Of course, the precise nature of the ‘group’ entitled to claim an entitlement to ‘privacy’, e.g. whether it includes families, social groups, commercial organisations, will again depend upon how the normative and (trans)actional variables are understood within a particular social context. This is different, however, from simply recognising the range of actions that might give rise to privacy concerns. The relational variable explicitly recognises that the relevant range of actions may well turn upon the size of the affected social unit(s); it is possible that only *an individual* might have privacy interests, it is also possible that a small group could have similar, *or different*, privacy interests, it is further possible still that the privacy of a society or population could be understood to be engaged by a different range of (trans)actions.

If group privacy is recognised, then it is recognised to be more than the protection of the collective privacy rights of members as individuals; it is a requirement in its own right, e.g. to ensure the health and viability of the group *per se*. This points to the significance of the ‘relational’ element of privacy as well as the significance of privacy itself as constitutive of a particular kind of society.

#### **b. There are a range of interests that might be engaged by GDBB research**

It became clear that literature on public attitudes towards research using GDBBs is rather patchy across Europe. We did, however, survey the literature that was available with a view to developing a spectrum of possibility with respect to the concepts in question and also the private and public interests that they might engage.

At the Europe-wide level, there are currently two Eurobarometer studies that might yield, at least indirectly, relevant information about public attitudes towards research using GDBBs. A third

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<sup>8</sup> One might have greater scope for autonomy when dealing with one’s own children than when dealing with somebody else’s. Each parent’s scope for autonomous decision-making in relation to the couple’s children might be reciprocally limited by the interests of the other parent more significantly than, for example, by the interests of the grandparents.

relevant study is planned for 2010. The two that have been undertaken give interesting comparative information, although neither is directly on the specific issues of using medical genetic information in medical research or the same through biobanking.

At the national level, the members of the study reported a wide difference. In countries with a biobank<sup>9</sup>, there was more survey activity. Likewise, where there are particular academics with interests in the area, again there may be a greater than average number of surveys. However, beyond these two limited groups, the average is relatively little survey activity on attitudes towards the use of genetic information and biobanking in medical research. Even when the members looked beyond the specific issues of genetic information and privacy and concentrated on privacy generally, they reported a similarly limited literature. If one takes a view that those who regulate should have a sense of what individuals' concerns are around the object of regulation, then this is a problem. Legislators are not necessarily bound to follow public opinion, and legislation has a role in shaping and tempering society, but the lack of information should be addressed by specific, Europe-wide studies.

That said, the studies that are available are interesting for informing regulation. First, there is an enthusiasm for research using genetic information and for scientific research generally. Scientists are not universally trusted, but they command respect from a larger proportion of the population than, for example politicians. This is the case even when the scientist is based in the commercial world. However, there are equally concerns voiced about the probity of scientific research on genes, for example where this relates to abortion. Concern is also voiced about allowing access to genetic information. Concern is expressed about research, more so for forensic use, again more about governmental access, and more again for commercial and employment reasons.

There is a very strong language of control used when expressing interests in genetic information. This relates to property claims made by others for the commercialization of the information, or products arising from the information. This language, however, does not extend into a claim for property in these products or uses. The issue of control is seen at its most interesting when subjects were asked about their rights and responsibilities in relation to telling family members about their condition or gaining access to the diagnosis of family members. Four positions are clear: those who see a clear duty to tell, and those who maintain a right not to tell; those who hold they have a right to be told, and those who do not wish to know. These positions are seen in relation to any person who holds information that is relevant to the individual questioned.

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<sup>9</sup> See, for example, Iceland, Estonia, UK

Therefore, a biobank may, in the mind of some respondents, have a duty to tell or to withhold information, as will a family member.

**c. The summaries show a spectrum of views**

Perhaps the most striking thing about the different surveys is the range of opinions held by respondents. As is indicated above in relation to the right to know or to tell, there are those who hold a particular position, and within the population there are those who hold the opposite position. This is, of course, obvious, and the case in relation to most issues before the regulators. However, in relation to creating a legal environment within which medical research using genetic information and biobanking is not only tolerated but is encouraged and facilitated, the law has to seek to accommodate the range of opinions of the citizens. This is made more complicated because as yet we do not have the depth of qualitative data that shows the ways in which individuals hold different positions in relation to different aspects of their view of medical research using genetic information and biobanking; whilst we can surmise that there are some model type responses - for example, the care-free altruist participant who wishes to participate in medical research without worrying about the use of his or her data, the reluctant participant who sees the need for participation but requires some safeguards to be comfortable with that participation, the concerned participant who wishes to retaining a very high level of personal control as a condition of participation, the individual who will not participate - these do not cover all the potential variable positions. It is important to seek to accommodate all types because the success of medical research using genetic information and biobanking depends upon wide inclusion across the population. It is clear that a one-size fits all approach will not be appropriate in this regulatory area. The question is then, how far is the current law responding to this range of privacy interests and perceptions?

**d. Some of these interests could be described as privacy interests (which of them could be so described depends upon the operative concept of privacy).**

A particular spectrum of the possible interests described within the survey literature is recognised and protected by the law. As with the concept of 'biobank', and 'privacy', it is not the purpose of the project to prefer any one of these alternative concepts or to say which interests *ought* to be described as 'privacy interests'. Our ambition is more modest; we wish only to indicate the implication of certain choices. Stage Two of the project set out to identify how research using BBGDs was regulated within the different jurisdictions represented by project partners. We sought to be able to describe how particular consistency, or inconsistency, in approach protected a particular part of the spectrum within the broader spectrum of possible 'privacy interests'.

## Summary - Stage One

- *The meaning of key terms in this area - in particular **'Biobank'** and **'Privacy'** - are heavily contested.*
- *Differences in terminology can be indicative of unmanaged inconsistency and can frustrate effective communication.*
- *If relevant comments can be made using inclusive understandings (or 'broad definitions') then these will be of more general application and are to be preferred. If 'thin' definitions are to be used, then they should be used expressly and with specific reason.*
- *This supports a working description of a **'biobank'** as **'an organised collection of biological material, or data derived from the analysis of biological material, taken from more than one person.'** This takes a relatively inclusive position with respect to the five primary features according to which definitions of biobanks vary: their association with other data; the (primary) purpose of the collection; whether the collection is prospective or retrospective; the scale of the collection; the period of storage. If comments are relevant to a more restrictive understanding of biobank than this, then this should be made clear within the text.*
- *The concept of **privacy** itself is prone to variation in three different, but related, ways: changes in the **normative, the (trans)actional and the relational variables**. Changes to the normative foundation of any privacy claim will be worked out in relatively contingent fashion within a particular social context.*
- *The **(trans)actional** content of privacy: the scope and nature of activity that might engage an individual's privacy, is therefore subject to variation over time and between cultures even if those cultures continue to share particular privacy norms.*
- *The **relational** content of privacy: the nature of the relationships that may themselves possess a private life, may also vary with some ideas of privacy focussed on the possibility that only individuals may have a private life and others recognising that entire communities might possess privacy.*
- ***Little empirical work** has been conducted across Europe establishing public attitudes towards privacy.*
- *It is not possible to determine whether there is a distinctively **'European Perspective'** on the (trans)actional or relational content of privacy or on how research using biobanks engages privacy.*
- ***There is evidence of a range of views within Europe about how biobank research should be regulated** (and what interests should be recognised by such regulation).*
- *There is reason to suspect some **divergence between these views and the concept of privacy implicit within regulation**.*

## **CONCLUSIONS FROM STAGE TWO**

### **Current Regulation**

A questionnaire requesting information about how research using biobanks and genetic databases is regulated was distributed to project participants. Particular focus was placed upon how national jurisdictions satisfied the requirements of data protection directive 95/46/EC, or equivalent protection outside of the European Union, in the context of BBGD research. The results of the questionnaires were compiled by the three different project centres: Sheffield, Coimbra and Vilnius; and regional reports were generated. The complete regional reports (together with the national responses to the questionnaires) are available on the project website. The website also contains links to and materials about the national laws for each of jurisdiction represented in PRIVILEGED. A number of key things can be drawn out from the combined reports, and they are presented here.

First of all, and importantly, the position currently taken by those implementing the Directive *vis a vis* the regulation of BBGD research is not consistent. Within their inconsistency, we can see different interests being protected or prioritised within protection. Taken together, this does not represent a singular position on privacy and/or its legitimate qualifications. It *might* represent a coherent position *if* the differences can be attributed to the effects of a common privacy norm being developed within different social contexts. To the extent that this represents choices by members states within their margin of appreciation, this may simply reflect alternate cultural, political and social realities. Even if this is the case, then the implications of such choices for the range of interests that *could* be protected (amongst the spectrum of possibilities earlier identified) should be understood.

### **European Law**

Nathan Cooper (Sheffield) and Claudia Pitz (Maastricht) worked from materials submitted by project members, and the primary literature, to construct a paper mapping European and International law regarding privacy (both generally and specifically in relation to genetic data and biological samples) against alternative concepts of privacy. The concepts of privacy found within European and International Law were compared with the concepts previously identified within the literature and the conceptual framework developed in stage one of the privileged project. A particular concern of the paper was to test the hypothesis that European and International law represents within its protections a relatively atomistic and individual conception of privacy. The

paper is titled 'Privacy in relation to Genetics: A Legal Framework' and is to be included within the Coimbra Special Edition (see also PRIVILEGED website).

Through applying the conceptual space identified by the meta-privacy framework to the international and European regulatory framework on privacy, data protection and biological samples in relation to genetics, the paper identifies three circumstances: (1) where phenomena in the context of genetic privacy and data protection are legitimately expressed as privacy interests that fall within the conceptual space and have a corresponding regulatory framework; (2) where phenomena are legitimately expressed as privacy interests falling within the conceptual space, but are not covered by a regulatory framework; and, (3) where the regulatory framework covers phenomena that are not expressed as privacy interests that fall within the conceptual space.

Of particular interest within the paper are some examples of phenomena within the second and third circumstance, since these highlight the partial (dis)connection between privacy as expressed conceptually and that set of circumstances governed by the international and/or European regulatory framework on privacy, data protection and biological samples in relation to genetics. Through these examples the adequacy and desirability of the relatively individual and atomistic model of privacy protection, (premised on individual autonomy and liberty) is considered.

The international binding and non-binding instruments, as well as the national legislation adopted by States, and judicial decisions reveal a number of core principles, including: a) lawful and fair data collection and processing; b) accuracy; c) purpose specification and limitation; d) proportionality; e) transparency; f) individual participation and in particular the right to access; g) non-discrimination; h) responsibility; i) supervision and legal sanction; j) data equivalency in the case of transborder flow of personal data; and, k) the principle of derogability.

These principles can clearly be linked to privacy interests, concerns and dimensions identified within stage one, but any characterisation of relevant law as solely or even essentially concerned with safeguarding privacy would be misleading. Even data protection laws serve a multiplicity of interests, which in some cases extend well beyond traditional conceptualisations of privacy. Few direct manifestations of intimacy-oriented conceptions of privacy are to be found in the provisions of data protection laws and, even broader privacy concepts are not of a nature to explain data protection principles such as purpose limitation, data quality or security.

