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Biobank perspectives

current issues in biobank ethics and law



Legal aspects of direct-to-consumer genetic testing

Regulating health services is challenging because of the multitude of legal questions it raises. Not only do they relate to the quality of the service and protection of its users, but also to the competence and authority of actors involved. Here Santa Slokenberga, LLD, offers insights from her research on regulating direct-to-consumer genetic testing at the European level.

WE LIVE IN a globalized world where several beyond-the-state actors have both the competence and authority to regulate direct-to-consumer genetic testing. This raises questions about the coexistence and interaction of these actors, and the effects this has on the national legal orders. I spent almost 5 years researching the regulatory challenges at the European level. My thesis *European Legal Perspectives on Health-Related Direct-to-Consumer Genetic Testing* examines how the Council of Europe and the EU interact through rules on direct-to-consumer genetic testing. I also studied the effect on the EU Member States' competence and authority to protect individuals within their jurisdictions.

IN MY RESEARCH, I trace how each of the legal orders regulate direct-to-consumer genetic testing. I also show how the Council of Europe and the EU use their law-making, interpretative and enforcement tools in order to accommodate the other legal order's laws in their system. As a result, it is becoming increasingly difficult to draw clear lines between the 'Council of Europe law' and the 'EU law' in these areas, and to ascertain



the Member States' obligations in each of the legal orders. By aligning its laws with the EU, the Council of Europe also creates far-reaching implications on regulation in those Council of Europe member states that are not part of the EU.

THE ANALYSIS DEMONSTRATES the challenging position held by national legal orders. They are required to navigate through a complex web of rules to ascertain if they have discretion to regulate direct-to-consumer genetic testing, and the extent to which they have this discretion. I argue that, in a way, direct-to-consumer testing can be seen as a form of 'test' to European legal orders. This test shows a need for formal cooperation and convergence also in matters that might seem small, but bring considerable consequences.

New research on cyber governance of health data

Digital technology creates both a chance and a pressure to use health data for research and commercial purposes. But this emerging 'health cyberspace' needs to be handled in a way that meets our social expectations on governance, security and privacy. And at the same time allows data to be used in ways that are beneficial to society. This is what a project supported by Nordforsk is setting out to do.



It is becoming both simple and efficient to assemble and use existing data for new purposes. But also to collect new data through IT tools such as smartphone health apps and self-reported data over the internet.

Data routinely collected in the clinical realm is already being used for research that serves public interest and sometimes access to that data sold to private companies. We have seen controversial proposals for repurposing of data in Norway, Sweden, Iceland and the UK. These countries will provide comparative case examples of issues raised by the health cyberspace that is being created around us. The project is led from the HELEX Centre at the University of

Oxford, and carried out in collaboration with the University of Iceland, the University of Oslo and the Centre for Research Ethics & Bioethics (CRB) at Uppsala University. Deborah Mascalzoni and Jorien Veldwijk from CRB will co-ordinate the empirical work. According to them, it is important to find solutions for this cyber governance that are both practical, and fit the expectations from society. They expect this project to produce results that can provide a solid basis for policy development.



Swedish research data inquiry on exceptions

The Swedish Government has decided to commission a Research Data Inquiry to review regulations regarding the processing of personal data for research. The reference group includes three researchers from CRB: Mats G. Hansson, Anna-Sara Lind and Jane Reichel.

THE GENERAL DATA PROTECTION REGULATION (GDPR) was enacted by the European Union in April 2016. It has the legislative form of a regulation instead of a directive and frequently refers to the national legislators in the Member States and the enactment of national law. This is why the regulation has an implementation period of two years, and will not enter into force until May 2018.

THE SWEDISH GOVERNMENT has decided to appoint several enquiries in order to meet the requirements posed by the regulation (some were discussed in the previous issue of Biobank Perspectives). For example, the Research Data Inquiry (U 2016:04) will focus on issues relating to processing of personal data in research to meet the requirement in article 89 of the GDPR where Member States, or the EU, may enact legislation in order to lay down appropriate safeguards for the processing of personal data in research, enabling the use of exceptions from general data protection requirements.

THE RESEARCH DATA INQUIRY will suggest a general framework for research, which, among other things, will entail an investigation of the possibility of extending the requirement for ethical vetting to all personal data. The inquiry is further tasked with analysing the need for adapted rules for the National Biobank Registry, the National Board of Forensic Medicine's Registry as well as other registries relevant for the research relating to health, genetics and environment.

The reference group connected to the Research Data Inquiry consists of around 30 experts from academia, public authorities and NGOs, who will support the work of the inquiry. Jane Reichel is presently working in the Horizon 2020-project B3Africa on biobank collaboration between the EU and several African states. For her, the question of transfer of personal data outside the EU is especially relevant.

"I look forward to the opportunity to discuss the consequences of the strict requirements for transfer of health data for research

outside the EU, which may prove to be an obstacle in international collaborations", says Jane Reichel.

Mats G. Hansson is interested in how the GDPR's emphasis on data minimization should be balanced against the need of data mining of big data sets for linking omic- and phenotypic data.

Anna-Sara Lind is interested in making the GDPR functional in a complex setting where personal integrity is involved and regulated in many different ways such as EU law, constitutional acts and statutory legislation.

"I believe protecting integrity should be balanced with the societal interests of good public health, well-functioning health care and research that has the most out of modern technological achievements", says Anna-Sara Lind

The Inquiry will present some of its findings on 1 June 2017 and a full report by 8 December 2017.



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Questions?

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Recent publications from CRB

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