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Biobank perspectives

current issues on biobank ethics and law

Updated analysis of the EU Data Protection Regulation

by Jane Reichel and Anna-Sara Lind

In this newsletter we will guide you through the recent updates and the implications on biobank ethics and law. In this issue, we focus on Articles 81 and 83 of the propsed Data Protection Regulation, dealing respectively with processing of personal data concerning health and processing of data for historical, statistical and scientific research purposes.

The negotiations concerning the proposed Data Protection Regulation has taken another important step as the European Parliament voted on an amended proposal at the end of October 2013.
If the European Council agrees on the amendment, the final step towards a Data Protection Regulation can be taken and the present Data Protection Directive (95/46/EC) will be abolished. It is however more likely that the legislative procedure will continue in with a second reading, in both legislative organs.

The amendement laid down by the European Parliament still allow the use of personal data for research, even without any consent. The general rule for personal data is set out in Article 83. However, concerning personal health data in research, specific conditions are laid down in Article 81.
The possibilities to make an exception from the consent criterion is found in Article 81.2 (a), where it is stated that the member states of the European Union may allow processing of health data in research, without previous consent, only if the research in question is of ”high public interest”.

The data should be anonymized or, if anonymisation is not possible, pseudonymised under the highest technical security standards.It is underlined that all necessary measures should be taken in order to prevent unwarranted re-identification of the data subjects.
Further, the demands put forth in Article 83 should be met: for example that data enabling the attribution of information to an identified, or identifiable, data subject should be kept separately from other information data (Article 81.2).

It is not indicated if other guarantees are needed in order to replace the consent, such as the Swedish rules on ethical review boards. Nothing is presented in the Regulation that would hinder such an order.
One limitation is, however, to be found in Article 81.3 where it is stated that it is the Commission that decides what is to be considered “high public interest”.
This, in turn, could lead to the result that the rules differ between member states, and that the possibilities to use health data in research without consent will vary in the EU. The impact of this on cross border research is not clear at the time of writing, but there is a potential risk that the positive aspects of a common regulation will be lost.

According to Article 81.1 (b) there is a possibility, in cases where consent is demanded, to collect data for several similar purposes, if the data is “medical data exclusively for public health purposes of scientific research”. This would mean that as long as the purpose of the research is public health, personal data can be gathered for several purposes. “Public health” should be interpreted broadly (compare paragraph 123 in the Preamble). The rule is, however, not that easy to interpret and it is highly important to follow what will happen in this regard.

As set out above, Article 81.2 (a) gives the member states a certain margin to make exceptions from the demand on consent that is the rule when research is done on health data. This indicates that when the research in question has a new purpose, it does not mean that processing the data would be unlawful. Also Article 81.1 (c) is of relevance in this context. The Article states that sensitive personal data concerning health, that has been collected in the public interest, cannot be used for *other* purposes without consent. Research, however, does not seem to be included in the group of excluded purposes that is enumerated in the preamble to the Article.
These exceptions mean that Sweden could have some possibilities to keep the health registers, but it depends upon how broadly the criterion is interpreted by the Commission.

It follows from Article 83 (a) that research can be conducted on information from archives, according to rules that are to be decided by the member states. These national rules should be decided in accordance with the Regulation’s general standards, such as consent and presumably its applicable exceptions. A clear rule is not included in the proposal for a regulation, but the Parliament has deleted a suggested paragraph 40 in the Preamble that admitted personal data could be handled for a new purpose in research, as long as that new purpose was compatible with the first (initial) purpose

Jane Reichel and Anna-Sara Lind are leading experts on the legal aspects of research conducted on human tissue samples within the BBMRI.se network. They are both lecturers at the Department of Law at Uppsala University and tied part-time to CRB.

One step forward with Biobank Act

The new Act on Biobanks entered into force in Finland on September 1st, 2013.

