



Risk of re-identification vs the need to identify individuals

There are risks associated with handling personal data in research. Unauthorised re-identification can cause harm. But there are clear benefits in terms of patient safety related to diagnosis and treatment if researchers are able to distinguish between individuals by identification.

DE-IDENTIFICATION OR CODING might not be sufficient for protecting the people who donate their samples and data against privacy invasions and breaches of confidentiality. But medical research, and especially rare disease research, needs to be able to identify individual patients to get results. According to a paper in EJHG, it is up to the research community to show they are up to the task of managing these risks and deserve the trust of the people whose data they are using.

THE AUTHORS SUGGEST open and transparent information and consent processes and using safe and unique personal identifiers, for example the GUID or HD. Mats G. Hansson is one of the authors. He says that researchers need to be careful not to promise too much when they describe data protection. He believes we need high professional standards and that researchers need training in research ethics, especially in the beginning of their career.

IN MOST CASES, using personal data in research produces benefits that far outweigh the risks. The authors suggest that an adequately informed consent contributes to responsible data sharing. But they also claim that broad consent is compatible with ethical access to data, sharing and use. And, they claim,

so is no consent: given that the justification is ethical and the use is lawful, and the data processing is up to demonstrably high standards of governance.

BUT FOR THIS to work, there needs to be structures in place. We need ethical, legal and regulatory frameworks

that recognise the need for unique identifiers that can handle complex and international data collection and sharing. Research projects also need governance structures that reflect the patient and publics' perspective. The authors write that to ensure that researchers are aware of societal concerns, it is important to have an ongoing dialogue with patients and the public. That includes communicating what research is, what the risks are, and how people can benefit from the results.

The risk of re-identification versus the need to identify individuals in rare disease research, online first



Feedback of individual genetic results in Europe still not feasible

When it comes to genetic research, there is a growing consensus that research participants could be offered their individual results. Provided that they are scientifically robust, analytically valid and there is some clinical action people can take to prevent disease. Despite this, it is not common practice to do this in European genetic research. The reasons are many, one being the lack of legal frameworks, guidelines and resources to support feedback processes in research.

ACCORDING TO A paper that was recently published in Biopreservation and Biobanking, we need to coordinate efforts on a pan-European level if feedback of results to participants is going to be equitable, scientifically sound and socially robust.



DEBORAH MASCALZONI IS one of the authors. According to her, we still lack European legal frameworks and professional guidelines, as well as financial, organizational, and human resources to support the feedback of results. If researchers are to give participants feedback on their results, there are some steps that need to be taken to facilitate the process. The authors believe we have to clarify the legal requirements and develop harmonized European best practices. But we also need to promote interdisciplinary and cross-institutional collaboration. They also suggest designing educational programmes and cost-efficient IT-based platforms. This work should involve research ethics committees. It is also necessary to document the risks and benefits of feedback processes.

Feedback of Individual Genetic Results to Research Participants: Is it Feasible in Europe?, Biopreservation and Biobanking, online first

Data Protection Regulation: final result

Here, Anna-Sara Lind gives us an update on the what the final results of the negotiations for a general data protection regulation in the European Union.

ON MAY 4, 2016, the phase of negotiating a new Data Protection Regulation officially came to an end as the text was formally published in the Official Journal of the European Union, after it had been decided by the European Parliament and the Council. The Regulation aims at protecting personal data and individual fundamental rights relating to this data. It is legally binding in all EU Member States and prevails over national law. It applies from May 2018.

THE IDEA OF a broad consent is mentioned in the preamble, but is not specifically handled in the articles. It is too early to be sure that broad consent can be used as some leeway in that regard is left to the Member States' national law.

AS TO MATTERS relating to welfare and research, it was finally decided that the Regulation should include rules opening up for the Member States to regulate some questions that earlier on was suggested to be explicitly part of the Regulation through national law.

SPECIFIC RULES ARE included in the Regulation that aim at handling historical, statistical and scientific research and enhance the importance of individuals' rights (data subject rights), such as the right to data portability and the right to be forgotten. As was the case in the former Data Protection Directive, the Regulation includes provisions regarding sensitive data such as health and genetic data. In Article 9 it is stated that exceptions to the prohibition of data processing in case of



sensitive data such as health and biometric information can be done if so is stated in EU law or Member State law also in case of research. The requirements in Article 89 need to be met, comprising safeguards such as strict technical measures so that the processing is kept to a minimum and pseudonymisation is used when possible. As was earlier the case with the Directive, the Regulation only applies to personal data, not to anonymous data. This will in the future require that risk assessments are done in order to ensure if the data can be considered as anonymous in research. It also follows from the preamble that genetic data is to be defined as personal data, if relating to the inherited or acquired genetic characteristics of a natural person shown in a DNA or RNA analysis.

A MAJOR DIFFERENCE compared to the Directive is that the data protection impact assessments and the procedures for handling data breaches now become mandatory, but also that remedies, fines and sanctions become more severe. Another important change is that a processor, someone processing data on behalf of the controller such as a cloud service provider, will have independent responsibilities for handling the data.

Call for ELSI experts

The BBMRI-ERIC ELSI Common Service relies on input from experts. They are now calling for your expertise!

We are part of BBMRI-ERIC's ELSI Common Service. If you are you an expert on ethical, legal or social issues related to biobanking, we need your expertise: Ethics checks for projects who want to use BBMRI-ERIC resources, workshops and the help-desk function for ELSI issues and more. Register your expertise by filling out a questionnaire and the corresponding letter of expression of interest on the BBMRI-ERIC.eu website by October 31 2016.

If you have any questions, please contact Gauthier Chassang (gauthier.chassang@bbmri-eric.eu).



Help to choose good bioethics journals

There are allegedly over 8.000 predatory journals out there that serve their own economic interests instead of supporting readers and science.

To help bioethicists choose where to publish, Stefan Eriksson and Gert Helgesson publish two lists on the Ethics Blog: 'Where to publish', and 'Where not to publish'.

If you want to discuss this and other aspects of bioethics and law, we welcome you to meet us at www.ethicsblog.crb.uu.se!

Questions?

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Recent publications from CRB

The risk of re-identification versus the need to identify individuals in rare disease research, Hansson MG, Lochmüller H, Riess O, Schaefer F, Orth M, Rubinstein Y, Molster C, Dawkins H, Taruscio D, Posafda M, Woods S, *European Journal of Human Genetics*, 2016, advance online publication, May 25, 2016; doi:10.1038/ejhg.2016.52

Feedback of Individual Genetic Results to Research Participants: Is it Feasible in Europe? Budin-Ljøsne I, Mascalzoni D, Soini S, Machado H, Kaye J, Bentzen HB, Rial-Sebbag E, D'Abramo F, Witt M, Schamps G, Kati V, Krajnovic D, Workin Group 1, and Harris J R, *Biopreservation and Biobanking*. April 2016, ahead of print. doi:10.1089/bio.2015.0115.