# Regulation of International Direct-to-Participant Genomic Research: Symposium Introduction

*Mark A. Rothstein and Bartha Maria Knoppers*

Many observers have remarked that the law usually lags behind new developments in science and technology, and the following symposium confirms this observation, at least in the context of international genomic research. The legal and policy analyses presented here attempt to reduce the lag time between science and law by calling attention to an emerging trend in genomic research, assessing the current state of the law in 31 representative countries, and proposing a series of recommendations to facilitate genomic research while remaining faithful to the ethical foundations of the laws regulating biomedical research around the world.

Research on genetic disorders requires biological specimens (for genome sequencing) and medical records from affected individuals (to confirm the diagnosis, document the symptoms, and track the effect of treatment). Because there are often relatively few cases of a rare disorder, the traditional method of identifying and recruiting potential research participants through a limited number of academic medical institutions has been ineffective. A newer method, using online recruitment — often with the collaboration of patient advocacy and disease-specific groups — has been successful in obtaining greater enrollment. This method has received approval from the IRBs of the researchers' home institutions. To further increase the number and diversity of participants, some researchers have attempted to use the same recruitment method to enroll participants from other countries. This expansion of scope, however, might be illegal in countries where a researcher from a foreign country may not recruit participants and solicit their biological samples for genomic analysis without ethics approval from the home country of each participant.

Because obtaining ethics approval from numerous countries would be infeasible, individuals from many countries are precluded from participating in such studies. Legal restrictions on participation also could delay the research and limit the generalizability of any findings. Consequently, a timely understanding and, if possible, successful resolution of the challenges of international direct-to-participant (DTP) genomic research is essential. Indeed, this issue lies at the intersection of two important and growing trends in biomedical research: internationalization of research and online recruitment of participants.

**Mark A. Rothstein, J.D.**, *is the Herbert F. Boehl Chair of Law and Medicine and Director, Institute for Bioethics, Health Policy and Law, University of Louisville Schoool of Medicine.*
**Bartha Maria Knoppers, Ph.D.**, *is Canada Research Chair in Law and Medicine and Director of the Centre of Genomics and Policy at McGill University.*



*The Journal of Law, Medicine & Ethics*, 47 (2019): 579-580. © 2019 The Author(s)
DOI: 10.1177/1073110519897734

Our research methodology involved the following four elements.

First, to identify the appropriate questions to ask about the regulation of international DTP genomic research, we planned a series of three meetings with experts in genomic and international research. In advance of each meeting, our co-investigators from Vanderbilt University, Laura M. Beskow, Kathleen M. Brelsford, and Catherine M. Hammack-Aviran, used a systematic process to identify priorities, including having the participants separately compose 5-10 draft questions reflecting their individual concerns to be used in generating discussion at each meeting. The questions were then aggregated and organized into broad categories, such as informed consent and privacy. The questions served to initiate discussions that culminated in the prioritization of questions across all categories.

Second, to support our research tool, we convened three meetings, with the initial one on September 12, 2018, at the Broad Institute in Cambridge, Massachusetts, one of our institutional collaborators on this project. Participants were Michelle Agee, 23andMe; Mark Barnes, Ropes and Gray, LLC; Paul R. Billings, Omicia; Denise L. Perry, Illumina; Thomas M. Morgan, Vanderbilt University; Martin Naley, MyTomorrows; Olivier Noel, DNA Simple; Michelle Penny, Biogen; and Christina Waters, Rare Science.

We held a second meeting at George Washington University, in Washington, DC, on October 8, 2018. The participants, experts in nontraditional research, including patient-directed research, were Jason Bobe, Icahn School of Medicine at Mt. Sinai; Shawneequa Callier, George Washington University; Melissa M. Goldstein, George Washington University; Sally Okun, PatientsLikeMe; James O'Leary, Genetic Alliance; Ernesto Ramirez, Evidation Health; Jennifer Thornton, A-T Children's Project; Bastian G. Tzovaras, Open Humans; and John T. Wilbanks, Sage Bionetworks.

We held the final meeting at George Washington University, in Washington, DC, on October 9, 2018, involving experts on international research regulation. Participants were Edward E. Bartlett, Office for Human Research Protections, Department of Health and Human Services; Shawneequa Callier, George Washington University; Anne Cambon-Thompson, University of Toulouse; Dominic Chiarelli, Quorum Review; David Forster, WIRB-Copernicus; Melissa M. Goldstein, George Washington University; Dina M. Lyon, Department of Defense; Ebony B. Madden, H3Africa Program, National Institutes of Health; and P. Pearl O'Rourke, Partners Health.

Third, informed by the compilations of priority questions and opinions from all three groups prepared by our Vanderbilt colleagues, the investigator team devised 10 standard questions. We then submitted the draft questions for review by the study's international advisors: Ruth Chadwick, University of Cardiff (UK); Ellen Wright Clayton, Vanderbilt University (US); Jantina DeVries, University of Cape Town (South Africa); and Daryl Pullman, University of Newfoundland (Canada). We incorporated their suggested revisions into the 10 questions.

In early 2019, the investigators sent the final version of the questions to leading experts in research ethics and law from countries selected because of their diversity in size, geography, legal system, and stage of biomedical research development. The experts submitted their responses in the form of country reports in the spring of 2019. Between March and August of 2019, Ma'n H. Zawati, with the assistance of Michael Lang, both from McGill University, reviewed the survey responses for completeness, comprehensibility, and standard publication form. The process involved email consultation with the country experts and was highly iterative.

The investigator team met in Montreal on July 2-3, 2019 to discuss the reports from 31 countries, compile key findings, draft recommendations, and plan for the international dissemination of the study's results. The investigators' concluding article at the end of this symposium contains our own analysis, recommendations, and implementation strategy.

The final step in the process was the release and dissemination of the findings and recommendations. Besides publishing this symposium containing the country reports and recommendations, we plan to present our research at professional meetings, stakeholder conferences, and other seminars around the world.

The investigator team included: University of Louisville: Mark A. Rothstein and Kyle B. Brothers; McGill University: Bartha Maria Knoppers, Yann Joly, Michael Lang, Dimitri Patrinos, and Ma'n H. Zawati; Broad Institute: Andrea Saltzman; and Vanderbilt University: Laura M. Beskow, Kathleen M. Brelsford, Catherine M. Hammack-Aviran, and James W. Hazel.

Note

The research reported in this symposium was funded by Regulation of International Direct-to-Participant Genomic Research, Mark A. Rothstein and Bartha Maria Knoppers, PIs, Grant No. 5R01HG009914-02, National Human Genome Research Institute, National Institutes of Health.



*The Journal of Law, Medicine & Ethics*, 47 (2019): 579-580. © 2019 The Author(s)