Regulatory Landscape of International Direct-to-Participant (DTP) Genomic Research: Time to Untie the Gordian Knot?

Currents in Contemporary Bioethics

Mark A. Rothstein, Ma'n H. Zawati, and Bartha Maria Knoppers

About This Column

Mark A. Rothstein serves as the section editor for *Currents in Contemporary Ethics*. Professor Rothstein is the Herbert F. Boehl Chair of Law and Medicine and the Director of the Institute for Bioethics, Health Policy and Law at the University of Louisville School of Medicine in Kentucky. (mark.rothstein@louisville.edu)

I. Introduction

Next generation sequencing of patient samples obtained from clinical investigators and biobanks have yielded critical new insights into human biology. Sequencing technologies have also promoted the development of new genomic-based health risk assessments, preventive interventions, and innovative therapies. Despite such progress, biobanking remains challenging when collecting large volumes of samples and health information from diverse and representative populations, whether in developing[1] or developed countries.[2] Indeed, existing genomic databases are extremely limited in their representation of human ancestry. A 2016 study revealed that 81% of subjects included in genome-wide association studies (GWAS) to date were of European descent, even though modern societies are heterogeneous.[3]

On a global scale, the existing research model is especially problematic for rare disease research, where cases are defined by their low prevalence, and patients sharing a specific genetic etiology are often geographically distant from physical collection sites.[4] For many rare diseases, efficient discovery of causal genes requires seamless aggregation of cases around the world. However, banked samples for rare diseases are often siloed by project and almost impossible for most researchers to access.[5] Furthermore, given the rarity of certain diseases, many specialist referral centers will not observe more than one case caused by mutations in a particular gene. Obtaining the multiple cases required to demonstrate genetic causality requires new approaches, such as having scientists engage in a global partnership with patients, rather than institutions, to collect sufficiently large volumes of either very scarce or representative samples.[6] An international rare diseases research consortium is working to overcome these limitations.[7]

Including participants from a large number of countries in genomic research is made more difficult by the various regulatory requirements found in each country.[8] They operate to thwart the inclusion of diverse patient populations needed to better understand the molecular underpinnings of disease.[9] Barriers to more inclusive genomic research include prohibitive or unclear regulatory requirements in some countries, lack of international harmonization of research regulation, and a lack of data sharing often due to a failure to foresee this in the consent process or through data hoarding practices.[10] Researchers, patient groups, and pharmaceutical companies are seeking to adopt new, internet-based research practices that avoid these traditional obstacles to data intensive research.

Although there is significant interest in developing a direct-to-participant (DTP) research model where scientists can routinely recruit eligible participants beyond their countries' borders via the internet, regulatory bodies governing human subjects research in the vast majority of countries have not yet developed legal standards to facilitate this in practice,[11] and there is great uncertainty surrounding DTP research. Hence, the urgent need to understand the international regulatory landscape in

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.* **Ma'n H. Zawati, Ph.D.**, *is Academic Coordinator of the Centre of Genomics and Policy, and an Associate member of the Biomedical Ethics Unit, McGill University.* **Bartha Maria Knoppers, Ph.D.**, *is Professor of Medicine and Director of the Centre of Genomics and Policy at McGill University.*

The Journal of Law, Medicine & Ethics, 47 (2019): 336-341. © 2019 The Author(s)
DOI: 10.1177/1073110519857291

order to foster greater potential for a global DTP genomic research model. As a first step towards this endeavor, a brief contextualization of the DTP model through its diverse research strategies will be necessary.

II. Research Strategies

A. Online Recruitment

A novel DTP model is emerging that utilizes new technology to facilitate more efficient and representative recruitment for genomic studies. Population-wide internet access and the proliferation of advocacy groups, social media, and empowered citizen scientists have created a substantial opportunity for the direct linkage of genomic researchers with vast numbers of potential research participants. Rather than recruiting participants through treating physicians, hospitals, or biobanks at physical collection sites, it is now possible for scientists to recruit, consent, and enroll patients directly using the internet. Typically, this involves a single "mega-site" responsible for recruitment, enrollment, management, sequencing, analysis, and follow-up of all participants, even though all interactions with participants are conducted virtually. Recruitment is usually limited to single countries.

