



## The principles for sharing

by Josepine Fernow

*To improve health care and validate research, we need to provide easier access to samples and data: Access that at the same time is ethical. This is the guiding principle in a new charter for sharing of biospecimens and data published by an international group of researchers in the European Journal of Human Genetics.*

THE VALUE OF COLLECTIONS OF DATA AND BIOSPECIMENS is rising. But this doesn't mean there is more sharing of samples or data. One reason is the different ethical and legal frameworks that are making it difficult for researchers in different countries to collaborate. Deborah Mascalzoni, philosopher at CRB, is one of the authors. According to her, another reason has to do with the investment it takes to build a sample collection:

*"Sometimes researchers are not that keen on sharing. There is a fear that the valuable work they have put into their sample collection will not be recognized. To try and solve that problem, we have provided a framework for recognition in the charter",* says Deborah Mascalzoni.

SHARING STIMULATES RESEARCH, making the process less burdensome. At least in theory. But the ethical and legal frameworks in different countries sometimes contradict each other, making collaboration difficult. The charter conforms with relevant regulation, both legal and ethical and provides



Photo: Tove Godskesen

a comprehensive tool for researchers. It deals with consent, data quality, criteria for acknowledgement and much more. It also provides a very hands-on tool: Data and material sharing agreements are often written in a legal language that can be difficult to understand for the scientists and administrators that use them. To help solve this, the charter provides a clear and simplified template. The same principles can be used for other access agreements.

### CHARTER FACTS:

- Contains template for Material and Data Transfer Agreements
- Provides framework for acknowledgement for the collections
- Incorporates relevant international legislation and ethical regulation

## New law for research databases?

by Pär Segerdahl

*The Swedish Government considers national registries a unique and important resource. But the legal situation for these registries is unclear and could stand in the way of research.*

THE GOVERNMENT APPOINTED A COMMITTEE to analyze the legal conditions for registry based research in Sweden. The report, "Unik kunskap genom registerforskning," was presented in June this year.

THE REPORT ANALYZES the legal pre-requisites for registry based research in Sweden. It suggests specific changes in the formulation of several current laws to address the problems identified by the committee. The committee also proposes a new law for research databases.

THE LAW IS MEANT TO REPLACE a temporary law on registries for research (2013:794) that expires at the end of next year. The new law is not specific to databases in a particular research field and would enter into force when the old one expires.

MATS G. HANSSON, DIRECTOR OF CRB, was one of the appointed committee experts. According to him, the report puts the spotlight on the difference between infrastructures for research and individual research projects. It also suggests a way to make this distinction clear in the new legislation. This, he says, is a significant step forward for registry based research.



## ELSI common service for BBMRI-ERIC

*BBMRI-ERIC is a platform for long term research collaborations between EU countries. Within the platform, groups can develop standards for technical, legal and ethical purposes and set up criteria for biobanks. It could also offer new possibilities for researchers to communicate with policymakers.*

THERE IS A NEED for an ELSI common service within BBMRI-ERIC. On July 28 BBMRI-ERIC received a joint proposal for an ELSI-service for the European biobank community.

THE PROPOSAL RECEIVED INPUT from all the national BBMRI nodes. It was coordinated by Anne Cambon Thomsen from Toulouse, and co-directed by Mats G. Hansson from Uppsala, Jasper Bovenberg from Leiden and Marialuisa Lavitrano from Milano.

THE PROPOSAL LISTS NINE MISSIONS for the common service: Monitoring, policy, advising, help-desk, dissemination, providing tools, experience sharing, education and ethics check.

