PRIM&R
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH



February 3, 2022

Lawrence Tabak, DDS, PhD
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

*RE: Request for Information on Proposed Updates and Long-Term Considerations for the NIH Genomic Data Sharing Policy*

Dear Dr. Tabak:

Public Responsibility in Medicine and Research (PRIM&R) appreciates the opportunity to respond to the National Institutes of Health (NIH)'s Request for Information on Proposed Updates and Long-Term Considerations for the NIH Genomic Data Sharing (GDS) Policy, published November 30, 2021, and to shape the policy going forward.

PRIM&R is a nonprofit organization dedicated to advancing the highest ethical standards in the conduct of research. Since 1974, PRIM&R has served as a professional home and trusted thought leader for the research protection community, including members and staff of human research protection programs and institutional review boards (IRBs), investigators, and their institutions. Through educational programming, professional development opportunities, and public policy initiatives, PRIM&R seeks to ensure that all stakeholders in the research enterprise understand the central importance of ethics to the advancement of science.

We applaud the NIH's proactive efforts to update the 2014 GDS policy, given new technologies and capabilities in this domain, as well as growing concern about public mistrust in government and science. We are also pleased to see this RFI's efforts to clarify the relationship between, and harmonize, the GDS Policy and the new NIH-wide Data Management and Sharing (DMS) Policy, steps PRIM&R requested in our response to the 2019 DMS Policy draft.

We have some comments concerning both the larger social context in which this revised policy is being considered and specific areas of focus in the RFI. In the first section below, we urge NIH to use the current moment and the opportunity of this revision to the GDS Policy to undertake a broad public engagement campaign about the potential value of genomic data sharing and desired safeguards. In the second section, we make some suggestions for specific provisions in the RFI.

## I. An opportunity to engage the public

The **Background** section of the RFI begins with the statement, "The GDS Policy has served the research community well, facilitating tens of thousands of genomics studies while preserving public trust in the biomedical research enterprise." Though by some measures public trust has increased since 2018,[1] the multiple crises of the last several years, including the COVID-19 pandemic, resistance to the vaccine rollout, and the national racial justice reckoning, suggest that public trust in science and its institutions in the US is alarmingly low. It's not clear on what basis NIH claims that is has successfully preserved public trust in the research enterprise. We believe preserving trust requires, in the first place, a clear, accessible articulation of the social value of genomics studies, both in general and in the particular case of those supported by the GDS Policy. It is also critical to more specifically define and measure what is meant by public trust in this context. Only then can benefits and risks be fully understood, and appropriate safeguards designed and implemented.

Relatedly, to consider the 2014 Genomic Data Sharing policy a success because it has "[facilitated] tens of thousands of genomic studies" and "served the research community well" fails to recognize the true intended beneficiaries of NIH's work: patients and the public. The NIH's mission is not to sustain researchers, but "to enhance health, lengthen life, and reduce illness and disability." Sharing of genomic data puts individual privacy at risk, a risk that may be worthwhile based on benefit, but that cannot be justified based on the number of studies conducted. Genomic data sharing and the policies that support it have the potential to benefit the public, but whether or not they have done so, and in what ways, is an empirical question, and cannot be assumed.

Seven years after the first GDS Policy was promulgated, and at a time when the scientific community, like society more broadly, is acknowledging that claims to advancing the "public good" have too often failed to recognize and address the needs and concerns of historically underserved groups, **we urge the NIH to use this RFI as an opportunity to undertake a more substantive and meaningful process of public engagement. We believe NIH should not proceed with a draft revised policy until this takes place.** While technically an RFI such as this one is open for "public comment," the RFI process tends to privilege insiders over laypeople, and does not truly reflect engagement of all relevant communities. Particularly in this instance, the immediate potential harms of GDS (loss of privacy) fall on individuals outside the research community, while the immediate benefits (access to data) accrue to those likely to respond to the RFI. **The NIH should consider holding town halls and listening sessions, running PSA campaigns, and conducting public surveys in service of the following goals:**

(1) Providing the public with data about whether and how the NIH's policies, including the GDS Policy, have contributed to scientific advancement and the

[1] P. 26, https://cms.wellcome.org/sites/default/files/2021-11/Wellcome-Global-Monitor-Covid.pdf.

advancement of public health—or, alternatively, being transparent about the fact that it has not yet done so, but promises future benefits;

(2) Educating the public about genomic data sharing, including its purpose, benefits, and risks, as well as the inherent tradeoffs involved in balancing those benefits and risks (for instance, that applying deidentification techniques and other safeguards to people's data often make the data less useful for scientific purposes); and

(3) Allowing NIH to better understand, and compare, perspectives from various sectors of society, including underrepresented groups, about what people expect, hope for, and care about regarding genomic data sharing.

