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# Biobank perspectives

## current issues in biobank ethics and law



## ELSI: Inter-connecting legal frameworks, ethical and social issues

*BBMRI-ERIC is a joint European platform for biobanking where ELSI service is considered a key asset. Moa Kindström Dahlin, doctor of public law, is the legal expert in the Uppsala team. Here she offers an update.*

BBMRI-ERIC WILL provide a workable research infrastructure to process, share and store human biological samples, including associated medical data. Part of this work is providing a common service for the ethical, legal and societal issues. Our expert team is part of this service with Mats G. Hansson, professor of biomedical ethics, Heidi C. Howard, geneticist and bioethicist, and myself representing public law.

FROM A LEGAL PERSPECTIVE, we map out and analyze the relevant law: locally and globally. Many of the legal themes relate to data protection and sharing of data: Situations where the individual's right to privacy is challenged by the public interest to promote research and gain new knowledge.

LAW IS CONTEXTUAL. The result of its application differs depending on situation, time and place. There is rarely an obvious answer, and often several different interpretations need to be made. When there seems to be a gap in the law, it is up to the lawyers to bridge it. The very idea that law is a system

that provides all the answers means that lawyers are trained to find them all. And if we can't, we have to create them. With this task

comes great power. If a lawyer states that something is a description of what law is, it can be used to argue for policy change.

LEGAL FRAMEWORKS ARE interconnected with ethical and societal issues. One of the main tasks for every lawyer is to handle colliding interests. This is also true for the biobank sphere. Biobank law is a legal field in flux affected by the ongoing international debate over which principles that should be applied and considered most important. This can be seen in interesting court cases, in the negotiations regarding the forthcoming EU-regulation on data protection and national (Swedish) statutes under revision.

THE SPECIFIC LEGAL issues that arise within BBMRI-ERIC pose questions of a more philosophical nature: Where do we draw the line between law and politics? Where does the law end? Being a lawyer in the ELSI-service team demands a high level of trustworthiness when handling these hard and very important legal questions that are also ethical and societal.



**BBMRI-ERIC**

## How people value risk information

by Josepine Fernow

*The Swedish SCAPIS study will identify individual risk factors for heart and lung disease. But how do research participants and patients perceive risk? And what do they want to know? Right now, two doctoral students are looking at people's preferences and perceptions.*

RISK INFORMATION IS complex. Risk can be high or low, sometimes there is treatment, conditions debut at different ages, are more or less severe, sometimes hereditary, and sometimes fatal. Finding out what people want to know requires more than simple 'yes and no' questions. Whole genome sequencing will become more common in biobank studies, and Jennifer Viberg is on her way to finding out whether research participants want information about incidental findings in genetic and genomic research.

THE SCAPIS (Swedish CardioPulmonary bioImage Study) population is large, collecting blood samples and health data from 30,000 men and women between 50 and 64. Hopefully, the results will be implemented in health care. Arvid Puranen is just starting his PhD, looking at how participants perceive risk for disease and how they would like health care professionals to communicate about it. Watch this space for updates!



## Unsafe harbours for researchers

by Anna-Sara Lind

*There are many research projects in Europe that have safe harbour as a legal ground for sharing data between the EU and the US. These projects could now be in a peculiar situation as a judgment from the Court of Justice of the European Union concludes that Safe Harbour is not anymore a legally valid ground for sharing data between countries in the EU and the US.*

THE COURT OF JUSTICE of the EU has during the last years at several occasions ruled in favour for a stronger protection of personal integrity. This development coincides with the intense negotiations of the EU regarding a new regulation for data protection. In a recent case (C-362/14 Schrems v. Data Protection Commissioner), the Court analyzed the possibilities of transferring personal data from the EU to the US. It found that commercial and political interests are less important than the individuals' right to personal integrity. This case concerned the so called Safe Harbour Clauses. The Court ruled that the US cannot be considered to be "a safe harbour" due to the fact that data as such is not protected in American legislation, where national agencies may have direct access to personal data. Further, there is no administrative or judicial infrastructure for individuals to turn to for remedy in case their rights are infringed upon.

FIRST, NATIONAL DATA protection agencies must according to the Court be able to assess the legality of Commission decisions allowing data transfer to third state, in order for the national agencies to fulfil their task of monitoring the compliance of data protection rules safeguarding the fundamental rights. In order to make possible for a national court to refer questions for preliminary rulings to the Court of Justice, the national agencies must be assured a judicial remedy to access the national courts. This is compulsory and should follow directly from national law.

SECOND, ONE NEEDS to identify other, alternative legal grounds for ensuring transfer of personal data cross borders. This could be

informed consent in the individual case or Standard Contractual Clauses. The Court is very clear with the fact that an informed consent needs to include information that the data will be sent to the US and that this country does not have a legal system providing for an adequate level of protection.

But one could question if that is enough. Is it, for example, possible to consent to not having access to court when this right is fundamental in EU law and forms the very basis of the rule of law?

THE EUROPEAN RULES on data protection are interpreted by the EU's Article 29 working party group. This expert group reacted on the Courts ruling within a couple of days. There is, however, still questions remaining that are not easily solved. Following the judgment, the Group conclude that all transfers to the US based upon safe harbour are illegal but that the Group and the national data protection agencies will give politicians and other stake holders in the US and the EU respectively a couple of months to try to negotiate a solution. After this intermediary period, the agencies will decide upon taking common decisions and actions.



### Want to discuss ethics?

Have a look, read, and discuss with us at the [www.ethicsblog.crb.uu.se](http://www.ethicsblog.crb.uu.se) or the Swedish sister [www.etikbloggen.crb.uu.se](http://www.etikbloggen.crb.uu.se)

### Questions?

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

ANNA-SARA LIND,  
Associate Professor of Public Law:  
[anna-sara.lind@crb.uu.se](mailto:anna-sara.lind@crb.uu.se)

MATS G. HANSSON, Director of CRB &  
Professor of Biomedical Ethics:  
[mats.hansson@crb.uu.se](mailto:mats.hansson@crb.uu.se)

### Recent publications from CRB

**The Cooperative Health Research in South Tyrol (CHRIS) study: rationale, objectives, and preliminary results**, Pattaro C, Gögele M, Mascalcioni D, Melotti R, Schwienbacher C, De Grandi A, Foco L, D'Elia Y, Linder B, Fuchsberger C, Minelli C, Egger C, KofinkLs, Zanigni S, Schäfer T, Facheris MF, Smáráson SV, Rossini A, Hicks AA, Weiss H & Pramstaller PP, *Journal of Translational Medicine*, 2015;13:348

**Higher cardiogenic potential of iPSCs derived from cardiac versus skin stromal cells**, Meraviglia V, Wen J, Piacentini L, Camprostrini G, Wang C, Florio MC, Azzimato V, Fassina L, Langes M, Wong J, Miragoli M, Gaetano C, Pompilio G, Barbuti A, DiFrancesco D, Mascalcioni M, Pramstaller PP, Colombo GI, Chen H-S V, Rossini A, *Frontiers in Bioscience, Landmark*, 2016;21(1):719-743

**LifeGene – a closed case?**, Lind A-S, in: Lind A-S, Reichel J, Österdahl I, (Eds.) *Law and Information in Transition - Freedom of Speech, Privacy, Democracy and the Internet in the 21st Century*, Liber förlag, 2015, pp. 339-350

**Transparency in EU research governance? A case study on cross-border biobanking**, Reichel J, in Lind A-S, Reichel J, Österdahl I, (Eds) *Information and Law in Transition – Freedom of Speech, the Internet, Privacy and Democracy in the 21st Century*, Liber, 2015, 30 pp.