Different “genetic” interests are shown to be covered by different international and European regulations (some binding others non-binding) which are themselves associated with different enforcement mechanisms. This leads to a lack of uniformity in protection of privacy interests. Some interests are covered by general privacy provisions or only in relation to specific target group (disabled or indigenous peoples for example) Others are covered by data protection legislation or legislation on research with humans. The claim that European Law, under either regime, operates with a relatively individual (atomistic) view of privacy is evidenced e.g. by demonstrating the emphasis upon the protection of individual interests (group interests only being acknowledged as an exemption/ qualification to the individual interests recognised).

The range of interests to be served by the law may be understood to vary between the two dominant international legal regimes operative within Europe today: the task of the ECJ is to advance the goals of Community law and the ECtHR is focussed exclusively on the protection of human rights. When it comes to protecting privacy, The European Court of Justice and the European Court of Human Rights show quite some differences in approach, particular with respect to the mechanism through which that private individual liabilities for 'privacy infringements' are determined. (The ECJ uses a system of preliminary references that allows for a judicial dialogue between national and European courts dissimilar to that available in the case of the ECtHR. The ECtHR cannot send back legal issues to national courts for final resolution and consequently must decide once and for all whether there has been a breach of the Convention.) There is also a difference in the scope of protection: ECHR broader and more general whereas EU is more specific to personal data (Charter) and common market (Data Protection Directive).

It is possible to understand privacy to encompass interests, such as group interests, that EU law does not readily acknowledge (at least not in the form of enforceable rights). If the Directive were to accommodate such interests, then a wider range of interests expressed by the public in research using biobanks and genetic databases could be protected. However, this possibility does introduce further variations on the privacy theme and one of the key challenges is the identification of the interests that *are* to be protected (ie. identifying the purpose of the directive as described above).

## **National Data Protection Law**

A legal comparison of EU implementation of directive 95/46/EC with respect to research using GDBBs shows national regulation to be inconsistent in some important respects. Interestingly, however, it is within the consistency across Europe that we can see a particular concept of privacy evidenced. A consequence is that a relatively narrow range of interests are protected. As noted above, these examples are drawn from the more detailed Stage Two Regional Reports. Quotes concerning the Law in Member States are made from the regional reports of the PRIVILEGED consortium (see website)(these reports are, in turn, made following the analysis of the individual member's country reports in the project).

### **Scope of protection**

As with the European law already discussed, national law across Europe tends to recognize anonymisation as a way to protect against the harm caused by research use of (genetic) data. The rationale appears to be that if individuals are not identifiable, then their (informational) privacy interests are not in jeopardy. This is an assumption that can be challenged from the perspective of a broad concept of privacy. As described above, a position that recognises only individuals - personally identifiable as such - as possessive of privacy interests adopts a restrictive position within the relational variable. To discount the fact that individuals may have privacy interests as members of an identifiable group is to discount an interest expressed by both the public attitude surveys we considered and one accommodated within the meta-concept of privacy we are using.

### *Group Interests*

The position apparent across the European regulatory landscape can be contrasted with that described by the project participant representing the position in Taiwan. In Taiwan, "group consent" was designed into the development of the Taiwan Biobank, to complement individual consent. This idea of 'group consent' does not replace the practice of individual consent but was designed to strengthen effective communication, to observe the value of the family, and to avoid future disputes.<sup>10</sup> Within this system the relevant "group" is defined subject to the Ethical Governance Commission (EGC)'s guidance. When broadly constructed, it is referred to as a community consent. When constructed in narrower terms, it is equivalent to a family consent. In either sense, we can see particular interests captured that appear to fall outside the scope of

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<sup>10</sup> See Case No. 151/2003 (Icelandic Supreme Court, 2003).

European law *unless* they contribute to reasons to restrict individual rights to privacy: they are not recognised as privacy rights themselves.

It seems, therefore that within the Taiwanese model of 'group' consent there is recognition (and respect) of a potential interest in privacy that European and national laws across Europe are consistently ill-equipped to protect as such. Within the consistently held view that only 'identifiable individuals' have privacy interests at stake, there are inconsistencies about what will constitute an 'identifiable individual'.

### *Identifiable Individuals*

Identifiability relies upon the association between two data sets: no identifier operates without a correlative 'look up list'. One cannot use name, address, or genetic sequence to identify anyone unless those same identifiers are attached (independently) to particular individuals. A regulatory position on 'identifiability' must describe (or, less desirably, assume) a position on not only the possibility or probability of a match being made but also the relevant category of person(s) able to make that match. There is inconsistency across Europe with regard to both of these variables.

The inconsistency, and its implication for privacy protection, can be illustrated by comparing just two countries: Denmark and the UK. In Denmark “It is of no importance whether the identifying information is commonly known or only available to a few persons. Coded or encrypted information is also considered identifiable if somebody has access to the code. Consequently, if somebody is able to identify the data subject, the data will be regarded as personal data.” This position could be understood to go even further that the idea of identifiability described within Recital 26 of the data protection directive 95/46/EC ('the directive'):

“whereas, to determine whether a person is identifiable, account should be taken of all the means likely reasonably to be used either by the controller or by any other person to identify the said person”

The directive only understands an individual to be 'identifiable' if the match between potential identifier and particular individual will take place using 'means reasonably likely to be used'. In Denmark, the very possibility of a match seems sufficient even if it is not '*likely* reasonably' in the circumstances. However, neither the position described in Denmark, nor the position described by the directive, place any limit upon the category of person(s) capable of making that match: if *anyone* is sufficiently likely/able to make the association, then the data will be

considered to be identifiable. This contrasts markedly with the position in the UK. The UK Data Protection Act 1998 states that,

“‘personal data’ means data which relate to a living individual who can be identified—  
(a) from those data, or (b) from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller”

The UK clearly recognises the impossibility of a data controller discharging certain duties to data subjects they are, themselves, incapable of identifying. This may reflect what is practicable given certain duties to a data subject (e.g. meeting subject access requests), but it represents a substantially weaker notion of identifiability than that offered by the position taken by Denmark or suggested by recital 26 of the Directive.

The interests that individuals might have in not being associated with particular data (or exercising rights in relation to data they are associated with) extend to data that can be related to them by others and not just the data controller. If this cannot be recognised within the context of the directive, due to this position placing unreasonable demands upon a data controller, then this may represent a significant problem for the directive as a standard of broad privacy protection.

If there is a desire to recognise, and protect, the interests that individuals may have in data that can be associated with them, either as an individual or as a member of a group, then close attention needs to be paid to the responsibilities placed upon a data controller by the directive. A broader perspective of the interests to be protected (perhaps even going so far as group interests) may need a modified set of obligations upon data controllers.

One group whose interests are currently diversely recognised by regulation across the jurisdictions represented by project partners is the family.

### *Family Members*

Some members of the European Union deal expressly with the position of family members within their regulatory frameworks. For example, Art. 7 Hungarian Biobanks Act<sup>11</sup> states:

“When necessary for the prevention of an illness of a close relative, <...>, the genetic data may be communicated to a close relative as<...> the medical practitioner shall

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<sup>11</sup> "Protection of human genetic data and regulations of human genetics testing, research and biobanking" ([law XXI/2008](#))

call the attention of the close relative known by them to the necessity of knowing genetic data in the framework of a genetic counselling or shall initiate the involvement of the direct relative into the genetic counselling with the person concerned.”

It is clearly anticipated by the Hungarian Act that, in the first instance, the medical practitioner will encourage disclosure by the patient under their care to their relatives, although direct contact with a relative is not ruled out. This position is similarly expressly provided for in Israel:

“Notwithstanding the objection of the person, the information may be given to another treating practitioner of the Ethics Committee set according to the Patient Rights Law, after having heard the person involved, is convinced of all the following: (1) Communication of the genetic information regarding that person is required of the maintenance of the health of a relative or to improve such person's health, and for the prevention of death, disease or serious disability of such relative, including an unborn relative; (2) Communication of the genetic information in the only way of achieving the object referred to above; (3) The benefit to the relative as a result of communication of the genetic information to the treating practitioner is greater than then harm that might be caused to the person, or the reasons given by the person for not communications the information are not reasonable in the circumstances of the case.”

Despite consideration of the issue by the Article 29 Working Party (WP29), there is no clear indication of whether the Directive itself raises any expectations with respect to the genetic data of family members. When WP29 considered the issue they recognised that there were legitimate interests at stake but suggested that these interests could be protected in at least two different ways: a) by recognising family members as data subjects in their own right; b) by recognising these legitimate interests outside of the data protection framework. It appears that it is the latter route adopted by Member States. This does, however, create a level of both inconsistency and uncertainty with regards to the status of family members that may well be considered undesirable.

It may be that a material difference is recognised between the rights of an individual in the data of a living family member when compared with the rights of an individual in the data of a deceased family member. A number of countries do expressly provide for access to information derived from the genetic analysis of the deceased. In Spain, for example, such analysis is permitted on condition that it is required for the protection of health<sup>12</sup>; similarly in Italy,

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<sup>12</sup> Ley 14/2007, de 3 de Julio

“The rights as per Section 7 [Right to Access Personal Data and Other Rights], where related to the personal data concerning deceased persons, may be exercised by any entity that has a vested interest therein or else acts to protect the data subject or pursues family-related purposes deserving protection”

It is submitted, however, that if an interest in the data of the deceased is recognised, then that interest must also be recognised in the data of the living. What may differ is the relative weight accorded to the interests of the different parties involved. It may be that the interests of a living data subject are considered, in every case, to have priority over the interests of a relative. This is a position on the relative value of the interests engaged, however, and does not deny the possibility that relatives possess an interest in each case. The point is, however, that this interest is itself not currently consistently recognised across project members. Another inconsistency surrounds the interests of the deceased themselves.

### *The Deceased*

Data protection principles continue to apply to the deceased in Portugal, Spain, and Italy but not, for example, in Lithuania or the UK. If the data protection principles are not operative, then in those countries reliant upon data protection law to protect the privacy interests of individuals engaged by research using GDBBs, there is no privacy protection afforded the deceased. The fact that there is specific regulation for genetic research does not mean that the position of the deceased will be expressly considered e.g. the Estonian Human Genes Research Act does not address the issue of protection of deceased persons.

In those countries where the issue *is* specifically considered, the interests of an individual *post mortem* are not consistently recognised. For example, in Latvia there is an 'opt-out' system: research is prevented if an individual does not 'opt in' when alive. By way of contrast, there is an opt-out system in Hungary

“Genetic sampling from a deceased person, the study of a taken sample stored together with personal identification data or which has been encoded, their use for human genetic research or the use of derived data is possible only when the deceased person did not make a declaration objecting to it in their life time.”

This clearly provides limited protection of the interests that may be perceived to persist in the data of the deceased. It does, at least, provide for the possibility of opt-out. If data protection law were to be relied upon to provide the minimum required standard of privacy protection, and that

is understood to apply only to the living, then the interests of the deceased need not be recognised at all. This would not, however, be consistent with the position on privacy in relation to the deceased described by the ECtHR.<sup>13</sup> If there is a desire to guarantee a minimum recognition that privacy interests may exist in data relating to the deceased, then a clearer indication of that expectation needs to be given at a European level and the implications of this, e.g. in relation to the public interest in research, needs to be fully considered.

