AAMC
655 K Street, NW, Suite 100
Washington, DC 20001-2399
T 202-828-0400
aamc.org

March 18, 2026

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

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

Submitted online via https://osp.od.nih.gov/comment-form-draft-nih-controlled-access-data-policy-and-proposed-revisions-to-nih-genomic-data-sharing-policy/.

The AAMC appreciates the opportunity to provide comments to the National Institutes of Health (NIH) in response to its request for information (RFI) on proposed changes to establish harmonized and transparent policy requirements for protecting human participant research data.

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, clinical care, biomedical research, and community collaborations. Its members are all 163 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 Canadian medical schools accredited by the Committee on Accreditation of Canadian Medical Schools; nearly 500 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 210,000 full time faculty members, 99,000 medical students, 162,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Through the Alliance of Academic Health Centers International, AAMC membership reaches more than 60 international academic health centers throughout five regional offices across the globe.

The AAMC has long supported policies which facilitate meaningful sharing and re-use of the data resulting from NIH-funded research projects, while also agreeing that there are the key privacy and security considerations necessary to responsibly and ethically share data acquired from human participants. However, we are concerned that the proposed policy and policy revisions represent changes that, if implemented as proposed, would constitute a tremendous burden on academic institutions and researchers, would hamper research and the data sharing which NIH has encouraged for many years, and would fail to incorporate a risk-based approach

that would facilitate the outcomes the policy is intended to address. In this letter, we offer feedback on the two policies identified in the RFI and urge NIH to solicit additional expertise from scientists and technology professionals, incorporate data from the extramural research community on compliance challenges, and ensure that any changes are harmonized and not conflicting with existing federal policies and regulations.

Draft NIH Controlled-Access Data Policy

In broad conversations with the academic medical research community on the proposed controlled-access data policy, AAMC received significant feedback on 1) questions and concerns regarding critical details and definitions which are unclear in the policy, 2) concerns about the increased breadth of data and data types covered by the policy without consideration of whether there is an increased risk to privacy or security, and 3) the institutional resources of time, infrastructure modifications, and financial investment that it would take to implement a policy of this magnitude. In particular, the funds necessary to implement this policy as written would be extremely challenging for lower-resourced institutions and it would restrict the ability of many organizations to carry out research with human data. AAMC is extremely concerned that institutions which are unable to meet the requirements defined by the policy would be forced to cease ongoing studies and that the policy will have a widespread, dampening effect on the data ecosystem which is so crucial for scientific progress.

AAMC's overarching recommendations for a new controlled-access data policy are that NIH conduct a careful, risk-based analysis of the data which should be subject to this policy, harmonize the policy with other federal standards and regulations, define a phased, multi-year approach for policy implementation and enforcement, and limit the scope of the policy to new awards so that institutions can include compliance costs in the budget for a grant application. To facilitate these recommendations and assist in the policy revision process, we strongly encourage NIH to develop an expert working group comprised of members from the federally-funded research community to assist in the creation of a revised draft, which would draw on institutional knowledge and provide specific input to facilitate appropriate levels of data security while minimizing administrative burden and ensuring clear, consistent, and implementable requirements.

Below we address specific provisions in the current draft policy.

Scope and Applicability. AAMC appreciates the stated exemptions in the policy for NIH-funded research that only involves (1) generation and sharing of non-human data or (2) collection and sharing of human cell lines and biospecimens. To streamline the language and increase clarity, we suggest that NIH add a third exemption in this section, that: "human data or data derived

from human cell lines or biospecimens already shared prior to the effective date of this policy," which is currently listed separately from the first two exemptions. We also urge NIH to reconsider the decision to apply the policy to derivative data sets, even when these may have little to no security risk. We recommend that these data sets only be subject to the policy in cases where a security or privacy risk has been identified.

Required Human Data Types. The AAMC has significant concerns about implementation of the draft policy requirements, which state that the listed data types "must be protected throughout the data lifecycle." This descriptor is vague and will undoubtedly be interpreted differently across the regulated community. To the extent that the "data lifecycle" is considered to include early stages of data generation, the policy would create an enormous burden on institutions and would be virtually impossible to implement. This interpretation would require additional security considerations and the use of specialized data enclaves at every step of the research process, including at the level of the individual laboratory collecting raw data, institutional core services which engage in data processing, and other cleaning and analytic steps prior to data sharing. Such a broad scope would considerably hamper researcher workflows for data analysis, which often utilize open-source tools, and increase the burden of generating data use agreements and sharing data with collaborators. AAMC strongly recommends that NIH revise the draft policy to limit its applicability to the "data sharing lifecycle," defining that term to begin at the time data from the initial study are required to be shared.

