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Harmonizing Privacy Laws to Enable International Biobank Research

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Biobanks of various types (e.g., public or private, single disorder or multiple disorder, open access or restricted access) have become an important part of modern biomedical research. Biobanks facilitate research on rare disorders, large-scale genomic analysis, and validation of promising findings using large cohorts, thereby promoting translational science and personalized medicine. An increasing number of biobanks are affiliated with or participate in international consortia to establish even larger repositories of biological specimens and health information.

Traditional legal and ethical principles, including informed consent and privacy, govern research using biobanks. The identifiability of specimens and health information is often the most important factor affecting the degree of regulation. The less identifiable the specimens and records are, the less restrictive the legal and ethical rules are that govern access to and use of biobanks. This fact would seem to make deidentifcation strategies appealing because they generally limit the oversight of research. Nevertheless, deidentification also decreases the utility of the specimens and data in biobanks because of the inability of researchers to obtain additional information from research participants and to share findings of clinical significance with the participants.

Protecting privacy without impeding research is a great challenge for biobank administrators, researchers, regulators, and scholars. The challenge is heightened for international research because the relevant laws differ widely among countries engaged in biobank-enabled research in terms of substance, procedure, and underlying public policies. The lack of international regulatory harmonization has been shown to impede data sharing for translational research in genomics and related fields. The daunting task is to identify and characterize the biobank structure and applicable standards in each country and then to

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devise possible ways to harmonize policies and laws to enable international biobank research while still giving effect to essential privacy protections.

In 2005, we edited a symposium for this journal on *Regulation of Biobanks.*[1] The increased significance and complexity of these issues is reflected in the fact that our new study of international biobanking occupies two complete issues of this journal. In all, the two-part symposium contains 27 articles, 40 authors, and analyses of the laws of 20 countries.

Part I begins with essential background articles on the need for harmonization and international norms. They are followed by country-specific articles on Australia, Brazil, China, Denmark, France, India, Israel, Nigeria, South Africa, Spain, Taiwan, and the United Kingdom.

Part II contains jurisdiction-specific articles on Canada, Estonia, the European Union, Finland, Germany, Japan, Mexico, the Netherlands, Uganda, and the United States. These are followed by articles evaluating the European Union-United States Safe Harbor program, and information technology issues. Our concluding article discusses the context for biobank research, provides a table of the laws in 20 countries on issues such as informed consent requirements and the legality of sharing samples and data, and contains our assessment of the key issues to resolve for international biobank research.

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