### **Other inconsistencies in scope of protection**

Within the regional reports other inconsistencies in the regulation of research relating to BBGDs is recognised as potentially leading to inconsistent privacy protection. For example, the age at which an individual might consent to participation in BBGD research differs between countries<sup>14</sup> and the circumstances in which such data can be processed without consent also varies. In Portugal, for example,

the processing of such data 'shall be permitted by a legal provision or by the authorisation of the CNPD when, on important public interest grounds, such processing is essential for exercising the legal or statutory rights of the controller'

In Spain conveyance of personal data to a research context can only take place, (without express written consent (art. 5.2 LBR)) with the permission of a Research Ethics Committee which must itself, before giving such permission, take into account at least the following:

a) that the research is of general interest; b) that the research is undertaken by the same institution that requested the consent for the obtaining of samples; c) that the research is less effective or not possible without the identifying data of the subject source; d) that there is no record of an express objection of the subject source; e) That personal data is guaranteed confidentiality.

This clearly places more specific limits upon research use of data, and therefore draws the boundaries of protection, rather differently than within other countries. In particular the requirement that the research be undertaken by the same institution that requested the consent for

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<sup>13</sup> Judgment by the European Court of Human Rights (Second Section), case of *Plon (Société) v. France*, Application no. 56148/00 of 18 May 2004

<sup>14</sup> In Greece, for example, only a person 18 years old or older may give consent, except in cases of an under-age person's potential physical injury or threats against his/her life. This differs from the position in other countries where a test of competence is applied.

the obtaining of the samples places a particular restriction upon potential research uses of the data. Just as different countries recognise privacy protection to extend to different degrees in different circumstances - e.g. data relating to family members, data relating to the deceased - different countries also recognise the limitations upon the privacy protection recognised to similarly vary. One particular limitation, related to the recognised public interest in research uses of persona data, is known as the 'research exemption'.

### *Research exemption*

To take again the examples of Portugal and Spain for the purposes of illustration. In Portugal (Law no. 12/2005, Article 19, no. 6) states that

“In case of retrospective use of samples or in special situations where the consent of the people involved could not be obtained due to the amount of data or the number of subject, its age or other comparable reason, the material and data can be processed, but only for purposes of scientific research or obtaining of epidemiological data or statistics”. In these exceptional situations, if consent is not necessary, there is no obligation to notify data subjects."

This can again be contrasted with the position in Spain where the LBR stipulates that

“Genetic data of a personal nature can only be used for epidemiological, public health, research or education purposes when the interested subject has expressly provided his consent or when this data has been previously anonimised” (art. 50.1).

In exceptional cases and cases of general health interest, the corresponding authority, after a favourable report by the authority on data protection, may authorise the use of codified genetic data, always when the assurance can be made that third parties may not be able to identify the source subject (art. 50.2). This represents an interesting position because it recognises research use of genetic data to constitute a use justifying 'prior checking'<sup>15</sup> but also because it requires assurance that *third parties* will not be able to associate the data with the source subject. The directive does anticipate that 'appropriate safeguards' will be attached to particular research uses of personal data that effectively exempt data controllers from particular requirements of data

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<sup>15</sup> Article 20 of the directive states that 'Member States shall determine the processing operations likely to present specific risks to the rights and freedoms of data subjects and shall check that these processing operations are examined prior to the start thereof.'

protection law.<sup>16</sup> It does not, however, specify what those 'appropriate safeguards' will be. This approach taken in Spain<sup>17</sup> recognises a responsibility to data subjects to extend even into situations where the data controller may not be able to identify them. A particularly strict position is taken in Spain on any change of purpose to a research end. The Data Protection Act ('Ley Orgánica 15/1999), establishes a special set of rules when the data have not been collected directly from the data subject (art. 5). These include that the consent of the subject source shall always be necessary when the aim is to use biological samples for biological research that have already been obtained for a different purpose, irrespective of whether the data are anonymised.

### *Tissue/ Biological Samples*

Certain countries have enacted legislation that applies data protection regulation to tissue or even includes tissue in the definition of data. Denmark is an example of the latter, and in Estonia and Latvia, laws on the national genome projects state that provisions of the data protection acts apply to tissue, and that the data protection agencies must supervise the processing of tissue.<sup>18</sup>

### *Summary - national data protection law*

- *A legal comparison of EU implementation of directive 95/46/EC with respect to research using GDBBs shows national regulation to be inconsistent in some important respects: e.g. Definition of Identifiability; Rights of Family Members; Rights of Deceased; Age of Consent to Research; Research Exemption*
- *A favourable reading of such inconsistency would recognise that it might reflect common privacy norms being worked out in different social contexts. The implications for the protection (or prioritisation) of particular privacy interests (and not others) should, however, be acknowledged.*
- *Interestingly, however, it is within the consistency across Europe that we can see a particular concept of privacy evidenced: the law regulating research using BBGDs currently presupposes a particularly individual-centric conception of privacy. In so doing the law protects a particular range of interests but leaves others unprotected e.g. Group Interests.*

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<sup>16</sup> See art.6(1)(b), (e) and 11(2) of the data protection directive 95/46/EC

<sup>17</sup> Spain is not unique in taking this approach, e.g. the UK also places as a requirement of any processing under the 'research exemption' that the results of the research or any resulting statistics are not made available in a form which identifies data subjects or any of them.

<sup>18</sup> Estonian Human Genes Research Act (2000), Section 7(1) and Section 28. Latvian Human Genome Research Law (2003, 2005) (Section 21).

**f. (In)consistencies in tissue law that demonstrate a particular range of protection of privacy interests**

**Informational Privacy**

Beyond data protection legislation, there is a range of other regulations over medical research using genetic information and biobanking. This is further complicated by the distinction between regulations concerning human tissue and genetic data derived from human tissue. At the European level there is the Clinical Trials Directive and the Good Clinical Practice Directive. These have some impact on parts of medical research. At the Member State level the legal environment is rather more patchy. A table showing the full range of the national legal regulations relating to medical research using genetic information and biobanking is included as Appendix 1 at the end of this report. As can be seen, some states have little further law directly applicable to the specific area in question, i.e. regulations that apply to the national genome project, or to genetic research and biobanking. Equally, some states have laws that are not directly applicable on their face, but that have an impact on the area, for example, more general laws about biomedical research. However, there is no uniform approach, and of course it follows that there is no harmony in the area. This reflects that only some of the Member States have national genetic information biobanks projects. By contrast, however, given the wide definition of ‘biobank’ it must be difficult to say that no Member State has no biobanking activity, what is missing is large-scale projects or systematic linking of projects.

This diverse range of definitions of genetic information and biobanking causes differences in coverage of the law, and goes to the heart of the level of informational privacy available in different regimes (i.e. what information is included within the regulatory purview). There are wide and narrow definitions, for example of genetic data, which capture greater or lesser amounts of data. At one extreme, genetic data is defined as data that is gathered from (laboratory) genetic tests, whilst at the other it includes any data that discloses genetic information (even including psychological and behavioural information as indicative of genetic information). Biobanks can be narrowly defined by size, the nature of the processing, for example scientific processing, or it can be defined broadly. The result is an uncertainty between Member States about what is covered and to what extent it is covered.

*Summary*

*There is too great a difference in simple coverage of medical research using genetic information and biobanking across the Member States. These differences can be seen in relation to narrow*

*and broad approaches to coverage. It appears that this difference in approach stems from the starting originating point of the legislation – the range of starting points for the debates; the initial question or problem that the particular legislation or recommendation seeks to address seems to set a context for the legislative response. The question of harmonization requires two questions to be addressed: 1) can the distinction between the data and the sample that contains the sample in relation to genetic data be harmonized in the data specific and tissue specific legislation?; and, 2) are there common harms shared between different types of problems in the range of debates in the area that can result from the mishandling of such data that require different legislative responses, and can these differences be accommodated within the same responses by adopting proportional responses to the breaches of rights?*

*Recommendation – that the approaches should be harmonized against a common harm based assessment, rather than other description-based differences.*

## **Relational Privacy**

The scope of relational privacy seen in this wide range of law is particularly interesting. There are laws and recommendations that are highly individual in their focus, affording explicit rights only to the donor of genetic material or data, and laws that relate to groups of individuals as full rights-holders. There is an interesting element in the law relating to the individual which produces a middle way for third parties. In this middle situation, there is the opportunity to make and appeal to the public interest to take account the interests of people other than the donor. In this situation, the interests of those who are within the genetically related group can be considered in balance with the donor, but they are not primary rights holders, theirs is an interests recognized in discretion, alongside the rights of the genetically unrelated members of broader society. In the situation of recognized group rights, third parties are again recognized through public interests mechanisms. However, the operation of the public interest is not a clearly defined discretion.

When group rights operate, the management of the impact of competing rights are not clearly defined in the law. For example, the right of a member of a recognized genetic group to gain access to genetic data derived from another member of the group is not clear; a group right holder may have strong or weak rights, for example he or she may be able to access information to prevent illness. It is not clear how far a group right holder should be consulted about the donor's proposed action. Such a right is not clearly expressed in the law. The group rights tend to have a secondary nature to the primary rights position of the donor. The competitive nature of the rights,

where group rights exist, is not clearly managed in the regulations; the fiduciary nature of rights holding is not explored, and the group rights tend to be presented as a bundle of individual rights holders, rather than beneficiaries of a collective reciprocal right scheme.

#### *Summary*

*There are both narrow and broad approaches to rights-holding in relational privacy. This spectrum also includes recognizable interests through public interest. If a narrow, individual approach is taken, the issue of consent, the management of the rights is easier, but the excluded genetic group tends to be dealt with by discretion and uncertainty; a broad inclusive group right tends to be a bundle of individual rights-holders, and lacks strategies for effective co-existence of competing rights.*

### **Normative Privacy**

One large normative privacy gap, an area where the law makes a normatively prescriptive stance about privacy rights that are not obvious, is in relation to previously gathered samples ('secondary processing'). The problem of tissue collections that have been gathered for one purpose and kept historically, often beyond the death of the donors, causes a great difficulty. There are two major questions that are not addressed adequately in the various laws: can such samples, and therefore the data that is contained within the samples, be used lawfully and ethically given the impossibility of gaining consent? and, should relatives (or members of the genetically related group) be approached to give consent (where they are available) as a fiduciary of the deceased person's wishes or in their own right as interested parties? It is also not clear in the law how the interest of family members is constructed and how far it extends. Again, the law is lacking a clear sense of the harms that it is seeking to prevent.

#### *Summary*

*Previously collected samples are not dealt with adequately in the law in many Member States. The assumption that without consent, there can be no use, and that relatives are proxies for the deceased would lead to the destruction of a great deal of valuable genetic information; to allow the use of this tissue without consent would require a strong argument that the public interest required the use.*

## **CONCLUSIONS FROM STAGE THREE**

Stage three of the project focused upon five areas of difficulty identified by the consortium following the first two stages of the project: Information Provision and Informed Consent; Research, Access and Best Interests; Genetic Data and Family Members; the Research Exemption; and, the Regulation of Research Using Samples.

