Tip Sheet: NIH Data Management and Sharing (DMS) Policy Tip Sheet

Tip sheet (FAQs) for Sharing of Human Data

What is the NIH DMS Policy?

The National Institutes of Health (NIH) Data Management and Sharing (DMS) Policy requires the submission of a DMS Plan for NIH-funded or NIH-conducted research that will generate scientific data, subject to limited exceptions and the applicable NIH activity codes. Applications with receipt dates on or after January 25, 2023, must include a DMS Plan.

Data must be shared at the time of publication or at the end of the award, whichever comes first. The requirement applies regardless of NIH funding level when the award or activity is subject to the Policy. NIH Career Development (K) awards are no longer required to submit or update a DMS Plan, including at application, Just-in-Time, or Research Performance Progress Report (RPPR). Scientific data must be shared no later than the time of an associated publication or, for other findings, by the end of the period of performance, including no-cost extensions, consistent with the approved DMS Plan.

The DMS Policy does not apply to activities that do not generate scientific data, such as certain training, infrastructure development, and non-research activities.

What is Scientific Data?

The NIH defines “scientific data” as follows: Scientific data are the recorded factual material commonly accepted in the scientific community as sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data do not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens.

Where do I create a DMS Plan?

NIH requires use of the updated DMS Plan format for applicable applications submitted for due dates on or after May 25, 2026. The updated format replaces the former optional six-element format and addresses:

1. maximum appropriate sharing;
2. required sharing timelines;
3. preservation duration;
4. ethical, legal, or technical limitations on sharing;
5. protections for the privacy, rights, and confidentiality of human research participants, including access controls; and
6. anticipated scientific data types and established repositories.

Additional questions apply to studies subject to the NIH Genomic Data Sharing Policy. UTSW investigators may use DMPTool.org for assistance, but the final plan must follow the current NIH-required format.

UTSW has created an institutional account with DMPTool.org, which you can access with your UTSW credentials. Template language for UTSW Principal Investigators to use in their DMS plans is available in DMPTool.org.

What is the requirement for DMS Plan Compliance?

Noncompliance with DMS Plans over the course of the award can result in the termination of funding and may also impact future funding decisions.

How to select an acceptable data repository?

NIH expects investigators to use established repositories for preserving and sharing scientific data when appropriate repositories are available. Investigators should select a repository that fits the data type, discipline, access-control needs, consent limitations, privacy protections, and applicable NIH or journal requirements. For a list of NIH-supported repositories, visit Repositories for Sharing Scientific Data. UTSW is in the process of developing a closed repository for the sharing of data.

What are expectations at UTSW for sharing human data?

Data can be shared in a closed (controlled) access repository or in an open access repository. With IRB approval, de-identified human data may be shared in a closed access repository. On rare occasions, human data may be shared in open access with explicit informed consent from subjects and approval from the IRB.

Will the IRB review DMS plans?

Yes. NIH evaluates the DMS Plan for programmatic and award compliance. The UTSW IRB reviews the proposed sharing of human participant data for consistency with the IRB protocol, informed consent, privacy and confidentiality protections (ETHOS SmartForm Section 13.0), Certificate of Confidentiality (ETHOS SmartForm Section 13.0) requirements, and applicable ethical and regulatory requirements. You may upload the DMS Plan in Section 6.0, Item 16.

What will the IRB review consist of?

The IRB will review the data management and sharing activities described in the IRB protocol, consent form, and current DMS Plan for consistency. The IRB will also evaluate risks to individual participants or groups, the identifiability of the data, repository access controls, data-use limitations, and whether the proposed sharing is consistent with the consent and applicable Certificate of Confidentiality protections.

Submit an IRB modification when the proposed data-sharing activities require changes to the protocol, informed consent form, privacy or confidentiality protections, data identifiability, repository access controls, or permitted secondary uses. Reconsent may be required when new NIH funding or a revised sharing plan changes what participants were previously told or authorized. Use the current HRPP consent templates and guidance available on the Research Consent webpage. Should there be plans to share materials from previously enrolled participants where consent and authorization was not provided to share, ensure that the modification addresses plans to reconsent participants. If the proposed DMS activities include sharing data or materials from previously enrolled participants whose original consent and authorization did not permit the proposed sharing, the modification should describe how those

participants will be reconsented and, when applicable, reauthorized before their data or materials are shared.

What information regarding the NIH DMS policy must be included in the consent form?

The consent form should include information on the types of data that will be shared, if the data shared will be identifiable or de-identified, a statement that a participant's individual-level data will be shared through a controlled (closed) access or open access repository, and the risks and benefits associated with each sharing method.

Submit a modification to update the consent form with the above information to inform participants of the NIH DMS policy. The HRPP will have language added to the informed consent form template available on our website Research Consent. Consenting/reconsenting of subjects may be required if the study receives new NIH funding.

