NIH Data Management and Sharing Policy

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The National Institutes of Health (NIH) has issued a Data Management and Sharing (DMS) policy (effective January 25, 2023) to promote the sharing of scientific data. Sharing scientific data accelerates research discovery, in part, by enabling validation of research results, providing accessibility to high-value datasets, and promoting data reuse for future research studies. However, data should be shared in ways that preserve and protect the privacy of research participants; as such, the NIH also issued Supplemental Information to the DMS Policy to promote the development of DMS plans that are consistent with privacy protections.

Of note, the NIH DMS Policy only applies to research funded or conducted in whole or in part by NIH **that results in the generation of** scientific data. It does not apply to projects that ***do not*** **generate scientific data** (e.g., training) or research that is not funded or conducted in whole or in part by the NIH.

Under the DMS policy, NIH expects that investigators and institutions:

- Plan and budget for the managing and sharing of data
- Submit a DMS plan for review when applying for funding
- Comply with the approved DMS plan

The NIH does expect adherence to DMS plans once NIH awards are accepted; thus, investigators should be aware of institutional and IRB policies when taking participant privacy into consideration for DMS plans. The NIH has issued NOT-OD-22-213, Supplemental Information to the NIH Policy for Data Management and Sharing: Protecting Privacy When Sharing Human Research Participant Data to help guide privacy protections, with some key considerations described below.

Practices for Protecting Research Participant Privacy in Data Sharing Plans

- De-identification
    - NIH recommends scientific data be de-identified to the greatest extent that maintains sufficient scientific utility. Unless participants explicitly consent to sharing identifiable data, data should generally be shared only in a de-identified format.
    - Investigators can leverage standards for identifiability outlined in the Common Rule at 45 CFR 46 and in the HIPAA Privacy Rule to formulate plans.

- Data Sharing and Use Agreements
    - NIH recommends the use of scientific data sharing and/or use agreements when sharing data through repositories as they establish the conditions that enable consistent, clear, and appropriate sharing with downstream users and promote common understanding of responsibilities and expectations in use of participant data.
    - Key sections of data use agreements include oversight, responsibilities, and restrictions.
- Controlled Access
    - The DMS Policy expects researchers to consider whether access to scientific data from participants should be controlled (i.e., restricted to verified requesters after assessment of proposed research use), regardless of identifiability of data.
    - Considerations could include proposed limitations on subsequent uses/further sharing.
- Clear Communication of Data Sharing Plans in Consent Forms
    - Consent forms should be consistent with the DMS plan for participant transparency
    - Include whether data will be identifiable.
    - Include plans for future uses, sharing, and access (controlled vs uncontrolled).
    - Elements above should be included in addition to the standard information describing to the extent to which confidentiality of records identifying the participant will be maintained and any other applicable, related consent elements.

As the NIH DMS Policy rolls out, investigators may expect to see additional questions on IRB Applications and informed consent templates related to DMS plans, though **it is ultimately the responsibility of the investigator and awardee institution to ensure adherence to the DMS plan.**

For more information, visit the NIH website at https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policies/data-management-and-sharing-policy-overview

For more information on Castle IRB: www.castleirb.com. Inquiries to: Sarah Attwood, Director of Client Services at sattwood@castleirb.com