These five areas were identified as important difficulties to European integration and harmonisation. Harmonisation was considered as desirable as stages one and two of the project did not identify major differences of the conceptualisation of the regulatory goals or the basic principles underpinning the area between the Member States. Further, a lack of harmonisation has consistently been identified by the research community as a major obstacle to the effective development of multi-centre or cross-border medical research using genetic information and biobanking.

To the extent that hindrance of research use of genetic data is deliberate, it may be defended. That defense must, however, be made in the public interest consistent with the fundamental rights and freedoms recognised within the European Community: it should present a *principled* obstacle to research. However, it is not always clear that there are principled differences in play. To the extent any hindrance due to inconsistency in regulatory approach is not deliberate, this presents a different difficulty. Such inconsistency may, or may not, represent a substantive difference - e.g. it could be that there is simply a lack of clarity in interpretation but an underlying conformity of purpose and intention that is simply not expressed clearly in the different legal and regulatory interpretations. This must be resolved. A lack of clarity that frustrates research, leaves researchers themselves unclear about their legal liabilities, and does so without good reason is to be addressed as a matter of priority.

### **The Recommendations from Stage Three**

#### **Information Provision and Informed Consent**

The Data Protection Directive 95/46/EC ('the directive') places data controllers under a responsibility to process personal data consistent with a number of data protection principles.<sup>19</sup> The first of these principles is the principle of 'fair and lawful' processing.<sup>20</sup>

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<sup>19</sup> Article 6

<sup>20</sup> Article 6(1)(a)

If a researcher intends to process personal data concerning health, then the directive would see them placed under a responsibility to ensure that, where it is a requirement, consent to such processing is a ‘specific’, ‘unambiguous’, *and*, ‘explicit’, ‘informed indication of wishes’ *unless* they are able to demonstrate that one of the other conditions set out in Article 7 and one of those set out in Article 8 may be satisfied.<sup>21</sup>

***We recommend that it be made clear that this requirement for 'specific', 'unambiguous' and 'explicit' consent does not preclude the possibility of legitimately seeking the kinds of broad consent for general purposes, e.g. the purposes of medical research supported by a Research Ethics Committee, before the detail of specific research projects is known (or knowable).***

The Directive does not state which information must be provided for an ‘informed indication of wishes’. What it does do is set out *separately* information provision requirements that must be satisfied whether or not consent is sought.<sup>22</sup> One might, therefore, *imply* that satisfaction of the informational provision requirements would adequately inform an indication of consent. This would suggest that satisfaction of the information provision requirements was *fundamental* to the obtaining of a valid consent. This would suggest that any change in the quality or accuracy of the information provided may undermine the legitimacy of a consent received.

It is important to remember that the information provision requirements exist even if consent is not required in the circumstances. In this sense, satisfaction of these requirements can be understood to be *independent* of any requirement to obtain informed consent. It is also possible, theoretically, to recognise some elements of the information provision requirement being fundamental to an informed consent and some being independent of it.

***We recommend that it be made clear that there is a distinction between the information provision requirement that is fundamental to an 'informed indication of wishes' and that requirement to provide information that is independent of the requirement to provide information to inform a consent.***

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<sup>21</sup> As a matter of fact a researcher may often be able to demonstrate that alternative conditions within Article 7 and Article 8 have been satisfied. Article 7(e) permits processing if it ‘is necessary for the performance of a task carried out in the public interest’ and Article 8(3) permits processing if it is ‘required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services’.

<sup>22</sup> Whichever conditions set out in Article 7 or 8 a researcher satisfies, they will remain under the information provision requirements set out in Section IV of the Directive and Articles 10 and 11.

The minimum information required to be given to data subjects is listed in Article 10 and includes the identity of the data controller, the purposes of the data processing, the recipients of data, and the rights of the data subject to access and rectify the data obtained. Article 10 also indicates that further information ought also to be supplied to a data subject

‘in so far as such further information is necessary, having regard to the specific circumstances in which the data are collected, to guarantee fair processing in respect of the data subject.’

It appears to be deliberately unclear exactly what kind of information this might be in any given case. While this provides flexibility to address a range of potential research projects and contexts it does not help provide clarity to a researcher (or arguably to a national legislator seeking to implement the directive). There is, in fact, some considerable disparity between national requirements with regard to the information to be provided to a research subject.

***We would recommend that it be made clear that the information indicated by Article 10 should be read together with The Council of Europe, Committee of Ministers, Recommendation No. R (97) 5 on the Protection of Medical Data (Feb. 13, 1997)<sup>23</sup> and that the information indicated should be considered fundamental to an informed consent.*** The form and character of provision should facilitate understanding and it should continue to be available for reference and to inform and subsequent decision to withdraw consent. It should be made clear to a research subject how they might continue to access this information as it may become more detailed over time.

***We recommend that it be made clear that the obligation to provide information is on-going and further relevant information should be made available as this becomes practicable. Later availability of specific relevant information should not, however, touch the validity of a consent previously given (so long as that information is not inconsistent with that which was provided***

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<sup>23</sup> The Council of Europe, Committee of Ministers, Recommendation No. R (97) 5 on the Protection of Medical Data (Feb. 13, 1997) which provides in Chapter 5 a list of information requirements to data subjects:

- a. the existence of a file containing his/her medical data and the type of data collected or to be collected;
- b. the purpose or purposes for which they are or will be processed;
- c. where applicable, the individuals or bodies from whom they are or will be collected;
- d. the persons or bodies to whom and the purposes for which they may be communicated;
- e. the possibility, if any, for the data subject to refuse his consent, to withdraw it and the consequences of such withdrawal;
- f. the identity of the controller and of his/her representative, if any, as well as the conditions under which the rights of access and of rectification may be exercised.

*at the time consent was obtained). Facilitating practicable access to current information should, however, enable a research participant to exercise any valid right to withdraw on-going consent.*

This should not be taken to imply that, if specific information is available about a particular research project, then a researcher is prevented from seeking consent to research use that extends beyond those specifics. Whilst specific information should be provided if available, and a research subject given the opportunity to consent only to that specific use of their data, this should not prevent a researcher seeking additional (layered) consent for broader research purposes than those necessarily to conduct the immediate research project. **It should be made clear that the (directive) requirement for consent to be 'specific' does not prevent this 'broader' consent also been sought at the same time.** Information relevant to the exercise of this consent should be made available as this becomes practicable (see above).

Currently, the responsibility to provide information imagined by the directive applies only to data subjects. While determining who is a data subject is not always straightforward, and the possibility that there may be multiple data subjects with respect to a particular piece of personal data remains moot (see below on familial interests), there is no expectation that the responsibility to provide information would extend beyond that category of persons from whom consent would need to be sought (if consent were necessary). However, receiving information about data processing capable of affecting them, even if they are not the donors of the information being researched, is an interest that may be described as a privacy interest if the idea of group privacy is entertained.

Indeed, a cogent argument can be made to the effect that because of the characteristics of genetic data, it is important for research using BBGDs to strengthen the effectiveness of public communication wherever possible. The example of the Taiwan Biobank above illustrates how both the idea of a community interest in research using biobanks and the idea of 'group consent' might be operationalised in practice. ***We would recommend that the possibility of a group interest in research involving biobanks be recognised and consideration given to the various ways such an interest may be respected in law.*** The alternatives vary between a version of 'group consent' to simply recognising an *independent* requirement to make available information about ongoing research to a relevant community (ie. one can anticipate may be affected by that research). Whether something along the spectrum of possibility vis a vis consent and information provision (or something else entirely is preferred, see 'Research, Access and Best Interests' below), there appears currently to be a deficit in the minimum protection assured by the directive vis a vis such group interests.

*We would recommend that the possibility of a group interest in research involving biobanks be recognised and consideration given to the various ways such an interest may be respected in law. There appears to be no responsibility within European law for communication with a potentially affected group for the purposes of (even) informed decision-making. The advantages of introducing a requirement to make information available to groups beyond individual data subjects (e.g. in relation to information capable of affecting groups) should be considered. It might, however, be more consistent with the existing data protection regime in the European Union to understand such a requirement as independent of any requirement to obtain consent rather than as being fundamental to any notion of group consent.*

### **Research, Access and Best Interests: identifying the limits in the name of privacy protection**

What follows in this section is not to contradict the first stage three issue above, which asked more specifically, what information is sufficient to inform in informed consent?

Informed consent remains an important means of protecting individual interests in research. Research involving an enduring (rather than temporary) BBGD cannot, however, effectively take place without any consent to participation being 'broad'. Given this, informed consent may be insufficient as a means to adequately protect privacy interests in biobanks. It is important that public trust in biobanks is maintained through ensuring only appropriate access to those biobanks and such access. Appropriate access is to be determined by 'the public interest'. The public interest is to be informed by, but not determined by, public opinion: only by understanding how particular research will impact upon persons can we estimate its relative worth according to fundamental principles of individual right and social justice.

*We recommend that, if the ambition is to regulate access to a biobank resource consistent with the public interest, access to biobanks should not be exclusively determined by the terms of a 'broad consent'.*

*We recommend that access to biobanks should be supplementally regulated by concerns motivated by the long term public interest in the research. Independent expert review of access decisions may be an effective way to support this ambition. Public consultation, and transparency, are also likely to be important means of ensuring, so far as possible, that decisions on access maintain public trust.*

## Genetic Data and Family Members

Before considering whether and, if so, under what conditions genetic data concerning a research subject may be disclosed to a member of their family, one should consider whether the latter already has a vested right that is grounded in the access right already in the personal data protection legislation. Article 2(1)a of directive 95/46/EC defines personal data as

“any information relating to an identified or identifiable natural person ('data subject')”

It is not entirely clear, however, when data will be understood to 'relate to' an individual or whether it may be said to 'relate to' more than one person at a time. When considering the meaning of the term 'relate to' the Article 29 Working Party (WP29) suggested that "a 'content' element OR a 'purpose' element OR a 'result' element should be present"<sup>24</sup> The latter element might be relevant in the context of genetic information: "Data can be considered to 'relate' to an individual because their use is likely to have an impact on a certain person's rights and interests, taking into account all the circumstances surrounding the precise case".

If one follows this interpretation, and considers that genetic information might unquestionably also impact on relatives, then one might argue that such information is also *their* 'personal data'. This would bring with it all the attending consequences from a regulatory standpoint, in particular as for access rights. The wording used by the WP29 is both general in scope and non-technical in nature, which results in expanding the concept of data subject excessively; indeed, it paves the way to potentially privacy-intrusive applications that may be detrimental to the individuals the personal information relates to directly, whenever such information may "have an impact" on other individuals – who would in turn become data subjects, if one follows the interpretation endorsed by the WP29.

To recognise relatives as data subjects would, however, bring with it a series of difficulties that are not currently resolved within the directive. In particular, it would appear to give relatives a right to veto the processing if they were able to satisfy the requirements of 'right to object' set out in Article 14.

