American Society of Human Genetics

6120 Executive Boulevard, Suite 500
Rockville, MD 20852

tel: 301.634.7300
email: society@ashg.org
web: http://www.ashg.org

November 26, 2024

By electronic submission:
Docket No. NSD 104
U.S. Department of Justice
National Security Division
Foreign Investment Review Section
175 N Street NE, 12th Floor
Washington, DC 20002

Notice of Proposed Rulemaking re:

Provisions Pertaining to Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons [Docket No. NSD 104]

The American Society of Human Genetics (ASHG) welcomes the opportunity to provide comments in response to the Department of Justice Notice of Proposed Rulemaking ("NPRM") to implement Executive Order 14117 of February 28, 2024 (Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern), by prohibiting and restricting certain data transactions with certain countries or persons. The NPRM proposes a framework to restrict or prohibit certain bulk data transactions to countries of concern and covered persons, including genomic and health data.

ASHG is the world's largest professional society dedicated to advancing genetics and genomics research, supporting a community of 8,000 members representing all areas of research and application in human genetics who share the common goal of encouraging people everywhere to realize the full potential and benefits of human genetics and genomics. Now more than ever, the American people are benefiting from new genomic applications that are improving health, saving lives, and contributing to the U.S. economy. As a professional community dedicated to these advances, ASHG stresses the profound role genomic knowledge is playing in the transformation of all biomedical research – from cancer to heart and lung disease, early child development, rare diseases, Alzheimer's disease, mental health, and more.

ASHG's interests primarily relate to the proposed restrictions on transfers of human genetic data. Below, we discuss how transfers of human genetic data for research are already carried out securely, ensuring the privacy of U.S.-based individuals and safeguarding U.S. national security. The

Society is concerned that portions of the NPRM could add unwarranted, potentially significant administrative burden and restrictions on U.S. researchers through roadblocks to global data sharing, which is already heavily regulated and has been an essential scientific component and value since the Human Genome Project launch. This could decrease the global competitiveness of U.S. geneticists, allowing those in other countries to out-compete us for discoveries of both health and economic value. There is also a potential risk from policymakers and media voices implying that genetic information is exceptional and dangerous, which may erode public trust in scientists and impact recruitment for research studies.

Protection of Research Participants' Privacy

The human genetics and genomics community takes data privacy and stewardship extremely seriously. For decades, our community has pursued both the opportunity and responsibility that come with research and the responsible use of new knowledge. As with most research fields today, large-scale data analysis is essential to advance genomic discoveries and, as with most medical information, these data must have strong protections. Globally, these data and biobanks are enhancing our understanding of the genetic health risks and resilience of individuals and populations. This newfound knowledge is leading to better disease diagnoses, innovative treatments, and greater insight into our shared human origins. To sustain these advances, the community must encourage broad public participation, continue research investments, and promote privacy protections. However, we have expressed concern when cases arise in which researchers exploit America's historically open and inclusive research environment.

Risks of Re-Identification and Privacy Considerations in Genomic Data Use

The NPRM highlights the potential risks of genomic data exposing individuals to discrimination or exclusion when combined with other personally identifiable information. Additionally, the rule notes that genomic data de-identified according to standard healthcare practices (such as removing names and birthdates) can, in certain cases, be re-identified and potentially used against an individual, their genetically related relatives, or even specific ethnic subgroups. In general, ASHG believes removal of Health Insurance Portability and Accountability Act ("HIPAA") identifiers is important to protect research participant privacy. However, the inclusion of select HIPAA identifiers may enable further scientific insight without significantly increasing the risk of re-identification. We therefore think there is value in working alongside the National Institutes of Health (NIH) and other agencies to provide alternatives to de-identification policies while recognizing the need to consider the greater risks of re-identification for individuals within particular populations or in certain circumstances, such as within lower population-dense regions or within or near tribal reservations/land. If the concern regarding anonymized, pseudonymized, de-identified, and encrypted data is that it may potentially be re-identified, such as with Artificial Intelligence (AI), the proper solution is to establish mandatory standards for the required level of de-identification.

It is important to emphasize that genetic testing generally offers no more information for identifying a research participant than other traditional forms of de-identified personal health information. Determination that a DNA sample contains a particular change is alone insufficient to uniquely distinguish a sample. The risks of re-identification grow as the number of distinct changes in a sample increases, or with whole genome sequencing. Genetic testing typically focuses more on looking for specific variants in one or more genes rather than on whole genome sequencing. Additionally, the predictability of genomic information is being overstated in the NPRM. While knowledge about a person's genome may offer insights into potential risks and tendencies, it cannot accurately predict health, emotional stability, or mental capacity for most individuals. Furthermore, genetically targeted bioweapons designed against a specific individual or group is impractical.

Biospecimens and Other 'Omics' Data

An exemption for genomic information derived from biospecimens, such as blood or tissue samples, intended for medical use would suggest that genomic information could only be shared if health or well-being is at risk, overlooking the importance of fundamental genetic research that also requires the responsible sharing of genomic data.

The U.S. Department of Justice is also "considering regulating, as prohibited or restricted transactions in the final rule, certain transactions in which a U.S. person provides a country of concern (or covered person) with access to bulk human "omic data". ASHG has affirmed that the sharing of non-genomic –omics data (e.g., transcriptome, proteome, microbiome, etc.) does not pose the same kind of risk of re-identification as the sharing of genomic information.

