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Biobank perspectives

current issues in biobank ethics and law



Bioethicists suggest broad consent for biobank research

by Pär Segerdahl

It is still unclear what kind of consent should be used when collecting biological samples for future research. Different forms of consent are practiced. This creates another uncertainty: which research is actually permitted with the collected samples?

THIS HAPHAZARD SITUATION leads to unintended constraints on research. But it also leads to research sometimes being carried out without consent. Against this background, the US National Institutes of Health (NIH) organized a workshop in September 2013 where bioethicists discussed whether it is ethically reasonable to manage these uncertainties by using broad consent for future research when collecting biological samples.

THE PARTICIPANTS RECENTLY published their thoughts and conclusions in the *American Journal of Bioethics*. They propose that broad consent is ethically reasonable and often the best option, if the consent is obtained at the start, in connection with sample collection. There also needs to be a system for oversight and approval of future research. The final requirement is that, as far as possible, there should be ongoing communication with, and information to, donors.

BIOLOGICAL SAMPLES ARE collected in a variety of contexts. It is here that the haphazard situation arises, if different forms of consent are used, or perhaps no consent at all.

BY INITIALLY INFORMING potential donors of the wide range of research that can be carried out, they can take a position on risks and benefits of donation (given the oversight and the general conditions of the future research that they are informed about).

THE GROUP EMPHASIZES that broad consent gives donors control over the use of samples, while minimizing costs and burdens for both donors and researchers. They also point out that empirical studies show that most people want to decide if their samples may be used for research. Most respondents also say that the decision is not influenced by the specific details of the future research (e.g. what diseases are studied, what techniques are used, or which parts of the sample are studied).

OF COURSE THERE are examples of research that can be perceived as controversial, such as human cloning. But broad consent can be combined with specific restrictions. Oversight moreover considers whether research proposals can be said to comply with the donors' values.

MATS G. HANSSON FROM CRB is one of the bioethicists behind the paper. According to him, broad consent respects donors autonomy and allows research that can improve medical treatments in the future.

Global research infrastructure for biobanking

by Josepine Fernow

The University of the Western Cape in South Africa just hosted the first meeting of B3Africa – a Horizon2020 CSA Action to bridge European and African biobanking and biomedical research. The partnership has two strategic aims: One is to create a harmonised ethical and legal framework between European and African partner institution. The second is to provide an “out-of-the-box” informatics solution for data management, processing and sharing that works with limited Internet access.

JANE REICHEL IS PROFESSOR of Administrative Law at Uppsala University and leads the ethical and legal work. According to her, a shared ethical and legal framework is necessary if the informatics platform is to fill its purpose and allow data and bio-resources to be shared between countries and continents.

B3AFRICA IS CO-ORDINATED by the Swedish University of Agricultural Sciences. Partners include BBMRI-ERIC, Karolinska Institutet, Uppsala University, University of the Western Cape, Makerere University, Stellenbosch Universitt, International Agency for Research on Cancer, International Live Stock Research Institute, Medizinische Universität Graz and the Institute of Human Virology Nigeria. More on www.b3africa.org.



Renewed European effort to agree on data protection

by Anna-Sara Lind

The European Data Protection Regulation keeps moving through the administrative and legislative process. This summer, The Council, The European Parliament and the European Commission started the 'trilogue' negotiations. Here, Anna-Sara Lind gives her comments on the process.

RIGHT NOW, INTENSE efforts are made to agree on a common view on data protection in the European Union. In accordance with the legislative process of the European Union, the three institutions have – at different times – over the last years produced one document each of their version of how a regulation should be written. It is noteworthy that the three versions differ rather heavily when it comes to matters having an impact on biobank research. When comparing the documents from the three institutions, it is clear that the Council is more generous towards research. The European Parliament on the other hand is striving for a stronger protection for personal integrity in all fields, even research.

THE EUROPEAN PARLIAMENT'S position regarding purpose limitation is one example of this. Today, the main rule states that data that have been gathered for a certain purpose should not be used for other purposes, unless consent has been given for the new purposes. This rule does however, contain an exception for research. The Parliament strongly objects to this, while the Council to some extent advocate it for the new regulation. Consent is problematic to handle in the negotiations. It is far from clear that the institutions could agree on a research friendly rule that allows for processing of large amounts of data without active consent.

ANOTHER MAJOR ISSUE for the research community is how anonymization and pseudonymized data should be handled in a new regulation. The main motive for enacting a new regulation is to strengthen the personal integrity in all fields. It has, however, turned out to be difficult for the European institutions to include

the possibility for researchers to conduct research on personal data when it is possible to identify individuals. The European Parliament demands that no person should be identified. To meet this demand, information would have to be removed, something that would undermine research results.

DURING THE NEGOTIATIONS this summer, the European Commission underlined that the present Data Protection Directive represents the minimum level of data protection that we need to guarantee in this process. The goal is to achieve a single set of rules on data protection, valid across the EU. A new regulation should reinforce rights in order to put people back in control over their data. The Commissioner in charge of these matters has also underlined the importance of achieving a system where the same rules apply for companies from both within and outside the EU. The regulation should also include a strong and effective one-stop shop mechanism to simplify the lives of companies and citizens. The negotiations will continue this autumn. When they close and the parties agree, it will take another two years for a new data protection regulation to enter into force.



Want to discuss ethics?

Have a look, read, and discuss with us at the www.ethicsblog.crb.uu.se or the Swedish sister www.etikbloggen.crb.uu.se

Questions?

If you have questions concerning biobank ethics and law, please feel free to contact

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Guideline for sharing specimens and data receives IRDiRC recommendation

The International Charter of principles for sharing bio-specimens and data has received a recommendation from the International Rare Diseases Research Consortium IRDiRC.

THE CHARTER IS part of CRB's work with the ethical, legal and social issues (ELSI) in the RD-Connect platform.



Recent publications from CRB

Broad Consent for Research With Biological Samples: Workshop Conclusions, Grady D, Eckstein L, Berkman B, Brock D, Cook-Deegan R, Fullerton SM, Greely H, Hansson MG, Hull S, Kima S, Lo B, Pentz R, Rodriguez R, Weil C, Wilfond BS & Wendler D, the American Journal of Bioethics 2015;15(9):34-42.