To avoid such difficulties, one approach, is to deny the possibility that family members are also data subjects (at least while the proband is living). The domestic laws adopted so far in connection with the processing of genetic data reflect this 'individualistic' approach: no

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<sup>24</sup> See the Article 29 Working Group's working paper 136, Opinion 4/2007 on the concept of personal data, 20th June 2007

importance is attached to the decision-making power of individuals other than the proband. Thus, the regulatory solutions would not appear to accommodate the highly radical proposal, the ‘family-centred’ approach, put forward in literature, whereby the family as a whole rather than the individual alone, would be regarded as the patient in the genetic context.

It does not follow, however, from a rejection of the idea that family members may be data subjects in their own right, that their interests may not be accommodated. As noted above, some countries have already started move in this direction, albeit very cautiously and with different approaches. That is to say, they have moved away from the (traditional) “hard” options – either abiding strictly by professional secrecy obligations or (by way of exception) disclosing the relevant information to relatives if the state of necessity precondition is met.

The most recent legislation would appear to endorse solutions other than those relying on professional secrecy in order to make available the necessary information also to family members other than the proband. It is possible to recognise the interests of family members as additional data subjects, but, this gives rise to a number of unresolved tensions within data protection law.

***We recommend that when considering whether genetic data 'relates to' a relative a way that would bring that relative within the scope of a 'data subject' for the purposes of the data protection directive (95/46/EC) should be avoided, and we do not recommend adopting a 'result' orientated approach.***

***We recommend that solutions outside of data protection law be explored that enable the proband's relatives to benefit (if possible) from genetic testing performed within the respective family group. Model solutions already exist within national laws and agreement over terms should be pursued in order that the conditions may be made transparent as soon as possible.***

## **Research Exemption**

There are considerable differences in the implementation of the research exemption between Member States. These different regulatory and procedural requirements cause difficulties, particularly for cross-border research projects. Biobanks will realise a greater value for research if they can be connected, increasing the numbers of individuals involved; research using information from these biobanks will be increasingly cross-border. The differences between approaches to the research exemption will potentially stand in the way of such research, or at best

make it very time-consuming to ensure that all legal and ethical standards between countries are observed.

This seems to have created a situation that is contrary to the intention of the Data Protection Directive (95/46/EC): to create a barrier-free area for the transfer of personal data according to standards that protect the fundamental rights and freedoms of all European citizens. Further, research (processing for historical, scientific and statistical purposes) was included as a special case not to make such activity more difficult, but to facilitate it. There are a number of issues that require attention in order to realise the aims of both the single market and research:

The label, ‘research exemption’, which is in common use, but which only appears once in the Directive, is unfortunate. research exemption is intended to give an alternative route through the Directive to facilitate research whilst protecting the fundamental rights of all citizens. This recognises that, whereas in most processing of personal data the rights of the data subject are placed at risk for interests of the data controller that do not invoke a claim to fundamental rights and freedoms, in the case of medical research the processing invokes both the rights of the data subject, but also the fundamental rights and freedoms of those who could potentially benefit from the medical research. Thus, the research exemption could be seen quite properly as a route through the Directive which concerns the public interest. The word ‘exemption’ does not suggest this alternative. It presents the route as deviance from a common obligation, from which one needs to be excused. This does not help in creating a positive view of this research route; the research track is a parallel and equally acceptable route to the protection of all the rights and freedoms that are engaged, protected by safeguards within the Member States.

***We recommend that the ‘Research Exemption’ be termed the ‘Parallel Research Track’ and suitably encouraged as a positive, equal route for Member States to construct using similar approaches to the safeguards.***

The ‘information provisions’ (Articles 6, 7 and 8) ensure that the data subject is informed that processing of his or her data will happen, the identity of the data controller and the purpose for which it will take place. This is central to the operation of the Directive. However, there is a lack of clarity in the Directive about the need to re-contact individuals about further processing of that data. This, again, is a situation that is highly foreseeable in biobanking. The data are gathered for one purpose and in the future another purpose for the data are envisaged. In part this depends upon how far ‘gathered for research’ is sufficiently detailed in relation to consent, or specification of the purpose for processing. The problem arises between a narrow and broad reading of Article 6(1)(b) in relation to the drafting of Articles 10 and 11. Article 10 concerns data gathered directly

from the data subject. In that case, the data subject must be told the purpose for the processing. Article 11 concerns the situation where data are not gathered directly from the data subject. Here, the data subject must be told the purpose of the processing unless it is impossible or involves a disproportionate effort (especially where the purpose is for research). Article 10 does not have the impossibility or disproportionate effort clause. In the Recitals relating to Articles 10 and 11 (Recitals 38, 39, and 40) there is some acceptance of the idea that there may be a change in purpose from the original purpose, but Articles 10 and 11 are written to deal with the gathering of data and the purposes foreseen at that time, rather than a future situation of responding to unforeseen purposes.

Article 6(1)(b) may hold the solution to this, if it is broadly interpreted. Article 6(1)(b) first indicates that data should be processed for specified purposes and not further processed for purposes that are incompatible with those specified purposes. It then goes on to indicate that further processing for scientific, statistical or historical purposes, is not to be considered incompatible with the original processing. Narrowly, this would mean that the emphasis is upon processing - gathering, and then analysing, storing, destroying the data - must be compatible with the stated purpose and can be contested as such, but that any research processing would be deemed compatible and not contestable. A broad reading would place the emphasis on 'purposes', and suggest that data can be processed for further processes that are not specified if this is compatible with the original purpose, and this can be contested in all cases except research purposes. The broad approach makes the section more proportional (if it is merely processing that is in question, it seems rather heavy-handed), and it fits with the lack of compulsion to require consent in Articles 7 and 8 (concerning routes to 'fair and lawful processing'). It also makes sense of Article 10 and 11: there is no reference to further processing in Article 10 and 11 because it is dealt with in Article 6, and there is no necessity to recontact the data subject if the processing is compatible (and this can be determined by the data processing authorities).

***We recommend that Article 6(1)(b) should be read broadly, resolving the difficulties of interpretation in Article 10, and allowing for a change in purpose for processing if the new purpose is compatible with the original, notified purpose.***

Further processing without the knowledge of the data subject needs reconsideration; there is not only a lack of clarity in the law, but the ethical position is contested also. Within the dominant tradition of medical law, informed consent is seen as a 'gold standard' It gives a right to the individual, in this case the data subject, to decide whether or not to participate in research. This approach respects the position of those who are very concerned about the use of their own data,

and the studies suggest that this is a widely held position. However, there is an alternative view that takes as its starting point the question, ‘if there is secondary processing, what harm is possible from that processing?’ This leads to a second and third question, ‘what are the benefits that such processing would bring?’ and ‘could particular safeguards reduce or remove the risks?’ The dilemma for the legislation is that in the situation is a balance between competing rights holders. However, the right to privacy and autonomy can be seen to outweigh other rights disproportionately. It may be possible to use safeguards to balance the risks to privacy and autonomy. For example, prior checking and public advertisements about the research may be seen as safeguards and checks in the system. However, it may be a matter of luck that advertisements are seen by the relevant people, and therefore it could be concluded that they are little more than symbolic acts. Likewise, one must ask how far imposing a time limit on the storage of the data are realistic safeguards.

The new research opportunities of biobanking make long-term usefulness of data, and data sharing norms rather than exceptions in research. There is a compelling argument that the harms at stake for the individual data subject do not warrant the automatic protection of individual, case-by-case informed consent. Broad consent with the safeguards of robust prior checking based upon assessments of proportionality, data security, and an opt-out register rather than a presumption of opt-in present a more proportional protection of all the rights involved. This would also reflect the structure of the Directive and the place accorded to scientific research by it.

***We recommend that the broad consent with the safeguards of robust prior checking by a data protection authority based on proportionality of risk, data security measures, and an opt-out register offers a more proportional regime to balance the community of rights in biobanking. We further recommend that much greater energy should be put into public participation in the planning and execution of research.***

### **Regulating Research Using Samples: Clinical Samples or Data Protection**

There are differences between biological samples and genetic information. To what extent are the differences, however, sufficient to justify attempts to harmonise the regulation of one, but not the other? Notwithstanding the existence of a research exemption (discussed above) under the Data Protection Directive 95/46/EC, there are a number of responsibilities imposed by the Data Protection Directive upon Data Controllers’ processing personal data for research purposes. These responsibilities do not extend to biological samples.

***We recommend that neither the data protection regime, nor the clinical trial model, provide a complete and appropriate legal framework for regulating tissue research. Even if the two models are combined, this would not result in sufficient regulation taking into account the specific features of tissue research.***

We recognise that there may be certain advantages to disparity in the regulation of biological material at the national level (enabling differing views of the sensitivity of different kinds of biological material (e.g. foetal tissue) to be recognised). However, whatever advantages might be attached to allowing states a margin of appreciation when it comes to the regulation of research using biological material, there are also undoubted *disadvantages* to the current lack of regulatory uniformity. Not least of these is the complexity, and frustration, of cross-border research. Harmonisation, so long as it respects legitimate distinctions drawn between samples and information, might help facilitate research that could be described as *protective* of certain interests in fundamental rights and freedoms, most notably a right to a private and family life.

Such harmonisation best be facilitated through a framework model more like the EU directive on data protection, or, the EU directive on the use of biological samples in the clinical context. We recommend the following six points are taken into consideration during the development of such a framework:

1. As obtaining biological samples for research purposes may affect physical integrity, the law should stipulate that physical interventions needed to procure human tissue are subject to safeguards comparable to the ones laid down in legislation concerning research with human subjects (including written informed consent and ethical review).
2. If tissue is already available (for instance as left over from treatment) there is no bodily interference in obtaining it. However, storing it for research purposes implies that it will be mined as a source of personal information. Given its potential identifiability together with its potential to yield new findings, informed consent is warranted to allow research subjects to decide on whether they want to participate or not. An additional argument to plead for informed consent in this context is the increasing difficulty of meeting requests to withdraw (or opt-out) from participating in research, years later. Eventual exemptions to this principle (e.g. in the case that the source of the tissue can no longer be found) should be strictly limited and be subject to additional safeguards such as ethical review.

3. In order to meet the informed consent requirements in relation to tissue research, individuals should be given adequate information. The information to be provided would depend on the context, but should include: possible inconveniences linked to the removal of the sample; technical information on the biobank and how it operates; foreseeable uses of the tissue; and the location of analysis, storage or archival of the tissue. As tissues contain ‘hidden future diaries’ and new findings (incidental or expected) may result from future analysis of human tissue, it should be ensured that research participants are informed about this and also able to choose whether or not they wish to receive all such information that is relevant to their present or future health. This choice should be accompanied by information on the potential consequences of the decision for the private and family life of the individual.

4. As tissue is a source of information, it could be used in future, as yet unspecified, research projects. The initial, and often necessarily broad, consent of research subject should be supplemented by additional ethical review of both biobanks themselves and specific research projects that include analysis of tissues, with a special view towards protecting participants from ‘informational harm’.