Exemptions for Federal Grants and Promoting Responsible Research

As in the Advance Notice of Proposed Rulemaking (ANPRM), the NPRM contains an exemption for grants, contracts, or other agreements entered with the United States Government. Notably, this exemption would apply to grantees and contractors of federal departments and agencies, including the Department of Health and Human Services, the Department of Veterans Affairs, the National Science Foundation, and the Department of Defense. This would allow these agencies to implement grant- and contract-based conditions to mitigate the risks of countries of concern accessing sensitive personal data through transactions linked to their grants and contracts. The acquisition, analysis, sharing of human genetic data, and use of genetic tools need to be conducted responsibly. ASHG is a major policy advocate to advance these goals, laying out core principles and supporting the Common Rule, the Genetic Information Nondiscrimination Act, the 21st Century Cures Act, and responsible NIH genomic data-sharing policies.

Ethical Protection of Genetic Data

Historically, the science of genetics has been misused by some to proclaim false biological distinctions between groups and to justify abhorrent practices such as forced sterilizations,

restrictions on reproductive freedom, loss of access to medical services, political retribution, loss of immigration status, and genocide. Just as any scientific knowledge has the potential for misuse and harm, ASHG also speaks out to oppose the misuse of genetic research that could harm individuals or populations, including opposition to the coerced collection of genetic data, which violates our community's core values.

Not-for-profit organizations like the Global Alliance for Genomics and Health (GA4GH) set standards and frames policies to expand genomic data use within a human rights framework standards that protect the privacy of genetic and personal data while allowing for the sharing of data for beneficial scientific and health purposes.

Advancing Collaboration to Solve Global Challenges

The prohibition on transfers of bulk genetic data is particularly problematic. The proposed rule prohibits "any U.S. person from knowingly engaging in any covered data transaction involving human genomic data that provides a country of concern or covered person with access to bulk (i.e., more than 100 U.S. persons) U.S. sensitive personal data that consists of human genomic data." Unchanged from the ANPRM, the proposal defines "human genomic data" as data representing the nucleic acid sequences that constitute the entire set or a subset of the genetic instructions found in a human cell, including the result or results of an individual's "genetic test" (as defined in 42 U.S.C. 300gg-91(d)(17)) and any related human genetic sequencing data. There are exemptions for global health purposes, such as during a pandemic; however, it is critical that this rule not stymie efforts for academic institutions to collaborate on existing and future international research projects, including those that investigate fundamental biology and are not intended to inform medical decisions.

The Importance of International Partnerships for Global Health

Genomics is a multinational, information-based enterprise with valued academic and industry research leadership worldwide. This includes clinical trials and research studies conducted by pharmaceutical companies and universities in countries around the world, which may need to report adverse events or return results to participants in countries of concern. Additionally, this data is often analyzed by researchers globally. International collaboration is vital for people everywhere to realize the benefits from human genetics research. Participation in and use of global datasets accelerates discoveries, such as during the COVID-19 pandemic, and moves the field toward representing all people in research cohorts. The inclusion of populations representing diverse ancestries helps us gain a fuller understanding of the genetics of health and disease, knowledge which can be used to develop more accurate diagnostic tests and more effective treatments that benefit all people.

Successful international collaboration relies on scientists' common agreement on, and consistent adherence to, foundational ethical standards for public participation in research. Long-standing ethical principles for genetics research help respect and protect research participants, and they are especially important for preventing harm to marginalized or vulnerable populations. ASHG

continues to advocate for the robust enforcement of international ethical practices in science, including the principle of informed consent for research participants. We must all continue to practice, teach, and demand ethical conduct of science through our professional capacities so that research participants' rights are honored, and scientific advances benefit all people.

Prioritizing Both Research and National Security Goals

To serve the American people, it is vital that the nation prioritize both robust medical progress and national security goals and ensure they co-exist and advance as two top priorities. There is a need for clear legislative frameworks that appropriately balance security with the advancement of scientific knowledge. Countries of concern have been noted in the NPRM as seeking to gather genetic information of U.S. citizens and people around the world.

ASHG has been engaged in national security discussions around genomic data for a number of years. For example, in 2021, ASHG was quoted in *Science* urging collaboration between scientific and security experts and reemphasized this point in a 2022 letter to House and Senate leadership during consideration of the *United States Innovation and Competition Act of 2021 (USICA)*. In 2022, ASHG 2021 President Gail Jarvik, MD, PhD, presented at the National Institute of Standards and Technology (NIST) National Cybersecurity Center of Excellence (NCCoE) virtual workshop on the Cybersecurity of Genomic Data. Dr. Jarvik spoke on the importance of broad data-sharing in conjunction with data privacy protections in order to continue scientific advancement and progress. Dr. Jarvik also highlighted the importance of collaboration between scientists and national security experts to address any national security concerns arising from human genome research to ensure that new national security measures do not stall biomedical advances.

If issues are addressed in the policy arena without active genomics input, policy prescriptions could in fact do harm to genomics research progress and resulting health applications, including increasing administrative burden, slowing access to data sets, exacerbating stigma of researchers of Asian ancestry, reaffirming "genetic exceptionalism", and slowing legitimate and ethical global research collaborations.

Sincerely,

Bruce D. Gelb, M.D.

President
American Society of Human Genetics