UPPSALA UNIVERSITET

2:2014

Biobank perspectives

current issues in biobank ethics and law

BBMRI.se
BioBanking and Molecular Resource Infrastructure of Sweden

Dealing with genetic risk information

by Magnus Alsne

How do we evaluate and handle genetic risk information? For the coming six years, the Centre for Research Ethics & Bioethics (CRB) will co-ordinate an international research project to support health care, patients and decision makers.

Rapid progress in biomedical research keeps providing us with new information on genetic variations and their connection to risk for disease and adverse drug effects. It gives us hope for personalized treatments and disease prevention. But do health care staff and the individual patient really have the skills to evaluate and handle all the risk information that is available?

The Centre for Research Ethics & Bioethics is about to start co-ordinating an international multi-disciplinary research project that aims to provide better tools to handle genetic risk information.

"There is a lot of funding and effort going into genetic risk information technology. Not least in Sweden with SciLifeLab. We will work at the other end and provide better clinical application of the results", says Mats G. Hansson, director at CRB and professor of biomedical ethics.

The scientific structure of this international research collaboration is made up of philosophy, psychology, medicine, health economy and empirical studies of risk assessment and preferences. The group will develop material for in depth ethical analysis to help guide people who have to approach and handle genetic risk information. One way of doing this is by analyzing how patients value risks and benefits of treatment.

"We need more research to understand the complexity of the individual's preference formation. We hope that the results of our research will help support health care, patients and policy makers evaluate and handle genetic risk information", says Mats G. Hansson.

ABOUT MIND THE RISK

- The project group consists of researchers from Uppsala, Göttingen, Manchester, Milan, Stockholm, Maastricht and Birmingham
- The work is funded by Riksbankens Jubileumsfond (the Swedish Foundation for Humanities and Social Sciences)
- One of the outcomes is a tool for assimilating and understanding risk information in the form of an interactive web based game

New law for Biobank researchers

by Anna-Sara Lind

The decision taken by the Swedish Data Inspection Board to stop the Life Gene research project was the point of departure for a lively nationwide debate on the legal criteria for biobank research projects in Sweden. The Data Inspection Board based its decision on the fact that Life Gene's research purpose was not specific enough: This made it incompatible with the requirements of both the EU Data protection directive and the Swedish Personal Data Act.

To make research like the life gene project possible the Swedish Parliament (Riksdag) has enacted a new legislative Act on registers for research on the health implications of heritage and environment (*Lag [2013:794] om vissa register för forskning om vad arv och miljö betyder för människors hälsa*) that entered into force on November 1st, 2013. This Act provides a legal ground for universities and colleges to process personal data.

This legislation creates the basis for research projects dealing with the implications of heritage and environment for developing different deceases and the health of human beings in general. A precondition for processing data is that the person (data subject) has given his or her expressed consent. The Act is in force until December 31st 2015, and will until then be evaluated in light of the legal changes in Sweden and in a European context such as the suggested EU Data Protection Regulation. The Riksdag has delegated to the Government to decide which universities will be entitled to carry out this data processing. This means that Life Gene is now up and running again!

Trust takes more than guidelines and review

Research ethics has developed into an extra legal regulatory system. Guidelines serve as steering documents, committees oversee and consent procedures are formal.

This is often justified with reference to past atrocities. In a recent article in Research Ethics, Linus Johnsson, Stefan Eriksson, Gert Helgesson and Mats G. Hansson call this 'institutionalized distrust' and claim that this approach has some limitations.

Regulatory systems can not be justified with past horrors unless the distrust itself is a necessary or efficient means to prevent future atrociousness. According to the authors, this distrust is a potential threat to researchers' moral competence and integrity because it encourages a blinkered view of ethical issues.

Making researchers moral: Why trustworthiness requires more than ethics guidelines and review Johnsson L, Eriksson S, Helgesson G & Hansson MG, Research Ethics 2014;10(1):29-46

HandsOn: Biobanks

The next HandsOn: Biobanks will be arranged by BBMRI.fi and held in Helsinki on 24-25 September 2014.

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
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
Mats G Hansson can be reached at:
mats.hansson@crb.uu.se

Data protection update – A word on the legislative process

On March 12, the European Parliament accepted the Data Protection regulation. When it comes to EU regulation, this is only the beginning of the process. Anna-Sara Lind, Associate Professor of Public Law, gives us her word on the legislative process.

We are on the way towards a European data protection regulation. On March 12, the European Parliament decided to accept the version of a new Data protection regulation that was suggested by its LIBE Committee in November 2013. The Parliament confirmed its standpoint and as we indicated in our newsletter of January 2014, we are now awaiting the outcome of the negotiations in the Council.

The process of enacting a new Data protection regulation is carried out in accordance with the ordinary legislative procedure. This means that the European Parliament and the Council (ministers of the Member States) jointly decide on the adoption of the regulation, after an initiative by the Commission. If the European Parliament and the Council agree on the same version of the text in what is called a first 'reading', the proposed regulation is enacted. But in some cases, they do not agree on the text and the procedure continues with a second and possibly even a third reading.

With the data protection regulation, we are now at a point where the European Parliament has communicated its position to the Council that in turn will give its opinion. If the Council and the Parliament do not agree, a process of communication between them starts. The Council will communicate its position and if the Parliament agrees with the Council then the wording of the Council's proposal stands. If not, then the proposal is rejected.

If no agreement is reached, during the second reading, the next step is to convene a Conciliation committee. This committee has members from both the European Parliament and the Council. Up to this point, each step taken is regulated so that it should not take more than three months. The Conciliation committee speeds up the negotiations. The committee's task

is to foster quick results. Therefore the institutions have only six weeks to react on each other's decisions. In this phase the Commission works more actively and openly as mediator. With the outcome of these negotiations, a third reading is initiated. At this stage the proposal has to be accepted by both the Council and the European Parliament if it is not to be rejected.

To summarize, we can conclude that these negotiations may take time! European elections are taking place this year. This means that a new European Parliament is entering the stage and may be adding new opinions or settings to the Regulation negotiations. We should also be aware of that the Commission, the Council and the European Parliament represent different interests, legally as well as politically according to the EU Treaties and to real politics. The different rules on time frames, decision making, voting quotas etcetera can be used as efficient tools to strategically plan the future of data protection – and research – in Europe.

Recent publications from CRB

Making researchers moral: Why trustworthiness requires more than ethics guidelines and review Johnsson L, Eriksson S, Helgesson G & Hansson MG, Research Ethics 2014;10(1):29-46

Regulating Data Protection within the European Union Reichel J & Lind A-S, in Dörr D & Weaver RL (Eds.) Perspectives on Privacy, De Gruyter, 2014:22-45