

STAGE TWO NEWSLETTER

Stage Two of the PRIVILEGED project focussed on identifying which common themes from existing expressions of the concept of privacy in relation to the use of genetic information and biobanks for research are present in the law. Differences in privacy interests expressed by individuals uncovered through existing sociological research across Europe in Stage One and those identified in the law in Stage Two will feed into the overall project recommendations for research practice and public policy to promote an optimal relationship between research, data protection, and privacy interests. Based on these analyses five key areas were identified that require detailed consideration. These themes pose particular difficulties for the protection of privacy in relation to genetic information and biobanking. An important conclusion drawn from the Stage One literature surveys is that there is no consensus in the expressions of privacy interests. There are differing opinions within a wide range of expressed beliefs. For example, majorities in different studies express a reluctance to accept the use of genetic information and the gathering of biobanks for the use of genetic data in prevention or detection of crime (public social control) and in relation to commercial interests, such as insurance premium determination or employment decisions (commercial social control). Insurance is an interesting pivot point to what can be described as commercial health.

There is expressed reluctance to allow the use of genetic data in setting health insurance premiums. However, within commercial health, there is a broader spectrum represented about the rights of commercial exploitation of, for example, drug development through research in genetic information or biobanking. The use of genetic information and biobanking in the area that could be described as public benefit health again displays a spectrum, but one that is more open to the use of data both for individuals' and society's benefit. The most interesting aspect of the stage one literature studies is how to read a variety of different studies. They cannot be aggregated; their methodologies are so very different. They offer a picture of a range of concerns. The legal regimes however show a narrower range of privacy interests. For example, 'proprietary privacy' rarely extends into full ownership in the hands of the donor; informed consent is a gold standard in health law; and the regime, particularly data protection, is constructed on an individual data subject, rather than group based right. The next page shows the key areas of concern that emerge for the consortium members from the first two stages of the work. The final recommendations will seek to enable policy makers to see the available spectrum of choice.

Publications

Material from Stages One and Two will be published in a special edition of the Portuguese journal *Lex Medicinæ*, and on the website. The publications from Stage One will include an introduction to the concept of privacy used in PRIVILEGED; a summary of the privacy interests expressed in selected countries on research involving genetic databases and biobanks; an article on whether there is a European perspective on relevant privacy interests; and selected outstanding articles from the members of the PRIVILEGED consortium on relevant privacy interests expressed in their countries. Stage two material to be published includes: a summary of international and European legal instruments and case-law regarding privacy, both in general and specifically in relation to genetic data and samples; an article on the regulation protecting the privacy of genetic information in PRIVILEGED countries; a linked article on the regulation protecting privacy in biological samples; and selected outstanding articles from the members of the PRIVILEGED consortium on regulation in their countries. Country reports from stages one and two will be published on the PRIVILEGED website, and in the German journal *Law and Ethics in the life Sciences*. Stage Three papers will be published in a special issue of *Medical Law International*.

Access

Who should have access to the data and tissues held in genetic databases and biobanks? A key theme of this paper is the limits of privacy. While supporting robust medical research may promote decisional privacy interests; balancing interests in genetic research may mean that other privacy interests cannot be recognised.

Consent

What are the information requirements for a valid consent in genetic research? This paper considers the challenges of broad, presumed, and group consents; opting out; re-contacting individuals to keep them informed; and the consequences of withdrawal.

Tissue

Do we need to look beyond the data protection and clinical trials regimes to regulate research using tissue? These regimes are evaluated by considering the factual differences between tissues and data lead to legal implications.

Scope of Personal Data

Can the definition of personal data in the Data Protection Directive be interpreted to include tissues, relatives or deceased persons? This paper focuses on the terms „relating to“ within the definition of personal data in the Directive, questioning to what extent relatives are also data subjects for genetic data.

Research Exemption

Is it legitimate to provide exemptions to the data protection requirements for research purposes? The paper considers the range of „safeguards“ put in place when using the research exemption, and the different regimes for the secondary use of data (and issues). Do existing legal instruments balance the different interests in biobanks and genetic research; protecting privacy and insuring public trust?

Five Key Issues

In Stage Three more specific project recommendations are developed by focussing on five key areas important for the protection of privacy when either genetic information or tissue samples are used in research. Consideration of these key areas has important implications for privacy in health-care in general for three reasons:

1. The increasing application of genetic testing within the health care systems;
2. Research using genetic databases and biobanks gathers increasing amounts of information through linking to the health-care record or through clinicians who request information directly from the patient blurring lines between health care and research; and,
3. It re-opens and challenges key areas of health law, previously considered closed, and requires re-consideration of individual, group and societal rights in health research and care.

Principal Investigators

Mr. D.M.R. Townend, Maastricht University, NL and Dr. M.J. Taylor, University of Sheffield, UK

Contact Details

Email:
privileged@sheffield.ac.uk
Phone:
0031 43 388 1124
Website:
www.privilegedproject.eu