From a technical standpoint, this approach is immediately applicable in developed countries, where internet access is widespread, and its utility in developing countries is growing rapidly. In June 2018, worldwide access to the internet was at 55.1%.[12] By 2020, there will be 6 billion smartphones used by about 70% of the world's population.[13] In theory, researchers can apply the same domestic model to create a study-specific website with targeted recruitment through disease-associated groups, advocates, and patients. In most cases, patients and families complete a self-guided, pre-screening questionnaire allowing researchers to determine eligibility. Qualified participants are re-contacted and offered an opportunity to complete an electronic, interactive, informed consent process. A medical records authorization completed as part of the consent process allows researchers to obtain the participant's medical records. Participants who meet all eligibility criteria are sent a sample collection kit to obtain and then ship a blood or saliva sample directly to the researchers.

Although there is significant interest in developing a direct-to-participant (DTP) research model where scientists can routinely recruit eligible participants beyond their countries' borders via the internet, regulatory bodies governing human subjects research in the vast majority of countries have not yet developed legal standards to facilitate this in practice, and there is great uncertainty surrounding DTP research. Hence, the urgent need to understand the international regulatory landscape in order to foster greater potential for a global DTP genomic research model. As a first step towards this endeavor, a brief contextualization of the DTP model through its diverse research strategies will be necessary.

An illustration of the power of the DTP model is the Metastatic Breast Cancer (MBC) Project at the Broad Institute. Participants are recruited in partnership with breast cancer advocacy organizations, which provides important validation for participants and raises awareness of the project. In the first year of the study, more than 2,900 women and men with MBC from all 50 US states enrolled.[14]

B. Challenges of Rare Disorders

For many disorders, especially rare genetic diseases and cancers, restricting DTP enrollment to the researcher's country limits the utility of research because it fails to take advantage of the opportunity to include appropriate participants from around the world. This is despite the fact that the mechanics of the recruitment, enrollment, consent, and sample collection processes are essentially the same for domestic and international research. Compared with current practices, international DTP enrollment could be more efficient and expeditious, generate more representative and diverse samples, be more participatory and democratic, and lead to scientific discoveries that have wider relevance for today's modern heterogeneous populations.

The primary challenge with this approach involves regulation. In many countries, it is illegal for foreign researchers to directly recruit domestic citizens to participate in research and to have data or samples sent out of the country for research, especially if that research has not been approved by a local research ethics committee. From the perspective of researchers, it is logistically untenable to identify and satisfy the separate requirements of regulatory bodies in every country where qualified and willing participants may reside. From the perspective of foreign governments, however, compliance with research laws and regulations is non-negotiable and non-waivable by individual research participants. This position may be traced to several notorious incidents of misconduct by international researchers[15] as well as the economic and dignitary interests of countries

The Journal of Law, Medicine & Ethics, 47 (2019): 336-341. © 2019 The Author(s)

concerned about the loss of control over research and the genetic legacy of their population.[16] While governments may legitimately be concerned about possible harm originating from the non-compliance of researchers with local laws and regulations, it may be noted that the inability to participate and to submit health data may itself entail certain harms.[17]

C. Infrastructure

The infrastructure for international DTP genomic research is already in place in developed countries. At the same time, infrastructure challenges with respect to biobanking and connectivity are of special concern in low and middle-income countries.[18] Global connectivity, through cloud computing, mobile devices, and the "internet of things," sets the stage for the unprecedented generation and international sharing of data for health research. These technologies are also democratizing research, allowing individuals to generate, manage, and share their own data. New services, including mHealth apps and direct-to-consumer (DTC) genomic sequencing, put more data in the hands of individuals. Health care providers are establishing policies and infrastructure (portals) to provide patients access to their health data and engage them in shared decision-making. Major translational research projects, such as the one million-person Cohort Program (known as All of Us) of the Precision Medicine Initiative in the US, and the U.K. 100,000 Genomes Project[19] plan to provide individuals access to their research data. In certain situations, commercial entities and genetics laboratories also may be legally required to provide access to health and genomic data results to individuals under the new General Data Protection Regulation of the European Union.[20]

In turn, businesses, researchers, and patient groups are innovating to recruit participants remotely. In addition to the sample collection kits mentioned previously, mobile health research platforms available from Apple (ResearchKit)[21] and Google (ResearchStack)[22] allow US-based researchers to collect data remotely from participants through mHealth apps. Web portals also allow individuals to submit their health information (Sync for Science),[23] genetic test results (GenomeConnect),[24] or genomic data (DNALand)[25] to researchers.