We also note that the draft policy states that "Institutions conducting NIH-supported research" must ensure that all the listed data types in this section are protected, suggesting that the policy applies to any research conducted by an institution that receives any NIH funding, regardless of the funding source for that research. We do not believe that was the intention of the policy, as the Applicability section states that the policy only applies to "NIH-supported research." We request that NIH make this language consistent throughout, clarifying that the policy applies only to data generated from NIH-funded research.

AAMC has strong concerns with the significant expansion in the proposed policy of the scope of data which institutions would be required to manage under extremely specific and rigorous standards. The eleven data types which would require additional protection under the proposed policy, "even when not shared through a controlled-access repository," encompass almost all human-related research. Given that institutions are already managing these data under a complex network of federal requirements, including the recently instituted Bulk Data Rule from the Department of Justice, we strongly urge the NIH to ensure that the policy does not conflict with or reach beyond the existing federal framework for research data security.

AAMC supports the current exemptions to sharing data with access controls in situations where the data is low-risk or where data sharing is required by federal law or international agreements. However, we are concerned by the inclusion of a broader requirement for "informed consent explicitly stating data are to be shared openly without controls," as this may not be possible for many long-standing or legacy data sets currently in use for research. We suggest that this provision be removed from the policy.

Requirements for Controlled-Access Data Sharing. In order for institutions to effectively implement new requirements for controlled access repositories, the policy must be clear as to the necessary security and operational standards which institutions must meet to be in compliance, as well as when these standards should be applied. It is imperative that the requirements allow researchers and institutions to engage in long-term planning and the type of financial investment required to bring institutional technical systems into compliance on this vast scale.

AAMC received feedback from many members of the research community that the lack of availability – and significant cost – of repositories which would meet the requirements for all the data types specified in the policy will make compliance difficult and could decrease the ability of the research community to share data. The policy currently states that controlled-access data repositories should meet "NIST-SP-800-171 or equivalent" standards. We recommend that NIH specifically list any additional security standards which would fulfill the agency's requirement or the process that would be required for an institution to demonstrate that the employed standards are equivalent to NIST-SP-800-171.

While some institutions have built infrastructure which can support the NIST SP 800-171 standard, we received input that this is an enormously time-consuming and expensive update, requiring the institution to completely re-write its institutional repository infrastructure over a period of several years. In the context of the large amount of data which would fall under the policy as proposed, we underscore the critical importance of instituting our earlier recommendation on the definition of the data sharing lifecycle to facilitate implementation of this aspect of the policy.

There is broad agreement across AAMC's biomedical research community and beyond that the currently available NIH-funded controlled-access repositories would not be sufficient for the volume of data that would need to be stored in this environment under the proposed policy and may not possess the needed analytic capability for certain research projects. We additionally note the complexity of applying a security standard not just to the data stored in an environment, but for all of the tools used during the research process. We urge NIH to revise this policy such that it is limited to research data for which there is a justified scientific and security rationale to apply the outlined standards and operational requirements.

Proposed Revisions to the NIH Genomic Data Sharing Policy

In advance of the AAMC's detailed recommendations for the description of the proposed revisions to the Genomic Data Sharing (GDS) Policy contained in the RFI, we are making both the assumption and the request that, as it has done in the past, after evaluating the RFI response from the impacted community, NIH will release a draft policy in its entirety so that it is clear whether the proposed language in the RFI will be replacing or adding to the existing policy. In some cases, proposed language would have a different meaning or impact, depending on how it is incorporated into the existing policy. Both the NIH and the research community would benefit from the review of and comments on the full text of a new draft GDS policy, including the incorporation of feedback from this RFI, before a final policy is issued. The proposed revisions also have elements that are dependent on the new controlled-access data policy discussed above, which has not yet been finalized, further complicating our ability to evaluate the GDS policy.

