



# Biobank perspectives

## current issues in biobank ethics and law

## Data protection update – one step forward, two steps back?

*The new European data protection regulation has moved through the administrative and political process last year. This spring, negotiations continue within the Council. Here, Anna-Sara Lind comments the process.*

THIS AUTUMN, THE Council met continuously to discuss the European Commission's suggestions for a new Data protection regulation. The regulation will replace the old directive. The debate has centered on matters that have great implications for biobanking and research. The December meetings focused on applying the regulation in the public sector and how to administer data processing cases. The discussions on the chapter dealing with special categories and processing health care and research (IX) came to a close. The Council summarized the outcome in an internal working paper.

IN THE WORKING paper, the Council shows that it has a different opinion than the European Parliament especially for the matters that are relevant for biobank research. Processing personal information in health and medical care should be allowed in case there is legal basis according to Union or Member State's law (article 9). The Council is thereby clarifying its intention to make special arrangements for the public sector by providing a data protection system that is adjusted to different functions of the welfare state. This is also underlined by the new wording in article 83 that aims at regulating data protection in research as it opens up for derogations from the Regulation for the fulfilment of scientific purposes, provided that safeguards explicitly mentioned in the Regulation are met. It is worth noting that the Council underlines that the Regulation would not be applicable on processing of data that contain anonymous information in

research (preamble para 23). On the other hand, the Council also clarifies that genetic data, in particular DNA and RNA-analysis, are to be considered personal data (preamble 25 a), as well as biological samples (preamble 26). The Council is reluctant to accept the one-stop-shop mechanism that would provide for one data protection agency being in charge of the supervision of a data processing case, simplifying the administrative burdens in the field of data protection. The Council has discussed a more complicated administrative model (articles 54-56) to which not all Member States seem to agree.



THE NEGOTIATIONS CONTINUE this spring. The next step for the Council is to take its position in what is called the first reading. This is followed by negotiations with the Parliament and the Commission. In the ordinary legislative procedure, it is not compulsory for all the Member states to agree for the opinion to be valid. But the majority of the Member States (15 states, representing at least 260 of a total of 352 Council votes) must vote for the opinion.

IN MY OPINION, the substantial differences between the views expressed by the Council and the Parliament indicate that this legislative process will take time. The outcome of this process is not yet foreseeable.

## Thinking about ethics

by Josepine Fernow

*Why would a cancer patient agree to test a drug that might not be effective on their own disease? And are researchers responsible if their research can be used to develop biological weapons? A new book provides some food for thought.*



THINKING ABOUT ETHICS is a collection of texts and reflections from the Ethics Blog. In the book, Pär Segerdahl invites you on a journey through some of the issues that the Ethics Blog has dealt with in the recent years. He writes about researchers' responsibilities, about participating in research and about information and integrity. But he also writes about ethics as such: What is it today? In this book you can read about data protection and population based biobank studies. But you can also read about apes writing articles and about the risk with knowing the risk.

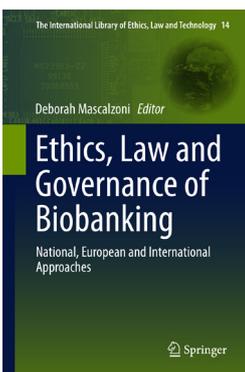
THE BOOK IS available in both Swedish and English and can be downloaded for free from [www.crb.uu.se/reports](http://www.crb.uu.se/reports) or read the blogs: [www.ethicsblog.crb.uu.se](http://www.ethicsblog.crb.uu.se) or [www.etikbloggen.crb.uu.se](http://www.etikbloggen.crb.uu.se).

## Regulating biobank research: new book

by Josepine Fernow

*Biobank research and genomic information are changing the way we look at health and medicine. So how can we regulate it? A recent book published by Springer shows us how the regulatory systems work and raises a critical voice.*

GENOMICS HAS A WAY of challenging our values with its promise of tailored medical treatments and pharmacogenomics somewhere in the future. Genomic research has always been difficult to regulate, but now the borders between medical research and clinical practice are becoming blurred. Sequencing platforms for research suddenly have a potential diagnostic value for actual patients. So what do we do now?



DEBORAH MASCALZONI is Senior Researcher at CRB and the editor of Ethics, Law and Governance of Biobanking that was recently published by Springer.

According to

her, we can't keep clinical applications and research separate anymore. But when we start blurring the lines we start challenging existing regulations and ethical frameworks. The book gives an overview

of the existing regulatory landscape for biobank research in the Western world. But it also raises some critique of how regulations and ethical frameworks are developed and work.

*"There are many questions that still need resolving, for example how researchers should share samples and data across borders. But we also need to figure out some of the basics. Like how we design an ethical informed consent. These are some of the questions that this book addresses",* Deborah Mascalzoni explains.

RIGHT NOW, THERE are some international efforts to build systems that meet these challenges, but according to some of the authors, perhaps it is time to stop and think for a moment before writing more policy.

DEBORAH MASCALZONI BELIEVES that biobank researchers have a moral responsibility put their work in relation to the norms and values we share as a society. According to her, research ethics isn't just about bioethicists that write guidelines for professionals to follow. Ethics is something that we practice both through discourse and regulatory frameworks.

*"If ethics is a part of public discourse, ethical review becomes an arena where researchers can discuss their projects instead of a burden and a bureaucratic exercise",* says Deborah Mascalzoni.

## Research ethics for medicine and the life sciences

by Josepine Fernow

*Research ethics and research integrity is not just following regulation. Researchers need the ability to identify ethical aspects in their own research. And to do something about them.*

STARTING THIS AUTUMN we offer a new kind of interactive online training to develop your skills. Regardless of whether you work with research or if you are a professional working with researchers, this training will give you the basic tools to identify and assess central ethical aspects in scientists' work.

WE ALSO OFFER some of the practical tools you need: Updated and research-based information, important issues and concepts. And provide you with a resource bank of instructions, forms, guidelines and principles.

Visit [www.ethicstraning.crb.uu.se](http://www.ethicstraning.crb.uu.se) to find out more!

## Research databases

The proposed Swedish law on research databases is currently under debate. In the next issue of Biobank Perspectives, Anna-Sara Lind will comment on the discussion.

## 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

**Ethics, Law and Governance of Biobanking**, Mascalzoni D (ed), Springer, National, European and International Approaches Series: The International Library of Ethics, Law and Technology, Vol. 14 2015, VI, 277 p.

**Current trends in biobanking for rare diseases: a review**, Graham CE, Molster C, Baynam GS, Bushby K, Hansson M, Kole A, Mora M, Monaco L, Bellgard M, Carpentieri D, Posada M, Riess O, Rubinstein YR, Schaefer F, Taruscio D, Terry SF, Zatloukal K, Knoppers B, Lochmüller H, Dawkins HJS, *Journal of Biorepository Science for Applied Medicine* 2014;2:49-61

**Privacy Threat Modeling for Emerging BiobankClouds**, Gholami A, Lind A-S, Reichel J, Litton J-E, Edlund A, Laure E, *Journal of Procedia Computer Science*, 2014;37:489-496

**Changes on the horizon for consumer genomics in the EU**, Kalokairinou L, Howard HC, Borry P, *Science*, 2014;346(6207); 296-298

**Practical Barriers and Ethical Challenges in Genetic Data Sharing**, Simpson CL, Goldenberg AJ, Culverhouse R, Daley D, Igo RP, Jarvik GP, Mandal DM, Mascalzoni D, Gray Montgomery C, Pierce B, Plaetke R, Shete S, Goddard KAB, Stein CM, *International Journal of Environmental Research and Public Health*, 2014;11(8):8383-8398