Providers of commercial services (mHealth developers and DTC testing companies), biomedical researchers, and even patient-directed biobanking initiatives will not be content to limit their recruitment within national borders and will seek to solicit participants from around the globe. Indeed, consumer service models, health research, and patient communities all naturally scale internationally. Remote, international collection of data and samples promises to accelerate health research. One example of such research is the Genographic Project, a joint effort of the National Geographic Society and IBM launched in 2005 to map historical migration patterns by collecting and analyzing DNA samples.[26] The primary objection to the collection of DNA from diverse populations is that it may exploit indigenous populations, but more medically oriented, genomic research activities are able to guard against this and foster the right of inclusion, receiving greater ethical and legal scrutiny and oversight.

In order to address these important considerations in international DTP genomic research, it is necessary to clarify the international legal landscape. To date, there have been no systematic assessments of the legality of international DTP genomic research in the vast majority of countries. The following section introduces some of the legal restrictions facing international DTP genomic research.

III. Legal Restrictions

A. Country-Specific Laws

International DTP genomic research must comply with internationally recognized legal and ethical protections for individuals, as well as any country-specific laws relating to sovereignty and benefit sharing. To begin with, international DTP genomic research needs to respect various biomedical research laws, genetic-specific laws, data protection laws, biomaterial import/export laws, and consumer protection laws. For example, some countries impose additional consent requirements for the transfer of identifiable (including coded) samples and data across borders, and others forbid such transfers altogether. Even where researchers strive to comply with applicable norms in other countries, in the absence of harmonization, they would need to retain international legal advisers to determine whether their consent practices and other safeguards satisfy the range of diverse national regulatory frameworks. Another important issue is whether companies, researchers, and patient cooperatives may disclaim responsibility for legal compliance, and merely insist that the participant is responsible for "complying with applicable laws."

Where international DTP genomic research is prohibited, restricted, or hindered by certain consent requirements and oversight, it may interfere with both progress in research and individual autonomy. Disproportionate protections of individual privacy or perceived national interests in data can undermine the internationally recognized human right of all citizens to benefit from and participate in the progress of science.[27] In countries where barriers undermine progress in research, future patients suffer. In terms of autonomy, if individuals understand the risks and yet desire to share their samples and data internationally, they should be able to do so. Ethics review restrictions — whether directly (by refusing to permit foreign-based studies) or indirectly (by insisting on additional, local review) — can also restrain individual freedoms and unwittingly contribute to an unethical, practical barrier to research.[28] National prohibitions, conditions, or oversight processes for export of citizens' data or samples similarly restrain individuals' freedom to share with whomever they please.

In 2016, the Council for International Organizations of Medical Sciences (CIOMS), in collaboration with the World Health Organization (WHO), published its International Ethical Guidelines for Health-Related Research Involving Humans.

The Journal of Law, Medicine & Ethics, 47 (2019): 336-341. © 2019 The Author(s)

The guidelines, applicable to research in low- and middle-income countries, contain restrictions on research using samples that may be appropriate for traditional research, but will make DTP genomic research in numerous countries impractical: "Biological materials and related data should only be collected and stored in collaboration with local health authorities. The governance structure of such collection should have representation of the original setting. If the specimens and data are stored outside the original setting, there should be provisions to return all materials to that setting and share possible results and benefits."[29] The guidelines make sense for traditional research, but may preclude genomic research on rare disorders using multinational internet recruitment.