## Epigenetics workshop

Welcome to a multidisciplinary workshop to explore the potential for multidisciplinary research initiatives. Uppsala 19-20 March 2015: [www.crb.uu.se/epigenetics](http://www.crb.uu.se/epigenetics)

## Want to discuss ethics?

Have a look, a read and a bit of dialogue with us at The Ethics Blog or the Swedish sister Etikbloggen: [www.ethicsblog.crb.uu.se](http://www.ethicsblog.crb.uu.se) [www.etikbloggen.crb.uu.se](http://www.etikbloggen.crb.uu.se)

## Questions?

If you have any questions concerning biobank ethics and law, please feel free to contact Anna-Sara Lind, Associate Professor of Public Law or Mats G. Hansson, Director of CRB and Professor of Biomedical Ethics. Anna-Sara Lind can be reached at: [anna-sara.lind@crb.uu.se](mailto:anna-sara.lind@crb.uu.se) Mats G Hansson can be reached at: [mats.hansson@crb.uu.se](mailto:mats.hansson@crb.uu.se)

## LifeGene: Case closed?

by Anna-Sara Lind

*The LifeGene project has been heavily discussed among biobank researchers in the last couple of years. The project gave rise to a number of both scientific and legal matters.*

THE SWEDISH DATA INSPECTION BOARD decided that the project was unlawful in December 2011, and that LifeGene didn't comply with Swedish or European law. I have already commented on the new Swedish law and how it applies to cases like LifeGene in a previous newsletter. Since then, the Administrative Court of Stockholm ruled against the Data Inspection Board. The Court found that LifeGene, with the new law in place, now is a lawful research project.

THE APPEAL WAS FILED IN JANUARY 2012 by Karolinska institutet, formally responsible for the project. The Court gave its ruling more than two years later on May 19, 2014. The Data Inspection Board had argued that LifeGene was in violation of the Personal Data Act (Sections 9, 10 and 15) and did not respect that personal information only can be collected for specific and lawful purposes and if the registered person has consented.

SINCE SWEDISH ADMINISTRATIVE LAW states that the act in force at the time of the ruling should be applied, the Court decided to apply the new act to the LifeGene appeal. According to the Court it is clear from the act and its ordinance that Karolinska Institutet has mandate to process personal information in the LifeGene register according to the purpose stated in the law.

NOT SURPRISINGLY, the Court considers that the purpose is specific enough. Since the participants have been informed and then consented to processing personal information, in accordance with the criteria in the law, the Court is of the opinion that the decision taken by the Data Inspection Board no longer is valid. WE CAN CONCLUDE that the LifeGene case is closed, at least for now. From a legal point of view, there are questions that remain unanswered. The Court did not analyze if and how the Swedish national legislation respects European law, especially fundamental rights in EU law.



ONE COULD ALSO QUESTION how informed consent can be considered valid in a situation where the legislation that applies to the consent is enacted more than one year after the decision is taken. Another matter worthy of a discussion is how principles of national administrative law can be united with other demands of rule of law, such as legitimate expectations and foreseeability. These are important for the nation state and the public sphere to function, but also for the realization of individual's rights.

## Recent publications from CRB

**International Charter of Principles for Sharing Bio-specimens and Data**, Mascalconi D, Dove ES, Rubinstein Y, Dawkins HJS, Kole A, McCormack P, Woods S, Riess O, Schaefer F, Lochmüller H, Knoppers BM, Hansson M, *European Journal of Human Genetics* 2014, in press, DOI EJHG.2014.197

**Communicating with the European Composite Administration**, Reichel J, *15 German Law Journal* (2014), pp. 883-906

**The Right to Health in Sweden**, Lind, A-S, in: Flood, C. & Gross, A. (Eds.) *The Right to Health at the Public/Private Divide - A Global Comparative Study*, Cambridge University Press, 2014, pp. 51-78

**Rare Disease Research: Breaking the Privacy Barrier**, Mascalconi D, Paradiso A, Hansson M, *Applied & Translational Genomics*, Available online 18 April 2014

**Perspectives on open science and scientific data sharing: an interdisciplinary workshop**, Destro Bisol G, Anagnostou P, Capocasa M, Bencivelli S, Cerroni A, Contreras J, Enke N, Fantini B, Greco P, Heeney C, Luzi C, Manghi P, Mascalconi D, Molloy J, Parenti F, Wicherts JM & Boulton G, *Journal of Anthropological Science*, 2014;92:1-22