



EU-US Privacy Shield to once again ensure safe harbours for data transfers

The annulled Safe Harbour agreement puts research collaborations in a peculiar position. Here, Jane Reichel, Professor of Administrative Law, gives an update on the negotiations.

THE EU COMMISSION recently presented a draft “adequacy-decision” with results of the negotiations with the USA on safe data transfer across the Atlantic, the EU-US Privacy Shield. This is a follow up on the previous, now annulled, Safe Harbour agreement. The decision includes the privacy principles that US organisations will need to apply in order to comply with EU law. It is drafted as a general decision, but is mainly directed to commercial organisations.

THE EU-US PRIVACY SHIELD is based on self-certification, where US organisations who have committed to the privacy principles are included on a list maintained by the US Department of Commerce. A yearly re-evaluation of the commitment is also foreseen. The Privacy Shield applies to EU data being processed in the USA: Before transfer, the EU controller must ensure that there is a legal basis allowing for the data to be sent, for example an informed consent. The Privacy Principles consist of 13 Framework Principles corresponding to basic data principles in the Data Protection Directive and Supplemental Principles, including specifications and exceptions to framework principles and informational and institutional rules for the US data controllers to abide by. These principles can be found in annex II to the decision.

AMONG THE FRAMEWORK PRINCIPLES are a notice principle and a choice principle. The first requires organisations to provide information to data subjects on key elements relating to

processing of personal data. The choice principle means data subjects can choose to opt out if their personal data is disclosed to third parties. For sensitive data, organizations must obtain new consent (opt in) before disclosing such information to a third party or using it for new

purposes. The Supplementary Principles offers some exceptions in relation to pharmaceutical and medical products (Article 14). A certain leeway is given regarding consent for future use. As long as the notice to the data subject has included an explanation that personal data may be used in future, yet unanticipated, medical and pharmaceutical research, data may be used for a new scientific research activity. However, there are clear limits to how broad the consent may be. On the other hand, key-coded data could, under certain circumstances, be considered not to be personal data (Article 14 g), meaning that the Privacy Shield Principles do not have to be upheld at all. The next step in the procedure is for the EU Article 29 Working Group to state an opinion whether the draft decision can be considered to be in compliance with fundamental EU law on data privacy rights.



Effective consent for effective research

by Josepine Fernow

New sequencing techniques and the increasing sharing of data in international research consortia challenges the informed consent process, adding complexities that need to be co-ordinated.



IN A RECENT ARTICLE in the European Journal of Human Genetics, a group of researchers point to rare disease research consortia. They present a special challenge to informed consent procedures because the data and samples available is very limited. If the aim is to ensure the best use of available resources and, at the same time, protect patient’s rights to integrity, these consortia have an ethical duty to plan ahead: They need to ensure the best consent procedures are in place and address ethical and legal hurdles that could hamper future research.

THE RD-CONNECT CONSORTIUM have met this challenge by identifying key core elements for informed consent in international collaborative research for new collections, but also for collections that don’t have informed consent or where previous consent doesn’t cover all elements. According to Deborah Mascalonzi, Senior Researcher at CRB, one of the authors and part of the RD-Connect consortium, this work is relevant to all international collaborative rare-disease projects.

Direct-to-consumer genetic testing companies lack clear consent processes for biobanking and research

By Josepine Fernow

Whole genome and exome sequencing are becoming cheaper and more available. High throughput techniques are no longer for research only. Today, both patients and consumers can have their genome sequenced.

EMILIA NIEMIEC AND Heidi C. Howard have studied the policies for storage and future use of consumer's data and samples on four company websites. Some of these companies may store and use consumer's samples and sequencing data for unspecified research and share the data with third parties. But the information consumers receive about this is often not adequate, or transparent, and could undermine the validity of the consent process.

ALL FOUR COMPANIES stated that they provide privacy safeguards for data. They also mention the limitations of these, but they are not providing information about the possibility of re-identification based on large amounts of sequencing data. Despite the fact that these companies include information regarding proprietary claims and commercialization of results of (possible) future research, it is not clear whether consumers are aware of the consequences of these policies.

EMILIA NIEMIEC is part of the Joint International PhD Programme in Law, Science and Technology at the University of Bologna and Heidi C. Howard is senior researcher at CRB. According to them, companies need to improve the transparency regarding the



handling of consumer's samples and data. This includes having an explicit and clear consent process for research activities.

SOON, THESE TESTS may be much more difficult to market and offer in Europe. Right now, the European Commission is proposing changes to the European Directive (98/79 EC) on in vitro diagnostic medical devices. In a recent article, Heidi C. Howard and colleagues at KU Leuven outline the main changes and amendments suggested by the European Parliament affecting genetic tests. This includes a clarification of scope of devices, a new risk based classification system, enhanced safety and performance requirements, the need for genetic counseling and prescription to obtain a health-related genetic test, and banning of advertising of tests direct to consumers. These developments have already provoked controversy among stakeholders. If they are adopted we will see a radical change in the European direct-to-consumer genetic testing landscape.

Workshop on genetic data in public research databases

ON APRIL 27-28, the CHIPme COST Action network will arrange a workshop in Bolzano, Italy, entitled Genetic data in public research databases: Which governance mechanisms should apply? National authorities, funding bodies, research database representatives, legal and ethical researchers are invited. For more information, please contact deborah.mascalzoni@crb.uu.se.



Want to discuss ethics?

Have a look, read, and discuss with us at the www.ethicsblog.crb.uu.se or the Swedish sister www.etikbloggen.crb.uu.se

Questions?

If you have questions concerning biobank ethics and law, please feel free to contact

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Recent publications from CRB

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Current developments in the regulation of direct-to-consumer genetic testing in Europe, Kalokairinou L, Howard HC, Borry P, Medical Law International, advance online publication December 7, 2015.

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