Given these inherent tensions, there is a potential for significant variation in policies concerning international DTP genomic research. Widespread variance in legal provisions for international DTP research can impede scientific progress almost as much as an outright ban on research. Even where a national regulatory framework is permissive or silent, countries may adopt new regulations to protect their citizens' privacy and national economic interests in the future. To avoid restrictive policies, it is essential that international DTP genomic research proceed in a legal and ethical manner that accommodates the societal benefits of research as well as the necessary protections for research participants.[30]

B. Informed Consent

It is an internationally recognized ethical and legal principle that consent to research must be adequately informed,[31] but there is no comparable international consensus on whether remote, online consent meets this requirement. For research with human subjects in the U.S. subject to HHS or FDA regulations, the FDA and OHRP have issued guidance on online consent.[32] For many other countries, however, traditional informed consent may seem inconsistent with DTP research for the following reasons. First, the consent process is different when it is mediated by a website or app, rather than a human being. Second, the bilateral nature of signing a written consent (where the formality of signing indicates to people that they are entering into a formal relationship) is weakened online, where people are conditioned to click through consents or sign online without careful or complete reading. Third, self-guided consent makes it more difficult for the researcher to assess the contextual vulnerability of the participant, or for the participant to ask for more information.[33] Fourth, countries may have different standards for the lawful age of consent or who may act as a guardian or personal representative.[34] Certain DTP research studies conducted by the Broad Institute seek to resolve many of these problems by having a video conference with each individual or family during the informed consent process. There is thus a need to explore the degree to which individual countries require oversight of online research consent, including consent processes for individual studies.

It is an internationally recognized ethical and legal principle that consent to research must be adequately informed, but there is no comparable international consensus on whether remote, online consent meets this requirement.

C. Privacy and Security

Ensuring that health information remains confidential and that privacy is protected across global networks requires adequate security. Privacy and security concerns arise when health information is collected remotely because the information has to be transmitted across a complex network of organizations and technology platforms. The facilitation of international transfer of data is important, as evidenced by the January 2017 OECD Recommendation of the Council on Health Data Governance.[35]

Certain concerns arise when information is sent internationally. Laws of foreign countries may not provide the same level of privacy protection and they may not be uniform across all sectors in all countries; foreign security requirements or oversight by privacy authorities may be lax or restrictive; legal exceptions allowing access by third parties and law enforcement without consent may be broader; and participants attempting to enforce rights concerning samples and data under foreign laws may encounter legal and practical challenges. These risks may also undermine informed consent because the complex networks and distinctions between legal regimes make it difficult to ensure that individuals will be adequately informed of how their health information will be protected, who will have access to it, and what it will be used for.

D. Communication to Participants

Participation in biobanking can be a longitudinal process and data can flow in both directions over time. Consumer services offer information and interpretation services to participants. Researchers may return general and individual research results, incidental findings, or raw research data to participants as per the consent agreement. Consumer protection laws and public health regulations, however, may establish what information should or may be provided to individuals in a given country, and under what conditions. The public health benefits, risks, and costs of communicating information vary across countries with different health systems. International DTP genomic research involves interna-

The Journal of Law, Medicine & Ethics, 47 (2019): 336-341. © 2019 The Author(s)

tional liability risks for all parties, and even where these are known, it may not be possible to disclaim all such risks in countries where a waiver of health risk is illegal.

E. National Sovereignty and Benefit Sharing

Every research project involving international DTP genomic research implicates the laws of various countries, international agreements, and different local research ethics committees or equivalents. Research laws and regulations attempt to ensure the welfare of research participants by regulating the conduct of researchers. If the laws or regulations of countries involved in DTP genomic research differ or are silent in one jurisdiction,[36] it is not yet established whether the laws of the country of the researchers or of the research participants should apply. Furthermore, the rationale for regulations on specimen and data collection and sharing, if stated, may be characterized as attempting to protect the country's unique genetic resources from exploitation, to secure intellectual property rights or other benefits for the country of origin, or to safeguard the rights of sample donors, including privacy, once the samples leave the jurisdiction. It will be a challenge to respect these concerns in the face of conflicting laws.

