

March 17, 2026

National Institutes of Health (NIH)
Office of Science Policy (OSP)
6705 Rockledge Drive, Suite 630
Bethesda, MD 20892

RE: National Institutes of Health (NIH) Office of Science Policy (OSP): Request for Information on Draft NIH Controlled-Access Data Policy and Proposed Revisions to NIH Genomic Data Sharing Policy (Notice Number: NOT-OD-26-023)

To Members of the Office of Science Policy:

Public Responsibility in Medicine and Research (PRIM&R), which has more than 3,500 active members throughout the research enterprise, and the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) appreciate the opportunity to respond to the National Institutes of Health Office of Science Policy's Request for Information on the "Draft NIH Controlled-Access Data Policy and Proposed Revisions to NIH Genomic Data Sharing Policy" (Notice Number: NOT-OD-26-023).

Although AAHRPP and PRIM&R are responding with the same comments, our organizations submitted them separately to underscore that they reflect the thinking of more than one entity.

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 protections community. PRIM&R seeks to ensure that all stakeholders in the research enterprise appreciate the central importance of ethics to the advancement of science.

AAHRPP, founded in 2001, is a nonprofit organization that accredits human research protection programs. Currently, more than 600 entities from diverse research settings—including hospitals, independent review boards, clinical research organizations, universities, and Veterans Affairs facilities—are accredited.

As stated in the RFI, the National Institutes of Health (NIH) is requesting public input on its "proposal to establish harmonized and transparent policy requirements for protecting human participant research data. Specifically, NIH proposes (1) establishing policy requirements for which data should be controlled access under NIH data sharing policies, and (2) revising the NIH Genomic Data Sharing Policy to simplify and harmonize requirements." PRIM&R and AAHRPP appreciate that NIH is "proposing a holistic update to its data policy framework to strengthen data protections, clarify requirements, and reduce duplicative burden."

Below, please find the replies to questions posed in the Request for Information. PRIM&R and AAHRPP will focus their comments on the following key areas:

Feedback on the availability of established repositories for implementing the proposed Controlled-Access Data Policy

Along with the expansion of capacity of controlled-access data repositories, PRIM&R and AAHRPP encourage NIH to ensure NIH Data Access Committees (DACs), which review all requests for access to datasets, have sufficient resources and bandwidth to efficiently review the potential increased volume of data requests.

The New York Times article, “Genetic Data From Over 20,000 U.S. Children Misused for ‘Race Science’,” ([1/24/2026](#)) suggests NIH may need further investments in resources to perform effective data oversight functions required to maintain the public’s trust, such as ensuring data are only released to eligible researchers and used for their approved purposes.

Inadequate oversight can adversely affect the entire research enterprise and lead to decreased participation in studies and negatively affect participants’ willingness to donate biospecimens to research or allow their data to be deposited in NIH repositories. Without sustained public trust and active participation in research, the trajectory of important scientific discovery may be significantly compromised.

PRIM&R and AAHRPP would like to offer the following recommendations:

- 1) Federal Oversight and Accountability: The NIH should strengthen its vetting and monitoring processes for data access requests, including developing clear policies that suspend review of any new data requests from researchers under active federal investigation for prior misuse. NIH could also require pre-registration of analyses using existing datasets, releasing only the variables indicated in accepted pre-registrations rather than entire datasets, and provide better transparency when data are accessed by ineligible researchers.
- 2) Transparency and Research Participant Engagement: NIH could consider developing a public-facing, accessible database of studies that have used federally held research data, including the categories of demographic data involved. Should misuse occur, a designated party could be responsible for communicating with affected participants and their families. A public-facing database of this kind could also be used to share notable advancements in scientific understanding and improvements in care that have resulted from research.
- 3) Training and Stewardship: While NIH has implemented training for data users, PRIM&R and AAHRPP recommend equal attention to ethics training for researchers who generate and deposit data.

Feedback on the appropriateness of the protected data types designated to be controlled-access

- 1) As proposed in this RFI, creating a series of FAQs or additional guidance on data types that would or would not benefit from placement in a controlled-access repository could be helpful; this should involve experts beyond NIH, especially from the Institutional

Review Board (IRB) and Human Research Protection Program (HRPP) community, as well as research participants.

