FASEB
Federation of American Societies for Experimental Biology

Representing Over 100,000 Researchers

6120 Executive Blvd., Suite 230, Rockville, MD 20852 | faseb.org

March 13, 2026

Lyric Jorgenson, PhD
Associate Director for Science Policy
National Institutes of Health
6705 Rockledge Drive
Bethesda, MD 20817

RE: Response to Request for Information on Draft NIH Controlled-Access Data Policy and Proposed Revisions to NIH Genomic Data Sharing Policy (NOT-OD-26-023)

Transmitted electronically via online form.

Dear Dr. Jorgenson,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide feedback on the Request for Information on Draft National Institutes of Health (NIH) Controlled-Access Data Policy and Proposed Revisions to NIH Genomic Data Sharing Policy (NOT-OD-26-023), which seeks input on proposal to establish harmonized and transparent policy requirements for protecting human participant research data. As a coalition of 20 scientific societies representing over 100,000 individual biological and biomedical researchers, FASEB appreciates NIH's efforts to provide clarity and reduce administrative burden by revisiting oversight measures for research involving sensitive human data.

While FASEB commends efforts to standardize Controlled-Access Data Policy and Genomic Data Sharing (GDS) Policy across all Institutes and Centers (ICs) and reflect the current state of the science, there are concerns regarding feasibility of implementation, a lack of clarity regarding protected data types and the role of institutions in protecting data, and the justification in defining "large scale" data sets.

1. Feedback on any aspect of the Draft NIH Controlled-Access Data Policy.

FASEB commends NIH's efforts to standardize Controlled-Access Data Policy across all ICs. In addition to points raised throughout our response, we also seek clarification on several aspects of the draft Controlled-Access Data Policy.

A core concern is feasibility of implementation. Several of the proposed requirements for repository eligibility and protected data types will increase demand for repository space, and it is unclear whether NIH-supported controlled-access data repositories have the capacity to

accommodate this new demand. The expanded scope of protected data types will also increase administrative and institutional burden, particularly for institutions with less experience and/or fewer resources to support projects covered by this policy. Combined, these factors risk slowing adoption and implementation of the policy due to lack of resources and/or lack of understanding.

The role of the institution in protecting data collected while conducting NIH-supported research is also unclear. The Policy states that institutions must ensure that the listed data types are protected, including data not shared in a controlled-access repository. Thus, FASEB recommends that the final policy clarifies responsibilities imposed on institutions. Additional clarification is also needed for the standards for institutional repositories and criteria for determining a dataset's lifecycle.

FASEB also recommends that the final policy includes clearer parameters regarding the need for "assessment" for both determining risk associated with data shared prior to implementation of this Policy and the need for controls. As currently written, it is unclear who is responsible for assessment, what the assessment criteria include, and how often data not managed by this Policy must be assessed.

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

FASEB encourages NIH to allocate funding to expand the capacity of existing repositories to accommodate the anticipated influx of controlled-access datasets. While NIH specifies that the use of other controlled-access data repositories is acceptable, many independent repositories previously utilized for these data are unlikely to meet the new restrictive requirements, particularly those pertaining to data sharing with countries of concern (as defined by 28 CFR Part 202).Thus, implementation of controlled-access data repository (CADR) restrictions may prove difficult as written if NIH controlled repositories are unable to accommodate greater demand.

Once the policy is finalized and the focus turns to implementation, FASEB urges NIH to ensure appropriate financial support for established NIH CADRs to meet the expected growth in demand. Increased funding will allow expansion of available CADR storage and increase access request review capacity. Oversight of NIH CADRs must also be expanded to ensure that repositories are operating at an acceptable level of risk, as established by the NIH Security Best Practices for CADR in accordance with NIST SP 800-53.

At present, established NIH CADRs are spread across multiple NIH Institutes and Centers (ICs) and utilize several different access systems. The current effort to standardize expectations for data privacy across all ICs presents the unique opportunity to consider a new and potentially more efficient NIH repository structure. For example, NIH might consider consolidating existing repositories. Unifying repositories has the potential to reduce both administrative burden and the risk of error in implementing the proposed Controlled-Access Data Policy and future policy measures.

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

While FASEB appreciates NIH's commitment to protecting the identity and personal data of human research subjects, there are questions and concerns regarding the scope of several stated protected data types:

- **Personal health data.** It is unclear whether NIH intends to distinguish between clinical personal health information and research health information. As personal health information is defined in this Policy, nearly all NIH-funded human subjects research would be subject to the Controlled-Access Data Policy. As this Policy is written, it will increase administrative burden and stymie open science initiatives.
- **'omics data derived from human cell lines.** Language defining the scope of this Policy indicates that research generating data derived from human cell lines is subject to the Controlled-Access Data Policy. However, the Policy also states that the collection and sharing of human cell lines are not covered, creating ambiguity. FASEB recommends revisions to provide clearer and more specific guidance regarding when cell lines become subject to the Policy and whether immortalized cell lines are covered.
- **Imaging data of the human head or face.** Additional specification of imaging techniques should be provided. Similarly, we encourage inclusion of language regarding whether the use of "de-facing" techniques to de-identify participants in images of the head and brain, are sufficient to negate the need for coverage by the Controlled-Data Access Policy.

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

FASEB appreciates the inclusion of updates to the NIH Genomic Data Sharing (GDS) Policy as part of this effort. The proposal to limit GDS coverage to only human data is a welcome update that will reduce administrative burden for researchers working with non-human subjects. However, there are several areas of concern for which additional clarification or supplementary guidance would be helpful for implementation.

First and foremost, we are concerned that defining a "large scale" genomic dataset as any dataset including data from 100 or more individuals is an arbitrary approach to an important policy matter. While risk for re-identification is often cited as a concern with small scale datasets, the Toolkit for Assessing and Mitigating Risk of Re-identification when Sharing Data Derived from Health Records suggests that small dataset size does not raise the risk of re-identification. Rather, high congruence between protected data and publicly available data is what drives re-identification risk. Thus, NIH might consider an alternative approach to determining inclusion or exceptions to the GDS Policy.

The application of GDS Policy to datasets including fewer than 100 subjects is particularly important for rare disease research, for which recruiting 100 participants is difficult or

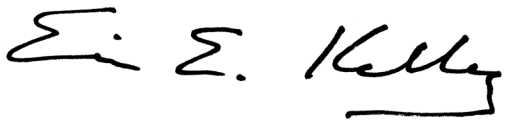
impossible. Provisions to include small scale datasets would minimize IC-specific interpretation of the GDS Policy, ultimately streamlining implementation and reporting for both researchers and program administrators.

Similarly, FASEB recommends inclusion of a clearer definition for the timing of genomic data release as part of the final policy. Specifically, our community seeks clarity regarding what is meant by "immediate" release of data to a NIH-controlled repository and whether it accommodates a reasonable delay for data cleaning and quality control, as indicated in the current policy. Current policy specifies that submission of human genomic data is expected within approximately three months of collection, only after data cleaning and quality control have been completed. FASEB supports this timeline to ensure the highest quality data are available in NIH controlled-access repositories, fostering reproducibility across studies and reducing administrative burden.

FASEB appreciates NIH's efforts to engage with the research community on these important policies. Throughout our comments, we identified critical points for clarification and highlighted potential alternative approaches to and considerations for implementing the Controlled-Access Data Policy and the GDS Policy. As these policies are adjusted and finalized, NIH may consider creating an extensive Q&A website addressing some of the common questions that appear in responses to this RFI.

Please do not hesitate to contact me should you have any questions related to our comments.

Sincerely,



Eric E. Kelley, PhD
FASEB President