

Introduction to the Country Reports

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In selecting the countries and expert legal reporters, the principal investigators began with the 20 countries and experts they previously used in their NIH-funded study of international biobanking laws.¹ That study mostly involved developed countries engaged in or initiating biobanking programs. To increase diversity for this research project, 13 additional nations were selected. The experts for Vietnam and the American Indian Nations were unable to complete their reports, thereby leaving 31 countries for this study.

The country experts were given a limit of 2,000 words for their reports. The limit did not apply to the reports from the United States and Canada, the home countries of the principal investigators and, in the case of the United States, the source of grant funding. Although all 31 reports answer the same 10 questions, they vary widely in substance and style.

With regard to substance, it is important to remember that none of the countries in the study had laws explicitly addressing the emerging issue of international direct-to-participant (DTP) genomic research. Therefore, the experts based their answers to the standard questions on various other laws dealing with related issues, such as genetics, biomedical research, and health privacy, or by extrapolation and analogy. Not surprisingly, many of the experts' answers to yes/no questions about their country's laws were "unsure" or "other." All of the answers were the educated opinions of the experts selected by the investigators, but other experts from the same country might disagree.

Notwithstanding these limitations, the country reports are extremely valuable. They represent the first systematic effort to assess the legal environment for international DTP genomic research in multiple countries, as well as the ethical, policy, and cultural factors that will likely affect new legal developments. The reports served as background documents for discussions leading to the recommendations culminating this symposium and research project.

Note

The author has no conflicts to disclose.

References

1. M.A. Rothstein and B.M. Knoppers, eds., "Symposium: Harmonizing Privacy Laws to Enable International Biobank Research," *Journal of Law, Medicine & Ethics* 43, no. 4 (2015): 673-826; and 44, no. 1 (2016): 7-172.

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