- 2) An apparently unrecognized issue is the effect of variation in how institutions and IRBs view data sharing (e.g., placement in open- vs controlled-access repositories) on protection of human participants privacy and options provided to participants regarding potential secondary use of their data.

Differences in IRB approaches toward informed consent expectations -- both in the language required within informed consent documents and inclination to waive informed consent -- also create confusion and frustration for researchers who may work with multiple IRBs.

PRIM&R and AAHRPP recommend NIH consider developing harmonized practices for IRBs and institutions regarding the review of research involving data sharing and expectations for when informed consent is required; options provided to research participants on when data will be placed in an NIH repository; and the language used to describe future use of data.

Whether NIH takes on this work or funds others groups with strong track records for advancing policy to do this work (e.g., SMART IRB, PRIM&R, Multi-Regional Clinical Trials Center, Advancing Effective Research Ethics Oversight), IRB/HRPP experts, researchers, and research participants all should be included to produce guidance or other materials that incorporate perspectives from the community that will be affected.

- 3) PRIM&R and AAHRPP recommend NIH provide clearer and more specific categories of permitted data uses or more concrete examples of how the data will be used so that informed consent materials can better provide participants with a sense of what future research with their data or biospecimens could encompass.
- 4) Although the NIH provides a list of studies which use data from database of Genotypes and Phenotypes ([dbGaP](#)) through the National Library of Medicine, this list is challenging for the general public and interested parties to access. Instead, the NIH could provide a public-friendly database of studies that have used data from research studies required to deposit their datasets and identify categories of demographic data associated with the research (e.g., race/ethnicity). As noted in our reply above, this would give the public and other concerned organizations a resource to assist in monitoring the potential misuse of data.
- 5) In general, PRIM&R and AAHRPP agree with the data types identified as triggering placement in an NIH Controlled-Access Data Repositories (CADRs), specifically: covered personal identifiers; precise geolocation data; biometric identifiers; genomic, epigenomic, proteomic, and transcriptomic data; personal health data and personal financial data; individual-level clinical trial data; and imaging data of the human face or head regions.

We also support requiring CADR placement for studies with potential sensitivities, such as information regarding potentially stigmatizing traits, illegal behaviors, or other information that could be perceived as causing group harm or used for discriminatory purposes. Further, we agree sensitive data may also include data from individuals, groups, or populations with unique attributes that increase the risk of re-identification.

Feedback on any aspect of the Proposed Revisions to the NIH Genomic Data Sharing Policy

PRIM&R and AAHRPP support NIH effort to consolidate, simplify and update protections regarding genomic data sharing -- as long as that does not result in lessening the level of protections and is consistent with what research participants agreed to when they provided their consent.

Feedback on the proposed updates to the GDS Policy for Imputation Servers

PRIM&R and AAHRPP support the NIH obtaining input from experts outside the federal government about methods for enhancing privacy and security of data maintained within NIH repositories and data obtained from NIH repositories.

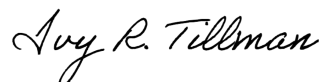
As a follow up to this request for information, we encourage the NIH to consider convening a group of experts to advise on options or strategies that maintain the privacy of imputation servers and reference panels similar to how the NIH Office of Data Science Strategy identified key issues on Streamlining Access to Controlled Data at the NIH through its 2021 [webinar series](#).

Further, PRIM&R and AAHRPP encourage NIH to convene experts regularly to assess whether new types of data should trigger placement in CADR and identify new privacy or security concerns that could affect NIH data sharing policies.

We appreciate and support NIH's goal to clarify when controlled access is needed and provide uniform expectations across NIH programs and align the GDS Policy with the NIH Data Management and Sharing Policy; these efforts should also help to streamline the process of data deposition for institutions.

We hope our comments are useful to the NIH. PRIM&R and AAHRPP stand ready to provide any further assistance or input that might be of use. Thank you for the opportunity to provide feedback on this critical issue and for your commitment to developing ethical research practices.

Sincerely,



Ivy R. Tillman, EdD, CIP

Executive Director

Public Responsibility in Medicine and Research (PRIM&R)