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# Biobank perspectives

## current issues in biobank ethics and law



## Information and law in transition

by Anna-Sara Lind

*New information and communication technologies have created exciting new possibilities for connecting individuals across borders and continents but also significant legal, ethical and political concerns.*

A NUMBER OF prominent scholars from Europe and North America analyze the developments of information and law from their respective perspectives in the new book *Information and Law in Transition*. New information and communication technologies have made it possible to create large registries and databases with the potential to lead to effective cross-border law enforcement, foster important new research as well as unwarranted mapping of individual persons' private life. At the same time, new needs of regulating privacy and Internet never cease to emerge. The process of negotiating a Data protection regulation in the European Union is one example illustrating this.

ONE THEME OF the book is entitled *Welfare, health and research* and includes three contributions from CRB researchers. Mats G. Hansson argues for new institutional structures in health care and medical research, aiming at a better balance between privacy and access to health data from registries. Privacy and health are considered important enough to be declared fundamental rights. The question Mats G. Hansson raises in the paper is how these rights and their underlying human interests should be balanced.

I DISCUSS HOW to deal with biobank research from a legal point of view. The case of the Swedish LifeGene project illustrates the complexity and interconnectedness between national and European law in modern welfare state law today.

The different legal systems need to be applied simultaneously, but they are not that easy to reconcile. Several interests have to be realized at the same time and the national interest are not always easy to reconcile with individual fundamental rights or data protection.



JANE REICHEL SETS out to investigate the question how a transparent and efficient, but still secure, regulatory regime for access to human biological samples and health data could be created within the EU. The main obstacle seems to be the lack of competence within the EU to establish an administrative structure for the use of biological samples and supervision of research on health data. A comprehensive approach to the policy area is needed, where existing soft law tools fit together in a bigger picture and act as bridges between national jurisdictions.

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## Swedish research database legislation: update

by Anna-Sara Lind

*Research databases like the Swedish Life Gene project have proven problematic and the Swedish Government has tried to find solutions for collections of samples and data for 'future research', a purpose that the Swedish Data Inspection Board doesn't consider specific enough.*

IN 2013, A TEMPORARY Act on research registries known as the "LifeGene Act" was enacted in order to legalize research conducted on registries that higher education institutions are responsible for. The act will be valid until 31 December 2015.

THIS SPRING, THE Act was reviewed and analysed. On March 24 this year, the Ministry of Education and Research published a memo where they suggested that the temporary Act should be valid until 31 December 2017.

THE REACTIONS TO this have not been silent. The consultation responses show that the reactions can be divided into two camps. On the one side, we find those in favor of the act. Research institutions such as the Swedish Research Council do support a renewal of the act. On the other, we find legal institutions that have a special concern and responsibility for integrity matters: Both the Data Inspection Board and the Chancellor of Justice are very critical.



## Trust based consent looks promising

by Mats G. Hansson

*Finding a model for informed consent that protects the integrity and interests of participants, future patients and researchers isn't easy. Recently, a group in Milano tested a trust based consent that I think looks promising.*

THE EUROPEAN INSTITUTE of Oncology (IEO) in Milano has designed and tested a new information and consent procedure for its tissue bank, the IEO Biobank and Biomolecular Resource Infrastructure (IBBRI).

THIS NEW MODEL of trust-based consent is a modified version of broad consent that has proven successful both for information to participants and for providing a useful resource for important research. The participants are informed that this participation pact concerns only and exclusively the collection and the use of biological materials, current and future medical records for research purposes, including the use of information that is generated by the research. They are informed that the biospecimens will be used for future, not yet specified research and about the different measures that are taken to protect data against unauthorised use.

THIS PACT FOR research represents a promising approach for biobank systems. 97.2 % of the participants accepted on this basis the use of identifiable data for broad and future purposes. The model shows



how trust can be maintained without having to go at lengthy and burdensome procedures for re-consent by using a broad consent in this way.

HAVING FOLLOWED THE discussions on informed consent for the better part of my career, I think this looks like a promising solution to the dilemma of weighing the interests of future patients, research participants and research.

The full article was recently accepted in *Bioethics*: Sanchini V, Bonizzi G, Disalvatore D, Monturano M, Pece S, Viale G, Di Fiore PP, Boniolo G, A trust-based pact in research practice. From theory to practice (In press). Virginia Sanchini will also present this trust-based model during the HandsOn: Biobanks Conference in Milano at the Ethics Round Table Discussion on 30th July, 10.am.

### HandsOn: Biobanks

29-31 July, Milan, Italy  
<http://handsonbiobanks.org>

## Do people want to know about risk?

by Josepine Fernow

*Sometimes researchers find unexpected information about participants in genetic studies. Asking people if they want this kind of risk information returned to them seems like a good idea. But is it fair to leave them to make that decision?*

SHIFTING THE RESPONSIBILITY from researcher to participant comes with a number of problems. Genetic risk information has uncertain predictive value. But there is another uncertainty: By asking people yes or no questions, researchers over simplify complex information. If participants really understood what they were deciding on, would their 'yes' or 'no' still stand?

CRB RESEARCHERS DISCUSSED this in *Bioethics* recently. According to one of the authors, Jennifer Viberg, what people say they want often depends on how we ask the question. And a complicating factor is that people tend to change their attitude to risk depending on what it is that is at stake. What seemed like a good idea might in fact be much more problematic and calls for more empirical research.

**Find out more:** Freedom of Choice About Incidental Findings Can Frustrate Participants' True Preferences, Viberg J, Segerdahl P, Langenskiöld S, Hansson MG, *Bioethics*, DOI: 10.1111/bioe.12160

## 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

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## Recent publications from CRB

**Freedom of Choice About Incidental Findings Can Frustrate Participants' True Preferences**, Viberg J, Segerdahl P, Langenskiöld S, Hansson MG, *Bioethics*, Article first published online: 23 APR 2015 DOI: 10.1111/bioe.12160

**Whole-genome sequencing in newborn screening? A statement on the continued importance of targeted approaches in newborn screening programmes**, Howard HC, Knoppers BM, Cornel MC, Wright Clayton E, Sénécal K, Borry P, *European Journal of Human Genetics*, 2015 online pre-publication, doi: 10.1038/ejhg.2014.289

**What Are Some of the ELSI Challenges of International Collaborations Involving Biobanks, Global Sample Collection, and Genomic Data Sharing and How Should They Be Addressed?** Bjugn R, Farisco M, Høstmælingen N, Simeon-Dubach D, Petrini C, *Biopreservation and Biobanking* 2015;13(2):70-71

**Reichel J, & Lind A-S, The New General Data Protection Regulation – where are we and where might we be heading?**, in: Mascialzoni D (Ed.), *Ethics, Law and Governance of Biobanking*, Springer, National, European and International Profiles, Dordrecht, the Netherlands, 2015