Finally, we note that the existing NIH GDS Policy was finalized in 2014, and there have been exponential advancements in the field since that time, all of which should be considered when developing an updated policy.

Scope. AAMC agrees with the exclusion of non-human genomic data from the GDS policy, although we suggest that NIH provide a specific definition for "human genomic data" to ensure clear and consistent policy implementation. Particularly, the agency should specify the circumstances under which cell lines and/or biospecimens would be included in the definition, since a broad definition would capture genomic data types with variability in identifiability and potential security risk.

We strongly support the provision that individual NIH institutes and centers (ICOs) will not be permitted to "expand the scope of the GDS policy through individual program or policy expectations." However, we also recommend the creation of additional guidance or FAQ from NIH on the additional data protections or use of controlled-access repositories that will be allowed by the ICOs, as this will allow institutions to prepare for the potential range of actions they will need to address when conducting NIH-funded research.

Finally, regarding the proposal that "any amount of human genomic data collected from 100 individuals or more will be defined as 'large scale' and required to comply with the GDS Policy's consent and data sharing requirements," we refer to previous comments from AAMC to the Department of Justice[1] where we note that if the primary intent of this policy is to ensure

[1] AAMC Comments Re: Docket No. NSD 104, Notice of Proposed Rulemaking: National Security Division;

appropriate privacy and security considerations, the risk profile of genomic data cannot be determined in a volume-based manner by the number of individuals represented in the data. This definition as written would apply to an enormous swath of genomic data projects, which by scientific necessity, require large sample numbers and are analyzed using high-throughput methods.

Timelines for Data Processing. The multiple timelines listed in the proposed policy for data sharing are unclear, and do not take into account the significant time needed to process genomic data. We recommend that NIH simplify the language to state that data should be shared in a manner that is consistent with DMS Policy requirements.

Modernization of Data Submission and Sharing Practices. This section introduces references to existing federal research regulations, which when taken out of context, are ambiguous and extremely challenging to interpret. We particularly cite issues within the section "Strengthening requirements for participant consent." The proposed policy states, more than once, that the policy is consistent with the Common Rule. However, this is not the case. In fact, the draft revisions set forth requirements that in some cases directly conflict with the Common Rule, a complex set of connected and integrated provisions, which already create a framework and requirements for seeking consent from human subjects. The consent requirement in the proposed revisions suggesting that "next of kin" should be consulted for the use of biospecimens from deceased individuals is inconsistent with the Common Rule, which, specifically *does not apply* to biospecimens from deceased individuals. Further, the draft revisions invoke the concept of requiring assent from minors, a requirement that is not in the Common Rule, which instead stipulates that an IRB should make that determination. Finally, the consent language in the revision is an excerpted definition from the Common Rule and concept known as "broad consent." We suggest, to avoid confusion and the potential for conflict with an existing regulatory scheme, that the GDS policy revision not create new consent standards that invoke but go beyond the Common Rule.

Thank you for the opportunity to provide feedback on this RFI. The AAMC looks forward to continued engagement with the NIH on these policy issues and would be eager to provide further feedback on revised policies that reflect input from the research community. We urge NIH to rely on the expertise of the research community to achieve the goal of creating policies that are clear, implementable, effective, and harmonized with other NIH and federal research policies and regulations. Specifically, we recommend that NIH continue to solicit input from the biomedical research community as it considers new initiatives and directions, whether through

---

Provisions Regarding Access to Americans' Bulk Sensitive Personal Data and Government Related Data by Countries of Concern (89 FR 86116). https://www.aamc.org/media/80566/download?attachment.

town halls, webinars, or more formal requests for information such as this one. AAMC would be happy to provide further feedback or connect NIH with individuals from the academic medical community who can provide detailed insights into the technical, scientific, and operational topics encompassed by these policies. For questions about these comments, please contact Anurupa Dev, PHD, Principal Science Policy and Strategy Leader (adev@aamc.org) and Heather Pierce, JD, MPH, Senior Director for Science Policy and Regulatory Counsel (hpierce@aamc.org).

Sincerely,

Elena Fuentes-Afflick, MD, MPH
Chief Scientific Officer

cc: David J. Skorton, MD, AAMC President and Chief Executive Officer