Endocrine Society comments in response to NOT-OD-26-023, "Request for Information on Draft NIH Controlled-Access Data Policy and Proposed Revisions to NIH Genomic Data Sharing Policy"

Response was informed by members of the Research Affairs Core Committee (RACC).

Comments were submitted electronically via online submission form on March 17, 2026.

Question 1
Feedback on any aspect of the Draft NIH Controlled-Access Data Policy
The protection of human participant data is important for maintaining patient privacy while simultaneously allowing researchers to accelerate our understanding of human health and disease. While we appreciate that NIH is aiming to balance these needs, the goal and rationale for the specific policy changes are unclear to us and should be laid out in greater detail so that the research community can more accurately comment on the costs and benefits of the proposed changes. We note two significant issues that should be considered in the establishment of the policy:

1. Cost: Setting up and maintaining highly secure environments for human data is expensive; unless funding for these environments is provided, only highly resourced institutions will be able to adhere to this proposed policy.
2. Administrative Burden: These policies will create significant work for research teams and support staff related to ensure compliance with strict access standards and controls.

Because the policy may conflict with some aspects of the existing NIH data management and sharing policy, NIH should provide detailed guidance for how research teams can ensure compliance with both of these policies.

Question 2
Feedback on the availability of established repositories for implementing the proposed Controlled-Access Data Policy
In principle, established repositories provide opportunities for researchers to view and analyze data sets from different teams and even combine datasets to increase statistical power or make new discoveries. We appreciate that controlled access to certain datasets may be necessary; however, this would create barriers to access and collaboration that may discourage innovation and discovery. For example, many research teams develop and use custom-made, novel analytical tools to answer their research questions. It may not be possible to use these resources within a controlled environment, necessitating new approaches that may not be suitable to quickly address the specific biological question under investigation.

Regional and international collaborations may be disrupted if researchers are unable to access and combine datasets from different environments, especially for projects that are

already underway. We are concerned about the ability of NIH-funded research teams to share data with other research teams that are not funded by NIH and may be generating, storing, or analyzing data governed by different regulations and policies. Different access rules may create barriers to collaboration or integrated analysis which is necessary for areas such as rare disease where existing data sets are already small and challenging to collect.

Question 3
Feedback on the appropriateness of the protected data types designated to be controlled-access
No comments were provided on proposed revisions.

Question 4
Feedback on any aspect of the Proposed Revisions to the NIH Genomic Data Sharing Policy
No comments provided on proposed revisions.

Question 5
Feedback on the proposed updates to the GDS Policy for Imputation Servers
Similar to the concerns expressed in question two, without policies that allow for copies of data to be transferred to other servers, any meaningful analysis of large data sets will ultimately be impossible for data that exists on different servers. This level of restriction, to only use servers that "are funded or operated by NIH or another federal agency" will hinder research efforts, particularly international collaborations, rather than promote access and collaboration.