Salokannel, M., Tarkkala, H. & Snell, K. Reply to: Comment on "Salokannel et al., legacy samples in Finnish biobanks: social and legal issues related to the transfer of old sample collections into biobanks". Hum Genet (2020).

https://doi.org/10.1007/s00439-020-02134-6

Published 27 February 2020

We would like to thank representatives from the Finnish biobanking sector and of the Ministry of Social Affairs and Health[1] for the interest shown in our article. Undoubtedly, Finnish biobanks are an important resource for biomedical research and we all share an interest in establishing sustainable biobank operations while maintaining the trust of the inhabitants. We believe that an essential part of building this trust is to follow the foundational principles of human subject related biomedical research as presented in the international human rights conventions and the EU Charter of Fundamental Rights and applied to the GDPR. We warmly welcome the discussion on the topics we raised and those raised by Liede et al. We would also like to add that we discuss issues related to socially sustainable biobank practices through the case of Finnish biobanks, but simultaneously we contribute to the ongoing international discussion concerning the storage of biobank samples and the transparency of their uses (e.g. Nordfalk & Ekstrøm 2019). Furthermore, we acknowledge that setting up and regulating biobank operations and practices in a developing and changing environment is a challenging task.

In general, the comments of Liede et al. seem to relate more to the Finnish biobank activities and the Biobank Act in general than to the actual main argument of our article. Their commentary adds valuable context to our article in terms of biobank practices, current legislation and consent, since comprehensive analysis of Finnish biobanking was not under the scope of our article. Regardless, the argument made in our paper still holds: Even though Finnish biobanks are presented in the public as autonomy preserving consent based sample collections, they are in practice based upon the transfer of old diagnostic collections (approx. 10 mil. samples) from hospital districts and research cohorts to the biobanks.

These transfers have occurred in conformity with the biobank legislation of 2013, which permits a public notification regarding each transfer. Our main concern is that the public notifications about the transfers don't reach the inhabitants, which leads to the fact that large part of the Finnish population don't have any knowledge about the storage and further use of their samples and related health data in biobanks. Liede et al. point correctly to the presence of biobanks in the internet and social media and biobanks have indeed made great effort to enhance public communication. However, the majority of public communication deals with new samples and the current possibilities to give a consent. There is very little discussion related to the transfer or existence of legacy samples. As demonstrated in our article the primary intention of the provision enabling the transfer of old sample collections was that the data subjects should be informed individually. This is also confirmed by the Constitutional Law Committee of the Finnish Parliament, which stated that only if informing the data subjects individually can not be achieved by reasonable means, data controllers could utilize the public notification procedure in public newspapers (PeVL 10/2012 vp).

As shown in our article the European Court of Human Rights has clearly stated that at stake in the confidentiality of health data are both the privacy of the patient as well as their confidence in medical profession and health services in general. It cannot be the case that privacy concerns would result in deterring people from seeking treatment or them feeling that they cannot reveal all necessary information

[1] *Liede, Sandra, Soini, Sirpa & Southerington, Tom:* Response to Salokannel, Tarkkala and Snell: Legacy samples in Finnish biobanks: social and legal issues related to the transfer of old sample collections into biobanks in Human Genetics, October 16, 2019.

needed in their treatment (Z v. FINLAND—22009/93 [1997] ECHR 10 (25 February 1997)). In other words, not respecting the purpose limitation in sample collection in health care could prevent people from seeking care and ultimately risk not only their own health but also, in case of communicable diseases, the health of others. The EU Clinical Trials Regulation similarly confirms the general principle of purpose limitation in human health related research.

GDPR provides for strict information obligations for data controllers when collecting data from data subjects which affects also the application of the Finnish Biobank Act. For diagnostic collections of hospital districts there is now a need to inform the data subjects of eventual further uses of samples at the time of collecting the samples according to article 13 of the GDPR. Exceptions to this rule are permitted only insofar the data subject is already in possession of such information. Even if data is collected from another source, such as from public administrative registers, the information obligation remains according to Article 14 GDPR. However, this Article permits exceptions for research uses when the provision of information would prove impossible or would involve a disproportionate effort. Availing of this exception requires a documented balancing of the rights of data subjects in relation to the disproportionate effort. It should also be noted that this exception does not cover commercial utilization of biobank samples or genetic data derived therefrom. The Finnish Data Protection Authority requires performance of a data protection impact assessment when utilizing this exception for scientific research. The information relating to transfers and further processing should also be made available publicly.[2] We are glad to notice that, for example, the Finnish Institute of Health and Welfare has published relevant information relating to research projects on its website.

Our article discusses at the general level the information obligations provided for in international and European human and fundamental rights instruments and in other EU law. The informed and voluntary consent of the person is the basis for any intervention with the integrity of a human being in connection with health care and related activities, including for research purposes. Exceptions to this rule are possible for serious public health purposes, such as prevention of spreading of certain communicable diseases or for the protection of vital interests of the person herself. According to Oviedo Convention in any balancing of the rights the interests and welfare of the human being shall prevail over the sole interest of society or science. (Art. 2). New risks rising out of utilization of genetic data further accentuate the risks for patients and research subjects.

We also present in our article an option of following the Danish example of setting up an opt-out register in which persons could choose whether they want to give their biobank samples and genetic data for research purposes or only for immediate health care. Inhabitants can also ask for destruction of their biobank samples.[3] We by no means want to set into question the importance the Finnish biobank operations have for the biomedical research setting. Our aim is to point out that the current practice of transferring diagnostic collections to biobanks for research and commercial uses without informing the data subjects about this seems problematic in terms of the GDPR and general principles of EU fundamental rights and International human rights law. This is an issue that has to be open for debate to ensure the legitimacy and compliance of biobank operations with respective legislations. The discussion on this specific topic is very timely, as the Finnish biobank legislation is currently under revision. At a more general level the case of Finnish biobank law and its practical application presents an example as to why core principles with regard

[2] See more closely WP29 Guidelines on transparency, WP260rev. p. 30.

[3] Danish Health Act Sections 29 (Tissue utilization register) and 33 (possibility to ask for destruction of samples).

protecting rights of weaker parties, in this case patients, must be provided for in the actual text of the law, to have real meaning in practice and be binding in terms of enforcement.

Compared to many European countries, there has been little public discussion about biobanking in Finland. However, during the last few months, there has been increasing activity. In an interview of the national public service broadcasting company YLE (2019), the national Data Protection Authority (Helsinki Times 2019) took a similar stance towards legacy samples as presented in our article. We look forward to further interdisciplinary discussion on the topic with community of scholars, experts as well as general public.

References:

Helsinki Times (2019) YLE: Data protection a concern with Finngen, a Finnish genomic research project. Available at: https://www.helsinkitimes.fi/finland/finland-news/domestic/17024-yle-data-protection-a-concern-with-finngen-a-finnish-genomic-research-project.html (accessed 20.12.2019)

Nordfalk F & Ekstrøm CT (2019) Newborn dried blood spot samples in Denmark: the hidden figures of secondary use and research participation. European Journal of Human Genetics, 27, 203-210.https://doi.org/10.1038/s41431-018-0276-2

YLE (2019) Punainen kulta. Available at: https://yle.fi/aihe/artikkeli/2019/11/25/monen-suomalaisen-geeniperima-on-voinut-paatya-laakeyhtioiden-analysoitavaksi (accessed 20.12.2019)