In light of global inequalities, some forms of international health research are exploitative, as where the research disproportionately benefits the companies, researchers, or people in countries extracting data and samples compared to the participants and their countries. Although sharing samples and data promises to accelerate research, it often disproportionately benefits well-resourced parties able to rapidly analyze data, commercialize results, and afford to purchase the products. Unfettered international DTP genomic research may exacerbate inequalities and foster resentment, leading to reactive policy making. To offset this potential unfairness, a variety of benefit sharing arrangements have been established or proposed, such as providing some form of recognition or benefits to participants,[37] and access to medical care or support for health services, among other things.[38]

IV. Conclusion

In order to foster greater potential for a global DTP genomic research model, it is essential to closely analyze these issues from a range of perspectives, including through the law, ethics, science, research administration, and industry. As outlined above, global DTP genomic research raises a number of novel challenges. At the level of research strategy, DTP genomic research shows great promise. Online recruitment, for example, will ensure that research participation is more efficient, representative, and extensive. At the same time, DTP genomic research design must account for the particular challenges raised by the regulation of rare disorder research and the lack of research infrastructure in low- and middle-income countries. Apart from potential difficulties facing research strategy in the DTC research context, a number of legal considerations warrant further exploration. Researchers will need to account for the jurisdictional issues raised in this emerging research context, as well as issues related to informed consent, privacy and security, patient communication, and data sharing.

Finally, the interests of individual participants and patients should be given particular attention. As DTP genomic research continues to develop, it may be increasingly capable of extending the social good of deeper public understanding of our shared genetic history. In order to facilitate this translation, it will be vital to address the legal issues raised from an international perspective. The aim is to create an international DTP model that not only advances science reflecting human diversity, but also empowers participants around the world. As research tools are placed directly in the hands of participants, such tools should seek to "engage the curiosity of individuals to find a personal interest and to further their own story."[39] DTP genomic research will certainly engage participants, but it has important social and ethical weaknesses, to say nothing of the legal challenges raised.

Note

Funding for this research was provided by National Institutes of Health grant No. R01HG009914A, Regulation of International Direct-to-Participant Genomic Research, Mark A. Rothstein and Bartha Maria Knoppers, PIs.

References

1. J. De Vries et al., "Ethical Issues in Human Genomics Research in Developing Countries," *BMC Medical Ethics* 12, no. 5 (2011), *available at* <https://doi.org/10.1186/1472-6939-12-5> (last visited April 26, 2019).
2. G. Kolata, "The Struggle to Build a Massive 'Biobank' of Patient Data," *New York Times*, March 19, 2018, *available at* <https://www.nytimes.com/2018/03/19/health/nih-biobank-genes.html> (last visited April 26, 2019).
3. A.B. Popejoy and S.M. Fullerton, "Genomics Is Failing on Diversity," *Nature* 538, no. 7624 (2016): 161-164.
4. J. Kinkorova, "Biobanks in the Era of Personalized Medicine: Objectives, Challenges and Innovation," *EPMA Journal* 7, no. 1 (2015): 4.
5. M. Capocasa et al., "Samples and Data Accessibility in Research Biobanks: An Explorative Survey," *PeerJ* 4 (2016): e1613.
6. C.E. Graham et al., "Current Trends in Biobanking for Rare Diseases: A Review," *Dovepress* 2 (2014): 49-61.
7. International Rare Diseases Research Consortium (2018), *available at* <http://www.irdirc.org> (last visited April 26, 2019).
8. See De Vries et al., *supra* note 1; Kinkorova, *supra* note 4; Capocasa et al., *supra* note 5.
9. See Popejoy and Fullerton, *supra* note 3.
10. M.H. Zawati et al., "Barriers and Opportunities in Consent and Access Procedures in Low- and Middle-Income Country Biobanks: Meeting Notes from the BCNet Training and General Assembly," *Biopreservation & Biobanking* 16, no. 3 (2018): 171-178.
11. J.W. Goebel et al., "Legal and Ethical Consequences of International Biobanking from a National Perspective: The German BMB-EU Coop. Project," *European Journal of Human Genetics* 18, no. 5 (2010): 522-525.
12. Internet World Stats, *available at* <www.internetworldstats.com/stats.htm> (last visited April 26, 2019).
13. "Letter From the Editor," *MIT Technology Review* 120, no. 1 (2017): 2
14. The Broad Institute and Dana-Farber Cancer Institute, "Metastatic Breast Cancer Project," *available at* <https://www.mbcproject.org/about> (last visited April 26, 2019).