5. In relation to the physical nature of tissue—apart from in jurisdictions where it is already beyond doubt that human tissue does not fall under the law of ‘goods’ and ‘property’—legislators should make it clear whether samples can be the object of ownership or property. If legislators decide it can, and the ownership is bestowed on the biobank or research institution to which the tissue has been ‘given’ by the research participant, the legislators should clarify how these ownership rights are limited to adjust for the legitimate interests of participants, or qualified by rights developed to protect them.

6. The law should ensure that in the case of competing claims on scarce tissue, biological samples that have been stored for research purposes can, as far as reasonably

possible, be reclaimed by research participants if necessary for their own diagnosis or treatment (unless patients have explicitly waived their right to re-use the tissue for their own medical treatment).

There are already two relatively well developed regimes that regulate medical research across the EU i.e. the data protection model and the clinical trial model. Neither the data protection regime, nor the clinical trial model, provide a complete and appropriate legal framework for regulating tissue research.

Tissue differs from data according to i) methods of acquisition ii) potential for (further) re-analysis iii) finite nature of tissue iv) physical objects give rise to different property questions. BBGD research differs from typical clinical trial research because i) the 'open' nature of BBGD research is relatively hard to accommodate within the established protocols of clinical trials e.g. it will often be impracticable to obtain specific informed consent for particular research uses of tissue ii) clinical trials regulation is underdeveloped with respect to informational risks and related privacy issues (as they are predominantly oriented towards physical risks).

***We recommend that both of the relatively well developed regimes that regulate medical research across the EU i.e the data protection model and the clinical trial model have elements that are very relevant to the collection and use of tissue for research purposes and that can be instrumental to achieve the required protection.***

***We recommend that despite the utility of these existing systems the differences between tissue and data and between clinical trials and database research means that even if the two models were to be combined, this would not result in sufficient regulation taking into account the specific features of research using biobanks.***

***We recommend additional and more specific protection. National law-makers should have the necessary discretion to decide how best to realise this but we prefer that approach that elaborates a comprehensive regime for tissue research (a 'third' model) that takes specific account of six elements:***

- 1) that physical interventions are typically needed to procure human tissue and should be subject to safeguards comparable to the ones laid down in legislation concerning research with human subjects (including written informed consent and ethical review).***

- 2) *even if tissue is already available (e.g. surplus to treatment) and there is no bodily interference in obtaining it, informed consent is warranted.*
- 3) *the information provided (to inform consent) should depend on the context, but should include: possible inconveniences linked to the removal of the sample; technical information on the biobank and how it operates; foreseeable uses of the tissue; and the location of analysis, storage or archival of the tissue. Research participants should express an opinion on whether they wish to receive any information (including any that is obtained incidentally) that is relevant to their present or future health. This choice should be accompanied by information on the potential consequences of the decision for the private and family life of the individual.*
- 4) *Consent to research use of tissue is not sufficient to protect individual interests. The initial, and often necessarily broad, consent of research subject should be supplemented by additional ethical review of both biobanks themselves and specific research projects that include analysis of tissues, with a special view towards protecting participants from 'informational harm'.*
- 5) *Issues of ownership should be put beyond doubt. Legislators should clarify how these ownership rights are limited to adjust for the legitimate interests of participants, or qualified by rights developed to protect them.*
- 6) *The law should ensure that in the case of competing claims on scarce tissue, biological samples that have been stored for research purposes can, as far as reasonably possible, be reclaimed by research participants if necessary for their own diagnosis or treatment (unless patients have explicitly waived their right to re-use the tissue for their own medical treatment).*

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## **PRIVILEGED - Future Work**

Whereas the funding of the PRIVILEGED project is ended, there are a number of pieces of work that naturally flow from the project. These take the form of a number of discussions of the project results with:

1. the Article 29 Working Group.
2. members of the European Parliament
3. the National Research Ethics Committees Group
4. the EC Ethics Review
5. other research projects and programmes

These discussions could be combined with discussions of the other Science and Society FP6 Genetic Information and Biobanking projects, notably GeneBanC, with whom the PRIVILEGED consortium already has very strong links. The two projects are complementary and the discussion of the two sets of recommendations together would make a very useful contribution to the general governance debate in the area.

### Rationale

The Article 29 Working Group is concerned with the implementation and operation of the Data Protection Directive (95/46/EC). It has, in the past, considered issues relating to genetic information and the Directive. However, this was some time ago, and the issues are not resolved, as is seen in the recommendations of the project. There are fundamental issues to resolve in the Directive, particularly in relation to the twin paths that are available in the Directive, and in relation to certain key interpretations of the Directive (particularly in relation to anonymisation, and to further processing of data). Further, the issue of group data, and multiple data subjects requires close further attention. The developments of alternative safeguards for the data subjects' interests, particularly in relation to the operation of the research exemption, also need new attention in the light of biobanking.

There is a regular suggestion that the solution to the issues raised in relation to biobanks and genetic information in medical research lies in the hands of ethicists and lawyers. The projects shows that there are a number of positions that are available, and that reflect different perspectives held by individuals in society. These choices require political solutions. It is therefore important to discuss the range of views and the range of regulatory and governance choices that are available to the elected representatives with Members of the European Parliament.

The importance of safeguards beyond the ability of the individual donor of genetic information, or relative of a donor of genetic information to protect him- or herself is key

to the successful operation of biobanks. One of the centrally important safeguards is through the Research Ethics structures in Europe. These are operating at the national level and at the European level, through the Ethics Review of research funded under the Framework Programmes of the EC. The robust operation of both the approval of protocols before funding and of the monitoring of projects during their lifetime, is central to public trust and confidence. PRIVILEGED identifies a number of key issues that require further consideration by research ethics committees. These include the issues raised above, but also include questions of the level of subsidiarity that can and should operate in this area. One of the major issues raised by the research community is about the differences in approaches between ethics committees; the issues raised by PRIVILEGED form the basis of a discussion about the common European values in play in relation to privacy and other fundamental freedoms in relation to biobanking and genetic information, particularly how the group nature of the data operates, and again, what the expectations concerning informed consent and broad consent mean in a research ethics committee context. Equally, the importance of new technical methods of taking individuals' sensitivities into account need to be discussed in the research ethics context. This discussion then is in part about further understanding ethical and social differences between countries, and it is about developing common approaches where such approaches are possible and an awareness of where difference is fundamental. In relation to the EC Ethical Review process, the PRIVILEGED findings point to issues for training of researchers.

There are a number of further projects, some of whom PRIVILEGED already has links. In other areas, there is a lack of awareness of the work that has been undertaken. There remains a need for more effective communication with research funders and with other projects to ensure that ideas are widely discussed. Whilst the publications and website of PRIVILEGED will go some way to ensuring that this dissemination is achieved, there is a continuing need for connections to be made and maintained between researchers in the area, and especially are an interdisciplinary level and within different parts of the Commission (particularly between Science and Society and DG Sanco).

Appendix 1:

National Laws relating to Medical Research Using Genetic Information and Biobanking

	Biobank	Data Protection	Human Tissue	Genetic Information	Biotechnology Research	Clinical Trials	Good Clinical Practice	(Research) Ethics Committee
<b>Austria</b>	X	Data Protection Act, amended most recently in 2009 (BGBl. I Nr. 35/2009)	Tissue Safety Act (BGBl. I Nr. 49/2008)	Gene Technology Act modified 2006 (BGBl. I Nr. 13/2006)	X	The Medicines Act 1983, amended most recently in 2009 (BGBl. I Nr. 63/2009)	The Medicines Act 1983, amended most recently in 2009 (BGBl. I Nr. 3/2009); GCP-Richtlinie	Federal order of June, 2001 (BGBl. II Nr. 226/2001) (Bioethics Commission); The University Act 2002, modified in 2009 (BGBl. I Nr. 81/2009); The Hospitals Act 1957, under which ethics committees were first established, modified in 2009 (BGBl. I Nr. 124/2009); Medicines Act; Medical Devices Act
<b>Belgium</b>		Law of December 8, 1992 on Privacy Protection in relation to the Processing of Personal Data modified by the law of December 11, 1998 and implemented by Royal Decree of 13 Feb 2001.	Act on the Removal and Transplantation of Organs (2006), amended in 2007; Law 19th December 2008 regulating the procurement and use of human bodily material for medical application to humans and for scientific research; Royal Decree (1987) regarding the Expression of Consent for the Removal of Organs and Tissues on Living Donors; Royal Decree (1997) regarding the Removal and Allocation of Organs of Human Origin			Law relating to Experimentation on Humans, amended by Law of 27 December 2004.		Royal Decree of 27 September 1994; Royal Decree of 22 September 1992

	Biobank	Data Protection	Human Tissue	Genetic Information	Biotechnology Research	Clinical Trials	Good Clinical Practice	(Research) Ethics Committee
<b>Bulgaria</b>	X	Personal Data Protection Act 2007; Health Care Act	Health Care Act; Law on Transplantation of Organ, Tissues and Cells (2006); Regulation No. 13 of 4 April 2007 for the Terms and Conditions of Informing Bulgarian Citizens on the Activities regarding the Transplantation of Organs, Tissues and Cells	Chapter IV in Health law act "Genetic Health and genetic tests" - art. 137-144	x	Regulation 26 of the Ministry of Health (1995); Regulation 14 of the Ministry of Health of 2000 and Law on drugs and pharmacies for human use, as amended; Law on the Medicinal Products in Human Medicine SG1 No. 31 of 13 April 2007	Regulation No. 31 for Determining the Principles of Good Clinical Practice	Regulation 26 of the Ministry of Health (1995); Regulation 14 of the Ministry of Health of 2000 and Law on drugs and pharmacies for human use, as amended
<b>Cyprus</b>		Processing of Personal Data Law 2001 (138 (I)/2001), as amended in 2003, through Law No. 37(I)/2003					Law for Good Clinical Practice (2004)	The Bioethics (Establishment and Function of the National Committee) Law of 2001
<b>Czech Republic</b>	Act No. 296/2008 Coll. - Human Tissue and Cells Act; Act No. 422/2008 Coll. – on quality and safety of the use of human tissues and cells	Act on the Protection of Personal Data and on Amendment to Some Related Acts (No. 101 of April 4, 2000)	Act No. 296/2008 Coll. - Human Tissue and Cells Act; Act No. 422/2008 Coll. – on quality and safety of the use of human tissues and cells	Act No. 321/2006 Coll. Amending the current Criminal Law (§ 114, 2); Police Act (§ 42e, 1e)	Act 78/2004 Coll. - On dealing with genetically modified organisms and genetic products	Act on Pharmaceuticals 378/2007	Regulation No. 228/2008 on Good Clinical Praxis and Clinical Trials; Decree No. 226/2008 on Good Clinical Practices and on Detailed Conditions for Evaluation of Pharmaceutical Products	Act on Pharmaceuticals 378/2007; Regulation No. 228/2008 on Good Clinical Praxis and Clinical Trials; Decree No. 226/2008 on Good Clinical Practices and on Detailed Conditions for Evaluation of Pharmaceutical Products
<b>Denmark</b>	Guideline No. 83 of 22 September 2004 on Biobanks in the Health Care Services – Patients Rights and Duties of the Authorities	Act on Processing of personal Data No. 429 of 31 May 2000 with later amendments	The Tissue Act - Law No. 273 of 1 April 2006); Ministerial Order No. 966 of 22 September 2004 on the 'Use of Tissue Register'; Act on Health - Consolidation Act No. 95 of 7 February 2008 with later amendments; Health Law, Chapter 7 (2005)	Regulations regarding the use of genetic information in insurance- and employment relations		Medicinal Product Act 382 of 28 May 2003 , which came into effect on 1 May 2004; Executive Order No. 295 of 26 April 2004	Executive Order No. 935 on Informed Consent from Patients in Biomedical Trials (2000); Executive Order on Clinical Trials on Medicinal Products, Human Use (2004); Danish Guideline on Notification of Clinical Trials of Medicinal Products in Humans (2004)	Act on a Scientific Ethics Committee System No. 402 of 28.5.03, amending the Medicines Act No. 656 of 28.07.95; Law 382 of 28 May 2003; Data Protection Law

