

Summary of Project Recommendations

Questions of Regulation of Medical Research Using Genetic information and Biobanking: The PRIVILEGED Project.

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 pri-

vacancy, 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 FP6¹. It was a co-ordinating action² 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 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);

¹ 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).

² 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.

- 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 up-dating 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.

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