If NIH is concerned about how successfully its policies balance the desire to accelerate science with the need to minimize risks in the service of preserving both individual interests and the public trust, this sort of engagement campaign is essential. It's also worth noting that NIH regularly requires this sort of public and stakeholder engagement of its awardees. To be sure, engaging the public will require additional time and resources. But public trust is at a critical juncture; it cannot and should not be rushed or shortchanged.

## II. Suggestions for Specific Provisions in the RFI: Protections and informed consent

Deidentification of genomic data should no longer be relied upon, as it once was, to fully protect individuals and the privacy of their genetic information. The data linkages the RFI considers permitting will make combined data readily identifiable in many cases. **We therefore welcome and appreciate that the RFI mentions other protection mechanisms NIH relies on,** including IRB review of risks associated with data submission, designating controlled access for some data types, use of data access committees to review data requests, data use agreements, and certificates of confidentiality. These mechanisms are not merely supplementary to deidentification; rather, each is an important tool in its own right in the arsenal of genomic data sharing safeguards.

As noted above (I.2), every constraint on data collection and use represents an explicit effort to balance individual rights with scientific utility. There are no protections that come without a cost, and the maintenance of this balance should be ongoing and explicit. Given the reality that the public will not have input on every proposed research design, the scientific community must acknowledge the need for these tradeoffs, and public entities such as NIH must embrace their role as representing public, as well as the scientific, interest. NIH has an opportunity with this GDS Policy update to help the research community understand these points and appropriately use the full range of safeguards available in the face of evolving technology and new possibilities of data linkage. **We therefore encourage NIH to review and assess its policies around each of these safeguards to determine whether they are adequate to the current genomic data sharing landscape, and if they need to be supplemented by additional approaches,** such as differential privacy, which involves using mathematical manipulations of datasets

to preclude, when looking at outcomes, the ability to determine whether any one individual's data was included in the original dataset.[2] If NIH determines that such additional mechanisms should be considered as part of the protections toolkit, it should undertake an explicit discussion of the benefits and risks of adopting them.

In addition, we ask NIH to provide more guidance and language to support the informed consent process for studies involving genomic data sharing. **Research participants must understand the risks to their privacy and the confidentiality of their data, even in the face of "deidentification," given the possibility of data linkage.** Engaging the public about genomic data sharing, as we noted in the previous section, provides an important foundation of understanding for the individual informed consent process. As we suggested in our response to NIH's 2021 RFI on Developing Consent Language for Future Use of Data and Biospecimens, **NIH can play an additional leadership role by also providing sample language and approaches for informed consent, specifically, that clearly and unambiguously explain these privacy and confidentiality risks, and why they are a tradeoff for the use of genomic data for research.**

Furthermore, collection of data that lacks explicit identifiers may be exempt from IRB review under the Common Rule (45 CFR.104(d)(2)), and subsequent use of that data may not be considered research with human subjects, raising the possibility that individuals may not be fully informed nor given the chance to agree to the use of their data. **The NIH should clarify in the next iteration of the GDS Policy whether affirmative consent or alternatives, such as an "opt-out" or "opt-in" process, are expected under these circumstances, despite the absence of a regulatory requirement for informed consent.**

**Finally, we urge NIH to consider mechanisms for punishing those who misuse data or share it inappropriately, such as fines, suspension of grants, ineligibility for future funds, or, in extreme cases, debarment**. These sanctions, as we have seen in the case of enforcement of HIPAA, can have a significant impact on compliance with data sharing policies and therefore serve as additional safeguards for research participants.

In closing, PRIM&R recognizes the enormous potential benefit of data sharing, genomic and otherwise, and supports the wide sharing of data among researchers as one means by which research participants can be sure that their contributions to science and society are maximized.[3] We also believe that utilizing the full range of protections available, combined with transparency and public engagement around the potential risks, unknowns, and tradeoffs genomic data sharing unavoidable involves, are key to preserving trust in the research enterprise and realizing the social benefits it promises.

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[2] https://privacytools.seas.harvard.edu/differential-privacy

[3] See, for instance, PRIM&R's comments in response to the 2019 Draft NIH Policy for Data Management and Sharing and Supplemental Draft Guidance: https://primr.org/getmedia/e0b4bf13-8baf-4aef-b3c3-5533ca5a7db3/01-10-20_PRIMR-Comments_January-10_final.pdf.

Thank you again for the opportunity to comment and for the NIH's continued leadership on this important issue. We hope our comments on the current draft policy will be useful in your next stage of policymaking in this area. PRIM&R stands ready to provide any further assistance or input that might be useful. Please feel free to contact me at 617.303.1872 or ehurley@primr.org.

Respectfully submitted,

Elisa A. Hurley, PhD
Executive Director

cc: PRIM&R Public Policy Committee, PRIM&R Board of Directors