Challenges of the EU General Data Protection Regulation on Consent and Data Transfer for Biobanking and Biomedical Research

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Abstract

In April 2016, after a long process of debate and negotiation, the European Parliament adopted the EU General Data Protection Regulation (GDPR), which was proposed by the European Commission in 2012 as a reform of existing fragmented EU data protection rules derived from the Data Protection Directive (95/46/EC) among EU member states. The main purpose behind this Regulation aims at setting out an EU-wide legal framework for the protection of the processing of personal data while at the same time facilitating the free flow of such data within the European Union. Unlike the EU Directive 95/46/EC that defines the basic elements of data protection for EU member states to enact individual national legislation on data protection, the Regulation will apply directly to each member states of the European Union and will override existing national data protection laws in the EU.

The Regulation sets forth a number of key changes to the EU Data Protection Directive and several principles relating to the enhanced rights for data subjects (e.g., the right to be forgotten and the right to data portability), the processing of personal data, and the obligations of data controller and processors, such as mandatory appointment of a Data Protection Officer and carrying out mandatory data protection impact assessment. It stipulates that personal data need to be proceeded “lawfully, fairly, and in a transparent manner in relation to the data subject”, even though it also instructs special provisions for scientific research. In the context of biobanking, it refers that in principle, purpose-specific consent will be required from individuals whose data are processed unless there is specific permission provided by law.

What impact the Regulation will have on biomedical research especially on existing biobanks remains to be discussed. For genomics research, biobanks have been deemed to be a useful infrastructure that can facilitate wide ranging, population-

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based prospective longitudinal studies. Such biorepositories usually collect large amounts of samples and data, including medical, health and life data, and make these available to researchers who apply for access for future unspecific research purposes. In order to maximize the utility of samples and data stored in biobanks and reduce the costs of re-contacting participants, broad consent has in practice replaced specific consent for data collection of biobanks. The extent to which this particular form of consent could be compatible with the Regulation or falls within special provisions for scientific research is worth further analysis.

In addition, the Regulation stipulates the general transfer provisions for personal data to be transferred to a third country outside of the EU to ensure an adequate level of protection. Subject to the Regulation, transfers under the principles of Safe Harbour are no longer valid, and the new specific rules, such as EU-US Privacy Shield are still in the process of negotiation. This paper discusses these challenges brought from the Regulation on consent and data transfer for biobanking and biomedical research. It analyses the Regulation’s conditions and argues why some rules may not be appropriately suited to the context of biobanks and to the processing of genomic data in terms of the nature of biomedical research. In the end, it will also provide a possible resolution to address these emerging challenges to balance the requirements of data protection and the need of scientific research.