	Biobank	Data Protection	Human Tissue	Genetic Information	Biotechnology Research	Clinical Trials	Good Clinical Practice	(Research) Ethics Committee
<b>Estonia</b>	Human Genes Research Act RT I 2000, 104, 685 (December 13, 2000), amended, in 2007 RT I 2007, 22, 111 and 2010 RT I 2010, 37, 221.	Personal Data Protection Act 2008; Public Information Act 2001, last amendment in 2010.	Handling and Transplantation of Cells, Tissues and Organs Act RT I 2008, 25, 163; Identification of the Causes of Death Act RT I 20056, 24, 179.	X	X	Medicinal Products Act, RT I 2005, 2, 4 (latest amendment in 2010); Regulation No. 23 of the Minister of Social Affairs of 17 February 2005; Minister of Social Affairs Regulation No. 26 of 17 February 2005; Conditions and Procedure for Conducting Clinical Trials of Medicinal Products. Regulation No. 23 (2005); RTL 2001, 90, 1258; Requirements for Membership of Medical Ethics Committees for Clinical Trials, Rules of Procedures for Committee, Rate of Fee for Evaluation of Clinical Trials, and List of Information to be Submitted in Order to Obtain Approval (2001)	Minister of Social Affairs Regulation No. 17 of 17 February 2005	Rules of procedure of medical ethics committee for clinical trials, a list of data to be submitted for obtaining approval, procedure for adoption of resolutions and format of application for obtaining approval, Minister of Social Affairs Regulation No. 17 of 17 February 2005 (RTL 2005, 22, 298), entered into force 1 March 2005.
<b>Finland</b>	X	Finnish Act on Personal Data (Act No. 523/1999); Act on the amendment of the Personal Data Act No. 986/2000. Further amendments: Act 528/2007, Act 512/2008 and Act 294/2010	Act on the Medical Use of Tissues and Organs (No. 101/2001) Amendments: Act 547/2007, Act 778/2009 and Act 653/2010	Gene Technology Act (No.377/1995) Amendments: Act 1019/1995, Act 90/2000, Act 414/2002, Act 847/2004, Act 387/2009, Act 782/2009, Act 1002/2009 and Act 955/2010	Gene Technology Act (No. 377/1995) Amendments: Act 1019/1995, Act 90/2000, Act 414/2002, Act 847/2004, Act 387/2009, Act 782/2009, Act 1002/2009 and Act 955/2010	Medical Research Act (295/2004), amendments Act 295/2004, Act 375/2009, Act 780/2009, Act 1556/2009 and Act 794/2010; Medicines Act and Decree No. 296/2004	Regulation 1/2007 on Clinical Trials on Medicinal Products in Human Subjects; Decree 841/2010 on clinical trials	Medical Research Act (295/2004), amendments Act 295/2004, Act 375/2009, Act 780/2009, Act 1556/2009 and Act 794/2010; Decree on the National Research Ethics Council of Finland No. 1347/2002

	Biobank	Data Protection	Human Tissue	Genetic Information	Biotechnology Research	Clinical Trials	Good Clinical Practice	(Research) Ethics Committee
<b>France</b>		Data Protection Act (Law 2004-801 of 6 August 2004 modifying law 78-17 of 6 January 1978 relating to the Protection of Data Subjects as Regards the Processing of Personal Data); Decree No. 2005-1309 of 20 October 2005 Enacted for the Application of Act No. 78-17 of 6 January 1978 on Data Processing, Files and Individual Liberties (Amended by Decree 2007-451 of 25 March 2007)	Donation and Use of the Components and Products of the Human Body (2004)			Law Hurriet-Serusclet of 20th December 1988, amended by the Law of 9th August 2004; Medications for Human Use (2004)		Law Hurriet-Serusclet of 20th December 1988, amended by the Law of 9th August 2004; Decree No. 97-555 Concerning the National Consultative Ethics Committee for Health and Life Sciences (1997)
<b>Germany</b>	X	Federal Data Protection Act, as amended 2003.	Transplantation Law (2007); Transfusion Law (2007); Act of Quality and Security of Human Tissue and Cells (2007)	Human Genetic Examination Act 2010 (Genetic Diagnosis Act) Covers genetic testing for medical purposes, testing for the purposes of determining descent, as well as testing in the insurance and employment sectors, but not to testing for research purposes.	x	Medicinal Product Act 2008; Act on Medical Devices 2002; Promulgation on the Principles of the Conduct of Clinical Trials of Drugs According to the Rules (1987), Second Promulgation on the Clinical Trial of Drugs in Human (1997); Principles and Responsibilities Related to Clinical Studies (2003)	Decree on Good Clinical Practice, Regulation for the Application of Good Clinical Practice of Clinical Medications for Human Use (2006)	Federal Decree 2 may, 2001; Medicinal Products Act (MPG); The Medicinal Drugs Act (AMG); amended 2004 Transfusion Act 1998

	Biobank	Data Protection	Human Tissue	Genetic Information	Biotechnology Research	Clinical Trials	Good Clinical Practice	(Research) Ethics Committee
<b>Greece</b>	Law 3089/2002 (Official Gazette A327/23.12.2002 (Medically Assisted Human Reproduction) 10; Law 3305/2005 (Official Gazette A 17/27.1.2005) (Implementation of Medically Assisted Reproduction); DNA Database Law 2008	Data Protection Act - Law 2472/1997, amended by Laws 2819/2000 and 2915/2001; Penal Code art. 371; Law 2619/1998, art. 10 (Convention of Oviedo)	Law 2737/1999 Official Gazette A 174/27.8.1999 (Transplantations of human tissues and organs and other regulations); Presidential Decree 26/2008 Official Gazette 51/24.4.2008 (Harmonization of the Greek legislation with Directive 2004/23 of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells	Greek Constitution 1975/1986/2001, Article 5.5; law 2619/98 (Biomedicine Convention of the Council of Europe) (1998) 3089/2002 (Official Gazette A 327/23.12.2002); Law 3305/2005 (Official Gazette A 17/27.1.2005)	Law 3418/2005 Official Gazette 12.1984 on (Code of Medical Ethics) Articles 24-26	Ministerial Decision A6/10983/1/12-20.1984 on Protection of the Human Being (1984) AND Ministerial Decision DYG3/89292/31.1.2.2003 (2003); Articles 24-26 Law 3418/2005 Official Gazette A '287/28.11.2005 (Code of Medical Ethics)	Articles 2, 3, 4, 89, 10, Law 3418/2005 Official Gazette A '287/28.11.2005 (Code of Medical Ethics)	A2/oik3061/5.6.1978; A6/10983/1/12.12/1984; Law 2071/1992; Law 2519/1997; Data protection Act 2472/1992
<b>Hungary</b>	Act XXI of 2008 on the Rules of Protection of Human Genetic Data, of Human Genetic Examinations and Research and of the Operation of Biobanks	Act LXIII of 1992 on Protection of Personal Data and Disclosure of Data of Public Interest, Amended by the Parliamentary Act No XLVIII of 2003; Act XLVII of 1997 on the Handling of Medical and Other Related Data	Act LXXX of 2006 on the Promulgation of the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Transplantation of Organs and Tissues of Human Origin; Decree 18/1998 (XII 27) EüM on Implementing Act CLIV of 1997 on Health Care as regards Transplantation and Storage of Organs and Tissues and Certain Histopathology Examinations	Act XXI of 2008 on the Rules of Protection of Human Genetic Data, of Human Genetic Examinations and Research and of the Operation of Biobanks		Act XCV of 2005 on Medicinal Products for Human Use; Decree 35/2005 (VIII. 26) of the Minister of Health on Clinical Trials of Medicinal Products for Human Use and Good Clinical Practice; Decree 235/2009. (X. 20.) Governmental decree on the licensing procedures of the biomedical research of the therapeutic products intended for the human use and medical technological equipments; Chapter VIII. within the Health Care Act No CLIV of 1997 on biomedical research	Decree 35/2005 (VIII. 26) of the Minister of Health on Clinical Trials of Medicinal Products for Human Use and Good Clinical Practice; Decree 24/2002. (V.9.) EUM of the Minister of Health relating to the implementation of good clinical practice in the conduct of clinical trials on investigational medicinal products for human use	23/2002 (V9) EuM decree on biomedical research on human beings; 34/2003 (V1.7) ESZCSM Health Science Council (ETT)

	Biobank	Data Protection	Human Tissue	Genetic Information	Biotechnology Research	Clinical Trials	Good Clinical Practice	(Research) Ethics Committee
<b>Iceland</b>	Act on Biobanks No. 110/2000	Act on the Protection of Privacy as regards the Processing of Personal Data, No. 77/2000, as amended (2003); Government Regulation on a Health Sector Database No. 32 (2000)	Regulations on the keeping and utilisation of biological samples in biobanks No 134/2001	Act on a Health Sector Database no. 139/1998		Medicinal Products Act No. 93; Regulation on Clinical Trials of Medicinal Products in Humans No. 443 (2004)		Regulation on Scientific Research in the Biomedical Field, No. 286 (2008)
<b>Israel</b>	Ministry of Health Regulations on the Establishment and Utilisation of Genetic Samples Banks (2005), on biobanks for medical research	Protection of Privacy Law	Ministry of Health Regulations on the Establishment and Utilisation of Genetic Samples Banks (2005), on biobanks for medical research	The Genetic Information Law (2000)		2006 Guidelines for Clinical Trials in Human Subjects in accordance with the Public Health Regulations (Clinical Trials in Human Subjects) 1980		
<b>Italy</b>		Legislative decree no. 196/2003; Administrative Decree: Electronic Data Transmission Pertaining to Clinical Medical Experimentation (May 25, 2000); Administrative Decree: Electronic Data Transmission Pertaining to Clinical Medical Experimentation (May 25, 2000); Regulation for the Implementation of Articles No. 20 and 21 of the Legislative Decree No. 196 of June 30, 2003	Act no. 91/1999 – ‘Provisions Concerning Organ and Tissue Collection and Transplantation’			Legislative Decree no. 211 of 24 June 2003; Ministerial Decree of 17th December, 2004; Decree of the President of the Republic: Regulations to Simplify the Procedures and to Verify and Check New Systems and Experimental Therapeutic Protocols (September 21, 2001)	Legislative Decree No. 211: Transposition of Directive 2001/20/EC Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Clinical Use (2003) Regional Bioethics Committees (1999)	Legislative Decree no. 502 30 December 1992; Ministerial Decree 23 November 1999; Statute on the National Federation of Ethics Committees (1995); Ministerial Decree: Terms of Reference for the Establishment and the Functioning of Ethics Committees (May 12, 2006)