The Journal of Law, Medicine & Ethics, 47 (2019): 336-341. © 2019 The Author(s)

15. M. Sleeboom, "The Harvard Case of Xiu Xiping: Exploitation of the People, Scientific Advance, or Genetic Theft?" *New Genetics & Society* 24, no. 1 (2005): 7-78.
16. J. Kaye et al., "Including All Voices in International Data-sharing Governance," *Human Genomics* 12, no. 13 (2018): 1-9; M.A. Rothstein et al., "Comparative Approaches to Biobanks and Privacy," *Journal of Law, Medicine & Ethics* 44, no. 1 (2016): 167-172.
17. K.H. Jones et al., "The Other Side of the Coin: Harm Due to the Non-use of Health-related Data," *International Journal of Medical Informatics* 97 (2017): 43-51.
18. See Zawati et al., *supra* note 10.
19. Genomics England (2018), *available at* <https://www.genomicsengland.co.uk> (last visited April 26, 2019).
20. Regulation on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (Data Protection Directive), General Data Protection Regulation, Regulation EU 2016/679.
21. Apple, "ResearchKit and CareKit" (2017), *available at* <http://www.apple.com/researchkit> (last visited April 26, 2019).
22. Research Stack (2018), *available at* <http://researchstack.org> (last visited April 26, 2019).
23. Sync for Science (2018), *available at* <https://github.com/sync-for-science> (last visited April 26, 2019).
24. Genome Connect, "The ClinGen Patient Portal" (2018), *available at* <https://www.genomeconnect.org/> (last visited April 26, 2019).
25. DNA Land (2017), *available at* <https://dna.land> (last visited April 26, 2019).
26. National Geographic, "The Genographic Project" (2018), *available at* <https://genographic.nationalgeographic.com> (last visited April 26, 2019).
27. Global Alliance for Genomics and Health, "Global Alliance Framework for the Responsible Sharing of Genomic and Health Related Data" (2014), *available at* <https://genomicsandhealth.org/about-the-global-alliance/key-documents/framework-responsible-sharing-genomic-and-health-related-data> (last visited September 25, 2018).
28. E.S. Dove et al., "Ethics Review for International Data-Intensive Research," *Science* 351, no. 6280 (2016): 1399-1400.
29. Council for International Organizations of Medical Sciences, "International Ethical Guidelines for Health-related Research Involving Humans" (2017), *available at* <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf> (last visited April 26, 2019); J.J.M. VanDelden and R. Van der Graf, "Revised CIOMS International Ethical Guidelines for Health-related Research Involving Humans," *Journal of the American Medical Association* 317, no. 2 (2017): 135-136.
30. See Zawati et al., *supra* note 10.
31. Declaration of Helsinki (2008), *available at* <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/> (last visited April 26, 2019); *Belmont Report*, *available at* <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/> (last visited April 26, 2019).
32. Food and Drug Administration, U.S. Department of Health and Human Services, "Use of Electronic Informed Consent, Questions and Answers, Guidance for Institutional Review Boards, Investigators, and Sponsors" (2016), *available at* <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/guidances/UCM436811.pdf> (last visited April 26, 2019).
33. M.V. McConnell and E.A. Ashley, "Mobile Health Research–App-Based Trials and Informed Consent," *New England Journal of Medicine* 376, no. 9 (2017): 861-863.
34. B.M. Knoppers et al., "Recontacting Pediatric Research Participants for Consent When They Reach the Age of Majority," *IRB: Ethics and Human Research* 36, no. 6 (2016): 1-9.
35. OECD Council on Health Data Governance, "The Next Generation of Health Reforms" (2017), *available at* <https://www.oecd.org/health/health-systems/Recommendation-of-OECD-Council-on-Health-Data-Governance-Booklet.pdf> (last visited April 26, 2019).
36. Sleeboom, *supra* note 15.
37. HUGO Ethics Committee, Statement on Benefit Sharing, 2000, *available at* <http://www.hugo-international.org/Resources/Documents/CELS_Statement-BenefitSharing_2000.pdf> (last visited April 26, 2019).
38. UNESCO, International Declaration on Human Genetic Data (2003), *available at* <http://portal.unesco.org/en/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html> (last visited April 26, 2019).
39. Editorial, "Our Shared History," *Nature Genetics* 50, no. 2 (2018): 159, *available at* <https://doi.org/10.1038/s41588-018-0049-4> (last visited April 26, 2019).

The Journal of Law, Medicine & Ethics, 47 (2019): 336-341.