

Policy experts advocate mutual recognition for reviews of data-intensive international research

March 25 2016, by Chris Chipello



Credit: NIH

Genomic research holds great potential to advance human health and medicine. But for the millions of data points now being collected through large-scale sequencing efforts to be truly valuable, they must be analyzed in aggregate and shared across institutions and jurisdictions. This raises many challenges, including navigation of complex ethics-approval processes at multiple sites and in multiple jurisdictions.

In a Policy Forum article published this week in the journal *Science*, members of the Ethics Review Equivalency (ERE) Task Team of the Global Alliance for Genomics and Health (GA4GH) Regulatory and Ethics Working Group discuss this challenge and ways to address it, particularly through ad hoc models for achieving [ethics review](#) "mutual recognition" around the globe.

"As more data are shared and research becomes increasingly networked and collaborative, national research governance structures are beginning to address the need for harmonization of procedures and standards between research ethics committees (RECs). For instance, only one REC is needed to approve a domestic multi-site [genomic research](#) project in the UK," said Edward Dove, a doctoral candidate at the University of Edinburgh School of Law in the UK, ERE Task Team Coordinator, and lead author. "But these governance or regulatory reforms don't apply when data are shared internationally. Internationally, the challenges are myriad and remain unresolved. Multiple, and often duplicative, ethics approvals are needed, without any evidence that these benefit participants, science, or society."

A first step

As a first step toward achieving mutual recognition among ethics committees, the ERE Task Team met in Switzerland in June 2015 to identify and develop models of ethics review used around the globe, as well as ethics review methods that will enable more efficient sharing of genomic and clinical data for research. Funded by the Public Population Project in Genomics and Society (P3G), the Wellcome Trust, and the Brocher Foundation, the meeting's attendees included ethics experts from Australia, Belgium, Canada, the Netherlands, the UK, the USA, and South Africa. Through discussions grounded both in theory and practical experience, participants identified three models of mutual recognition: reciprocity, delegation, and federation. In many cases, some

combination of all three takes place, leading to an ad hoc, mix-and-match approach.

Current models for reform have multiple variations and come with advantages and disadvantages, which are outlined in the article. For instance, reciprocity allows for flexible review standards, but can be time-consuming at the initial implementation stage. Federation, while reducing costs and duplication efforts of multiple RECs, is difficult to implement because of challenges in getting several jurisdictions to agree on policy and standards.

Symposium to be held in Montreal

"Ultimately, what we need is an international organization that has the authority and multi-stakeholder support to enable an ethics review mutual recognition system for data-intensive international research," said Bartha Knoppers, Director of the Centre of Genomics and Policy at McGill University, Chair of the P3G in Montreal, and Chair of the Regulatory and Ethics Working Group of the GA4GH. In the meantime, however, the ad hoc models outlined in the paper provide a framework to guide current international data-sharing initiatives.

Knoppers added that "the GA4GH has a key role to play by working with regulatory authorities on regional, national, and international levels." To that end, the ERE Task Team will hold a second symposium to take place in Montreal in May 2016 that will convene researchers, industry members, ethics experts, policymakers, and regulators from around the globe to extend the work that began in 2015.

More information: E. S. Dove et al. Ethics review for international data-intensive research, *Science* (2016). [DOI: 10.1126/science.aad5269](https://doi.org/10.1126/science.aad5269)

Provided by McGill University

Citation: Policy experts advocate mutual recognition for reviews of data-intensive international research (2016, March 25) retrieved 19 April 2024 from

<https://medicalxpress.com/news/2016-03-policy-experts-advocate-mutual-recognition.html>

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