	Biobank	Data Protection	Human Tissue	Genetic Information	Biotechnology Research	Clinical Trials	Good Clinical Practice	(Research) Ethics Committee
<b>Lithuania</b>	X	The Law on Legal Protection of Personal Data No. X-1444 (2008)	The Law on Ethics of Biomedical Research No. VIII-1679 (2007); Law on Human Tissue and Organ Donation and Transplantation (2006); Decree on the Conditions of and the Procedure for the Donation, Procurement, Testing, Processing, Preservation, Storage, Distribution of Human Tissues and Cells No. V-397 (2007)			The Law on Ethics of Biomedical Research No. VIII-1679 (2007); Ministry of Health Decree of May 11 2004; Law on Pharmacy (2010); Health Care Ministry Decree on the Procedure to Issue Approvals to Conduct Clinical Trial on Medicinal Product, No. V-435 (2010)	Decree on the Rules of Good Clinical Practice, No. 320 (2006)	Law on Ethics of Biomedical Research No. VIII-1679 (2007); Ministry of Health Decrees on: Procedure to Issue Approvals to Conduct Biomedical Research 2000; Procedure for the Estimation & Covering of Expenses Incurred by Research Subjects; List of Documents to be presented by the sponsor of Biomedical Research; Law on Legal Protection of Personal Data 2003
<b>Malta</b>		Data Protection Act of 2006	ACT IV of 2006 (Human Blood and Transplants Act), as amended by legal notice 427 of 2007, chapter 483 (also applicable to human tissues and cells intended for human transplants)			Medicines Act, 2003 As amended by Act No. III of 2004; Legal Notice 490: Clinical Trials Regulations 2004		
<b>Netherlands</b>		Personal Data Protection Act 2004	Safety and Quality of Human Tissues Act of 6 February 2003; Requirements for Human Tissue Decree 2006; Civil Code, article 467 (1994)			Medical Research Involving Human Subjects Act 2006; New Medicines Act of 8 February 2007, which came into force 1 July 2007; Medicine Act Decree (2007); Medicine Act Regulation (2007)	Act of 24 November 2005, modifying the Medical Research Involving Human Subjects Act and the Medicines Act, implementing Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use	Medical Research Involving Human Subjects Act 2006

	Biobank	Data Protection	Human Tissue	Genetic Information	Biotechnology Research	Clinical Trials	Good Clinical Practice	(Research) Ethics Committee
<b>Norway</b>	The Act on Medical and Health Research - Health Research Act, implemented on 1 July 2009. Replaced the Personal Data Act, the Personal Health Data Filing System Act, the Act on Health Data and the Filing System Act, <b>The Act on Biobanks</b> and the Act on Human Medicine the Application of Biotechnology in Human Medicine Health with regard to medical and health research.	The Act on Medical and Health Research - Health Research Act, implemented on 1 July 2009. Replaced the <b>Personal Data Act</b> , the Personal Health Data Filing System Act, The Act on Biobanks and the Application of Biotechnology in Human Health with regard to medical research.	The Act on Medical and Health Research - Health Research Act) Research biobanks and research involving human biological material are regulated in Chapter 6	Act on the Application of Biotechnology 2003	The Act on Medical and Health Research - Health Research Act, implemented on 1 July 2009. Replaced the Personal Data Act, the Personal Health Data Filing System Act, The Act on Biobanks and the Act on the Application of Biotechnology in Human Medicine Health with regard to medical and health research.	FOR 2003-09-24 nr 1202: Regulation relating to clinical trials on medicinal products for human use (2003)		Biobank law; Freedom of Information Act; Public Administration Act
<b>Poland</b>		Act on the Protection of Personal Data (2006)	The Polish Transplantation Act (2005); Laboratory Diagnostics Act (2001); The Medical Devices Act (2004); Act of 26 October 1995 on the Collection and Transplantation of Cells			Medical Profession Act 1996; Ministry of Health Decree 1999; Ministry of Health Decree 2002; Ministry of Health Act Nr.221 poz.1864; Pharmaceutical Law, Act of Sept. 6, 2001, Article 6; Law of 20/04/2004 on Amendment of the Pharmaceutical Law, Law on the Profession of Medical Doctor, and Regulations Introducing the Pharmaceutical Law, Law on Medical Devices, and Law on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Journal of Laws No. 92, Item 882)	March 11, 2005 Order of the Minister of Health Concerning Detailed Requirements of Good Clinical Practice (2005); Ministry of Health Decree 1999; Ministry of Health Decree 2002	Medical Profession Act 1996; Ministry of Health Decree 1999; Ministry of Health Decree 2002

	Biobank	Data Protection	Human Tissue	Genetic Information	Biotechnology Research	Clinical Trials	Good Clinical Practice	(Research) Ethics Committee
<b>Portugal</b>	Act on personal genetic information and information regarding health, Law no. 12/2005 (also regulates banks of biological material)	Data Protection Act, Law no. 67/98, October 26	Law no. 12/2009, March 26	Act on personal genetic information and information regarding health, Law no. 12/2005, January 26; Data Protection Act, Law no. 67/98, October 26; Law no. 5/2008, February 12	Decree-Law no. 36/2003, March 5 (Code of Intellectual Property)	Approval of the Applicable Legal Standards for the Conduct of Clinical Trials of Medicines for Human Use, Law No. 46/2004, August 19 Decree-Law No. 102/2007 of April 2; Decree-Law No. 102/2007, April 2	Doctors' Code of Practice, Regulation no. 14/2009, January 13	Decree-law No. 97/95, May 10; Law no. 46/2004, August 19; Regulation no. 57/2005 January 20
<b>Slovakia</b>		Act on the Protection of Personal Data in Information Systems; Act No. 489/2008 Coll. on Personal Data Protection; Coll. on Protection of Personal Data (English consolidated version), as amended by Act 90/2005 Coll.	Act No. 576/2004 Coll. On Health Care, sections 35-39; Act No. 489/2008 Coll. On Drugs and Medical devices, Section 18 (296); Governmental Regulation No. 20/2007 Coll. On Tissue and Cell Collection			Act on Drugs and Medical Devices No. 140/1998, Coll., as amended by Acts No. 9/2004, 542/2006, 489/2008 and 402/2009 Coll.	Ministerial Regulation No. 239/2004 Coll. on Clinical Investigations and Requirements for Good Clinical Practice (2004), as amended by Ministerial Regulation No. 148/2009 Coll.	Law 140/1998 on Drugs & Health Equipment; Law 277/1994 on Health Care Laws 13,14,27/1992
<b>Slovenia</b>		Personal Data Protection Act No. 59 (1999); Act Amending the Personal Data Protection Act No. 57/2001	Act for Quality and safety of tissues and cells for the medical treatment since 2007; Regulations on Interventions into the Human Corpse Which are not Part of the Routine Autopsy and on Handling with Biologic Material of Human Origin (2004)			Slovenian Directive on Clinical Drug Testing No. 67.8372-8385 (2000)		Regulations on the Ethical Review of Phase IV Clinical Studies (2003); Slovenian Directive on Clinical Drug Testing No. 67.8372-8385 (2000)

	Biobank	Data Protection	Human Tissue	Genetic Information	Biotechnology Research	Clinical Trials	Good Clinical Practice	(Research) Ethics Committee
<b>Spain</b>	Ley 14/2007 (Not specific for Biobanks but applies to biomedical research (Chapter IV is on Biobanks - articles 63-71); <i>as at January 2011, Royal Decree pending</i> )	Data Protection Act 15/1999, December 13; Real Decreto 1720/2007, December 21; Ley 41/2002, November 14 (applies to health data protection patient's autonomy and rights and obligations on clinical information and documentation)	Royal Decree 1301/2006 of November 10 Regarding the Use of Cells and Human Tissue; Royal Decree 2070/1999 of 30 December, Regarding Activities of Collection and Clinical Use of Human Organs for Organ Transplants and Tissues; Law 14/2007 of July 3 on Biomedical Research, Title I, Article 11, Title III, Article 37, Title V; Royal Decree 65/2006 of 30 January, Requirements for the Import and Export of Biological Samples (2006)	Law 14/2007 of July 3 on Biomedical Research: Title I: General Provisions (arts. 1-12); Title V: "Genetic analysis, biological samples and biobanks. This title has four chapters: Chapter I: General provisions (Arts. 44-45); Chapter II: Genetic analysis and the treatment of personal genetic data (arts. 46-57); Chapter III Use of human biological samples for biomedical research (arts. 58-62); Chapter IV: Biobanks (arts. 63-71)	No specific law exists - But with regard to genetic modified organisms Law 9/3003, of 25 April and Royal Decree 178/2004, of 30 January apply	Royal Decree (Regulation of Medication Clinical Trials) 223/2004, Article 60, 62 and 65 of Law 25/1990	Order SCO/ 256/2007 That Establishes the Principles and Detailed Directives on Good Clinical Practice, and the Requirements to Approve the Manufacture and Import of Research Medications for Human Use	Law 25/1990 on Medicines; Royal decree 561/1993 which establishes requirements for the accomplishment of clinical trials using medicines; Royal Decree 223/2004 clinical trials with medicines – Chapter III is dedicated to Ethics Committees of Clinical Research
<b>Sweden</b>	Biobanks in Health Care Act (2002:297), May 23 2002; Promulgated January 1, 2003	Personal Data Act (1998:204); Police Data Act (1998:622); Act (1998:543) on Health Data Registers; Act (1999:353) on Research Registers for Forensic Psychiatry; Patient Data Act (2008:355)	Act (2008:286) on standards of quality and safety in use of human tissues and cells	Act (2006:351) on Genetic Integrity	Swedish Patent Act(1967:837)	Act (2003:460) on Ethics Review of Research Involving of Humans; Pharmaceuticals Act No. 1992: 859; Medicinal Products Agency's regulations dealing with Clinical trials of medicinal products (1996:17)	Act (2003:460) on Ethics Review of Research Involving Humans; Pharmaceuticals Act No. 1992: 859; Medicinal Agency's regulations dealing with Clinical trials of medicinal products (1996:17)	Act (2003:460) on Ethics Review of Research; Act (2002:297) on Biobanks in Health Care; Ordinances: 2003:515, 616 & 617; Government Bill: 2002/03: 50

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<b>UK</b>		Data Protection Act 1998	Human Tissue Act 2004; Human Tissue (Scotland) Act 2006; Statutory Instrument 2006 No. 1260, The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006; Statutory Instrument 2006 No. 1659, The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006; Codes of Practice of the Human Tissue Authority			Medicines Act 1968; Medicines for Human Use Regulations 2004, Statutory Instrument No. 1031; Amendment Regulations, Statutory Instrument 2006/1928	Medical Research Council Guidelines for Good Clinical Practice in Clinical Trials (1998)	Medicines for Human Use Regulations 2004