A big step for Finnish biobanking

Joanna Stjernschantz Forsberg[1] *and Sirpa Soini*[2]

A new law in Finland pioneers the way for improvements in research using biobanks.

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Human tissue samples and their associated data have become increasingly important in biomedical research. This development has led to a debate about the appropriate ethical and legal standards for their use, which has focused largely on the issue of informed consent[1–3]. The traditional consent requirements of clinical research demand that individuals are informed about the specific details of every study, which presents substantial challenges for biobank research. A key question has therefore been how to weigh the interests of the individuals whose samples are used against the interests of research.

Previously, similarly to many other countries, the Finnish legislation on biobank research was built on the principle that specific consent should be obtained when samples are used. Although exceptions were allowed, the default position of requiring consent led to an underuse of existing materials and a suboptimal spending of financial resources. A new law on biobanks entered into force in Finland from 1 September, 2013 (REF. 4), the aim of which is largely to improve the prerequisites for performing biobank research. For example, it allows broad consent for future research and secondary use of stored samples. It also strengthens the position of sample donors and better protects their integrity. Here, we briefly describe the main aspects of this new law.

In the law, a biobank is defined as a collection of samples that are stored for research purposes. Unless otherwise specified, the biobank owns the samples and the data that are stored in it. However, biobanks are regarded as common resources and can only deny researchers access to samples under certain conditions, for example, to ensure that rare collections are preserved. Researchers, in turn, are obliged to return results from analyses, so that information accumulates in the biobank. Six clinical biobanks and a population-based biobank have so far been planned in Finland.

According to the law a person can consent to samples being stored in a biobank and used for future research, and also to personal data being disclosed and linked with data in registries. The material can then be used, without obtaining re-consent, within the registered area of operation of the biobank, which can be very broad. This can include research into health-promoting activities, causes of disease, and disease prevention and treatment, as well as research and development projects that serve healthcare. Each individual has a right to know the following: whether samples that have been taken from him or her are stored in a biobank and why; where data has been collected from; and whom the samples and the associated data have been provided to. The individual also has a right to obtain information about his or her health that has been derived from a sample.

Clinical samples and associated data that were stored within the healthcare system when the law came into force can be transferred to a biobank after approval by a regional ethics committee. In such cases the individuals concerned should be notified and can opt out. If they cannot be reached with reasonable efforts, public notification combined with an opt-out mechanism is sufficient. This also applies to samples that have previously been taken for research purposes.

Although some questions remain regarding the exact interpretation of the law, it is clear that the prerequisites for performing research on samples and data will improve greatly following its enactment. The concurrent commitment to create an effective research infrastructure — for example, by harmonization of data standards and systems — will also be a valuable step forwards.

To our knowledge the new legislation is unique in combining two key aspects: the possibility to store samples with broad consent for future research and the opt-out mechanism that is used to include existing samples. Time will tell whether the Finnish example can influence legislators in other countries. From an ethical point of view it should; the new law makes it easier to contribute to medical advances (both for individuals in general and for researchers), while fundamental rights and interests remain well-protected.

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Acknowledgements
The research underlying this article was made possible by funding from the Swedish Research Council through the BioBanking and Molecular Resource Infrastructure of Sweden and the research infrastructure project Swedish Initiative for Research on Microdata in the Social and Medical Sciences. The funders had no influence on the design and the content of the article, and are not liable for any use that may be made of the information herein.

Competing interests statement
The authors declare no competing interests.

[1]*Centre for Research Ethics & Bioethics, Uppsala University Box 564, 75122 Uppsala, Sweden.*
[2]*National Institute for Health and Welfare (THL), Mannerheimintie 166, 00270 Helsinki, Finland. Correspondence to J.S.F. e-mail: joanna.forsberg@crb.uu.se*
doi:10.1038/nrg3646
Published online
10 December 2013