Human tissue samples and associated data are increasingly important in biomedical research. In order to deal with the ethical and legal standards for using these samples and data, informed consent is crucial. In practice, informed consent mirrors the general question of how the interest of the individual can be balanced against the interests of research and, to some extent, the public interest.

In the report *Finsk biobankslag till fördel för alla*, Joanna Stjernschantz Forsberg analyses the Act with focus on two questions where the Act clearly differs from the legislation in the other Nordic countries. The first subject matter is that the Act allows broad consent for future research and for secondary use of stored samples. Secondly, the position of the sample donors is strengthened and it is underlined in the report that their integrity is, at the same time, better protected. Dr Joanna Stjernschantz Forsberg also underlines the unique feature of Finlands Biobank Act as it combines the possibility to store samples with broad consent for future research with an opt-out mechanism used to include already existing samples.

Order the report

Order Joanna Stjernschantz Forsbergs report **Finsk biobankslag till fördel för alla** (in Swedish only) on the recent Finnish Biobank Act. Send an email to: linda.johansson@crb.uu.se

Questions?

If you have any questions concering biobank ethics and law, please feel free to contact Anna-Sara Lind, Jur. dr, LL.D, or Mats G. Hansson, Director of CRB, Professor of Biomedical Ethics.
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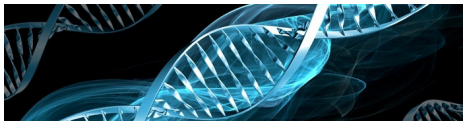
Incidental findings and possible policy pathways for biobanks

The return of incidental findings to the research participants is a highly discussed issue, in connection to biobank research



In a recent article the matter of how to handle incidental findings, i.e. findings that has a potential importance to the research participants' health but that does not fall within the aim of the study, is analysed from an ethical perspective. Jennifer Viberg et al. discuss specificities of genetic biobank research and stress the importance of making a distinction between disease and genetic risk for disease.

The lack of such a distinction has led to situations where more complex issues related to incidental findings fail to be addressed in biobank research, for example the unproven predictive value of incidental findings. There are several reasons arguing for disclosure of incidental findings relating to genetic information, as well as there are reasons against.

The authors investigate the characteristics of these incidental findings, in comparison to incidental findings containing other forms of health relevant information.The authors also apply ethical principles on these different types of incidental findings.

The authors suggest that the actual nature of genetic risk information and the complexity of understanding of genetics should be taken into account when deciding on how to deal with

incidental findings. Potential participants in studies should be asked questions that are based on realistic presentations of risk information and what this information means. They should not be subjected to general questions, such as if they would like to have health relevant genetic information, regardless of the implications.

This means that new empirical studies need to be designed in which the informants are informed about genetic risk of unproven predictive value. The responses to these offers of genetic risk information are relevant only if the informants have understood the information and how it differs from other information on disease or immediate disease risks.

To conclude, more research is demanded before ethical principles can be applied to support a reasonable and comprehensive policy for handling incidental findings in biobank research.

Jennifer Viberg is a licensed Prosthetist and Orthotist, who is involved in the IMI-funded BTCure project on Rheumatoid Arthritis and BBMRI.se.

Recent publications from CRB

A big step for Finnish Biobanking Forsberg JS, Soini S, Nature Reviews Genetics 15, 6 (2014) doi:10.1038/nrg3646 Published online 10 December 2013

Incidental findings: the time is not yet ripe for a policy for biobanks Viberg J, Hansson MG, Langenskiöld S, Segerdahl P, European Journal of Human Genetics advance online publication, 25 September 2013; doi:10.1038/ejhg.2013.217.

International guidelines on biobank research leave researchers in ambiguity: why is this so? Forsberg JS, Hansson MG, Evers K, European Journal of Epidemiology, 2013, Page 1

Rare diseases and now rare data? Mascalzoni D, Knoppers BM, Aymé S, Macilotti M, Dawkins H, Woods S, Hansson MG, Nature Review Genetics, published online 23 April 2013; doi:10.1038/nrg3494.
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