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Legal and Ethical Implications of Data Sharing in International Biobanking Research: Toward a Global Response

Anne-Marie Tassé,¹ Marianna J. Bledsoe,² Lisette Giepmans,³ and Vasiliki Rahimzadeh¹

THE STUDY OF POLYMORPHISMS and multifactorial causation of disease raises a keen interest in population-wide genetic and genomic research. This type of research requires the collection and analysis of large numbers of biological samples and associated detailed phenotypic data sets, as typically done in population-based biobanks and biorepositories.

The understanding of the interactions among genetic make-up, modifiable and non-modifiable risk factors, the onset of disease, and healthy aging research requires large sample sizes. This necessitates combining multiple data sets, increasingly from biobanks internationally.

Although combining information from different biobanks creates a number of scientific challenges, protecting participants' rights without impeding research constitutes a baseline postulate for legal and ethical scholars working in biobanking. The combined use of data from different biobanks for international research is largely dependent on each biobank's legal and ethical right to share the data. Such international sharing and use of personal, medical, and genetic data are guided by various legal and ethical frameworks, including a large number of documents of different jurisdictional (international, regional, national, local, cohort-specific, etc.), legal (laws, regulations, guidelines, policies, etc.), and disciplinary (law, ethics, social sciences, etc.) scopes.

In the absence of universal ethical standards and uniform legal frameworks, assessing the right to share data for international research proves a daunting task. In this regard, differences between national and local frameworks are likely to curb the production of new knowledge. Additional challenges to international data sharing include the lack of standardized terminology and data harmonization, governance, privacy, as well as unresolved ethical issues, such as the return of research results.

Funded from 2010 to 2015 by the European Union under the FP7 scheme, the Biobank Standardisation and Harmonisation for Research Excellence in the European Union (BioSHaRE-EU) project has addressed some of these challenges and provided practical solutions. BioSHaRE-EU was a consortium of leading population-based cohort studies, with international researchers from diverse domains of

biobanking science, including epidemiologists, statisticians, software developers, and ethical, legal, and social implications (ELSI) experts. It produced tools and methods for data harmonization and standardization, data sharing, and analysis across multiple biobanks and databases, and applied these tools in a series of scientific projects where data from multiple biobanks were harmonized and jointly analyzed, while securing data and participant's rights and privacy. The combination of developing and applying the tools, and bringing developers, users, and ELSI experts together provided the optimal setup to identify ELSI issues related to this new way of working. Central to the BioSHaRE-EU mission was to align the rights and interests of research participants with those of the broader scientific community. Positioned at the intersection of these rights and interests, BioSHaRE-EU aimed to ensure scientifically promising biomedical research, which leads to clinical progress, and, at the same time, holds the research enterprise accountable for promoting the public good. To provide a better understanding of the specific ethical and legal issues related to international data sharing, the BioSHaRE-EU project required ethical, legal, and social researchers to analyze international, national, and cohort-specific frameworks. It emphasized the development of pragmatic tools and methods to facilitate data sharing in the complex regulatory environment of biobanks.

This Special Issue presents the research results of the BioSHaRE-EU ELSI experts. The first series of articles provides in-depth comparative analyses of pressing legal challenges related to international data sharing and demonstrates the impact of non-harmonized ELSI frameworks in biobanking research. Kaye et al. outline various consent models for biobanking and provide a comparative analysis of the data access governance for five BioSHaRE-EU biobanks, since harmonization of ELSI policies and governance often begins by identifying similarities and differences in data use, collection, and sharing across jurisdictions, Tassé demonstrates how the secondary use of data can be retrospectively assessed for ethical and legal interoperability purposes for large-scale research consortia. Next, Bovenberg et al. examine data linkage between environmental exposure data using Geographical Information System (GIS) technologies and biobanking data

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under the current European Union Directive. In the era of Google maps and ubiquitous location-based capacities of various social media platforms, the authors draw from existing European laws to demarcate the spheres of privacy and data protection.

These first legal analyses are followed by articles discussing emerging ethical concerns in the domain of international research, such as the challenges associated with inconsistent terminology for data protection. Biobank harmonization entails building on the procedural and infrastructural similarities across these biobanks, but also speaking the same governance language. Wallace helps to avoid biobanks from getting “lost in translation” by interrogating the definitions used across different European jurisdictions. She warns of the potential complications that such definitional inconsistency can invite for biobank harmonization, and the potential impact on participant trust. Murtagh et al. add to the pressing international discussion on the state of data sharing and the underlying motivations therein. Using ethnographic methodologies, the authors aim to better understand where the value of sharing originates for members of the biobanking community and, in turn, make an original contribution to how such values are sustained. To conclude this second section, Budin-Ljøsne et al. provide recommendations for the latter, calling for a harmonized return of results policy.

Finally, the Special Issue presents practical solutions. An assessment “filter” (Tassé et al.), for example, provides researchers with a schema for assessing how to share data across Europe and the world. It furthermore highlights how new models of sharing can complement existing data protection

regulation, and next steps to further develop a global framework for international data sharing. A human rights approach to collaborative science echoes many of the same values Murtagh et al. identify in their study, and reflects the values upon which the Global Alliance for Genomics and Health developed its *Framework for Responsible Sharing of Genomic and Health-Related Data* (genomicsandhealth.org). In fine, Rahimzadeh et al. discuss this human rights-based foundation and the future the Global Alliance envisions for international data sharing moving forward in the post-genomic era.

Taken together, the articles that compose this Special Issue testify to the solution-oriented approach of the BioSHaRE-EU project. They speak of a shared philosophy of facilitating innovative clinical research in areas where ELSI challenges abound. It is our hope that the results generated from the project will help promote greater data sharing and collaboration internationally, thereby catalyzing important research to advance our understanding of complex diseases.

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