What is the difference between controlled (closed) access and open access repository?

Controlled Access refers to measures such as requiring data requesters to verify their identity and the appropriateness of their proposed research use to access protected data. There are explicit limitations on subsequent use (laws, regulations, policies, informed consent, and/or data use agreements). Controlled-access repositories are for data that is sensitive, can't be fully de-identified, and have unknown risks to participant privacy. The investigator will be responsible for de-identifying the data. Controlled access is the gold standard and investigators are encouraged to share in controlled-access repositories as much as possible. The consent form must specify that the data will be shared in a controlled repository and the consent form should specify the type and identifiability of the data to be shared.

Open Access is when data is available to data requesters without additional restriction. Scientific data are de-identified, and institutional review has determined that they pose very low risk when shared and used. Participants explicitly consent to share data openly without restrictions. The identifiers must be removed, and the consent form should specify the type

and identifiability of the data to be shared. The consent form must also specify that the sharing will be open access (allows anyone to access and use the dataset).

Will I need to update the ETHOS application?

Yes. For a new study, complete the applicable sections of the ETHOS application to describe the NIH data management and sharing activities and upload the current DMS Plan.

For an existing study that was originally approved in eIRB, if new or revised NIH data sharing activities will occur, the study must first be submitted in ETHOS. The ETHOS submission should include the proposed data sharing plans and any corresponding updates to the protocol, consent/HIPAA authorization, and other applicable study documents. The IRB will review the proposed sharing as part of the ETHOS submission.

Will I need to update the grant application?

If IRB review results in changes to the proposed data-sharing activities, revise the DMS Plan and other award documentation as appropriate. NIH prior approval is no longer required solely to modify an approved DMS Plan. Effective October 1, 2026, recipients must report progress and changes through RPPR Section C.5.c., including changes in scientific direction, repositories, or sharing timelines. Contact the NIH Program Official or Grants Management Specialist when guidance is needed or when another award term requires prior approval.

Will I be required to provide progress updates to the IRB?

Yes, when applicable. At continuing review or another IRB progress-reporting event, provide a summary of data shared under the approved protocol and identify material changes to repositories, access controls, identifiability, consent limitations, or sharing timelines. NIH progress and DMS Plan changes must also be reported through RPPR Section C.5.c. beginning October 1, 2026.

What if I need to change my data sharing plan after initial approval?

NIH prior approval is no longer required solely to modify an approved DMS Plan. Effective October 1, 2026, recipients must use RPPR Section C.5.c. to report progress and notify NIH of changes, including changes in scientific direction, data repositories, or sharing timelines. Consult the IRB before implementing a change involving human participant data. Submit an IRB modification when the change affects the approved protocol, consent language, privacy or confidentiality protections, data identifiability, repository access controls, data-use limitations, or risks of secondary use. Include the current DMS Plan and revise the protocol, consent form, and applicable ETHOS responses as needed. Obtain IRB approval for applicable human-subject research changes before implementing the revised sharing arrangement.

What format-transition requirements apply to existing applications and awards?

Beginning in FY 2027, existing awards and applications subject to the NIH DMS Policy must transition to the updated DMS Plan format, regardless of when the competing application was submitted. Competing applications submitted on or after May 25, 2026 must use the updated format with the application. Applications submitted earlier but not yet awarded must provide the updated plan at Just-in-Time. Active awards subject to the 2023 DMS Policy must provide an updated plan with the next RPPR; if the FY 2026 RPPR was already submitted, transition with the FY 2027 RPPR. Older active awards expected to generate scientific data, including awards subject to the 2023 policy, must submit the updated plan with the FY 2027 RPPR.

Are NIH Career Development (K) awards required to have a DMS Plan?

No. Active K award recipients are not required to submit or update a DMS Plan, including through the RPPR. Pending K applications do not need to provide a DMS Plan during pre-award or Just-in-Time, and future K applications do not require a DMS Plan. NIH states that the absence of a DMS Plan for a K award will not be considered noncompliance with the DMS Policy.

Resources:

UTSW Intranet NIH DMS Policy

Data Management and Sharing Policy | Data Sharing (nih.gov)

NOT-OD-21-013: Final NIH Policy for Data Management and Sharing

NOT-OD-21-016: Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research

NOT-OD-22-213: Supplemental Information to the NIH Policy for Data Management and Sharing: Protecting Privacy When Sharing Human Research Participant Data

FAQs - NIH Data Management and Sharing Policy

NOT-OD-26-046: Updated Elements of an NIH Data Management and Sharing Plan

NOT-OD-26-100: Implementation Update: NIH Data Management and Sharing Plan Requirements

NOT-OD-26-120: Accelerated Implementation of DMS Plan Changes for NIH Career Development (K) Awards

Questions or Assistance:

Reach out to DataSharing@utsouthwestern.edu if you have questions or need assistance with developing a plan for a grant submission.