



SRA INTERNATIONAL
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UTSouthwestern
Medical Center

Institutional Readiness for the NIH DMS Policy: What Did and Did Not Work

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Outline

- Overview of NIH DMS Policy Requirements
- Learning Objectives
- Questions

Overview of NIH DMS Policy



Requirement

Beginning **January 25, 2023**, the NIH requires the submission of a Data Management and Sharing (DMS) Plan for all new or competing renewal grant applications for research that generates scientific data, **and** data must be shared at the time of publication or at the end of the award, whichever comes first.

Applicability

The new NIH DMS policy applies to all new projects which meet the following criteria:

- All applications received on or after January 25, 2023
- NIH-supported research regardless of funding level
- Research that results in the generation of scientific data
- It is not retroactive and will not impact current awards

<https://sharing.nih.gov/>

Learning Objectives



1. List the administrative infrastructure and resources needed to support investigator compliance with the new NIH Data Management and Sharing Policy

2. Analyze the latest developments with the NIH Data Management and Sharing Policy including NIH's feedback and suggestions on initial DMS Plans

3. Identify the challenges and potential avenues for compliance monitoring, allowable costs, and data sharing timelines

Importance of Administrative Infrastructure

- Spread the word far and wide
- Ensure all researchers understand what is going on
- Manage multiple channels of distribution, communication, and recording of new developments
- Collate feedback and comments made on the submitted DMS Plans at JIT
- Identify potential avenues for compliance monitoring

Institutional Readiness Group

Ensure readiness for the new NIH Data Management and Sharing (DMS) Policy, and communicate ongoing changes.

- Coordinate activities across business units
- Craft template language for investigators to use in data management and sharing (DMS) plans
- Ensure communication within the UTSW research community

Institutional Readiness Group Members

- UTSW Readiness Group Members:
 - Human Research Protection Program (HRPP)
 - Research & Academic Systems (RAS)
 - Research Integrity Officer (RIO)
 - Research Support and Regulatory Management (RSRM) including (COI, EC, IACUC)
 - Sponsored Programs Administration (SPA)
 - The Library
- New web page on MyUTSW: [NIH DMS Policy Readiness Page](#)
- Dedicated email: DataSharing@utsouthwestern.edu

The screenshot displays the UTSouthwestern Medical Center website. The header includes the logo, navigation links (About Us, Administration, Departments & Centers, Education, Hospital & Clinics, Human Resources, Research, Services, Tools), and a search bar. The main content area is titled "NIH Data Management and Sharing Policy" and includes a "Print this page" button. The text states that the NIH DMS Policy went into effect on January 25, 2023, and provides information about the policy's impact on grant applications. It also mentions an update regarding NIH application instructions for DMS costs and the availability of two pilot DMS templates (Alpha and Bravo) in the DMPTool.org. A "Quick Links" sidebar on the right contains links to the NIH Data Management and Sharing Policy Guidance, NIH DMS Frequently Asked Questions (FAQs), UTSW NIH DMS Frequently Asked Questions (FAQs), and UTSW Suggestions for Data Management and Sharing Plans for Animal Study Data. A "Contact Us" section at the bottom right provides an email address (datasharing@utsouthwestern.edu) and a phone number (214-648-0456). A video player at the bottom shows a presentation titled "NIH Data Management and Sharing (DMS) Policy Readiness" from a UTSW Faculty Informational Session.

Highlights of Dedicated Web Page

- NIH web site providing general information on the Policy and Data Sharing: <https://sharing.nih.gov>
- NIH developed an [optional DMS Plan format](#) that aligns with the recommended six elements of a DMS Plan:
 1. Data Type
 2. Related Tools, Software and/or Code
 3. Standards
 4. Data Preservation, Access, and Associated Timelines
 5. Access, Distribution, or Reuse Considerations
 6. Oversight of Data Management and Sharing
- In mid-January , NIH provided examples of data management plans or data sharing expectations for the new “optional” DMS Plan template that follows their policy.
 - Just because you follow their examples, does not guarantee acceptance of the DMS Plans.

OMB No. 0925-0001 and 0925-0002 (Rev. 07/2022 Approved Through 01/31/2026)

DATA MANAGEMENT AND SHARING PLAN

If any of the proposed research in the application involves the generation of scientific data, this application is subject to the NIH Policy for Data Management and Sharing and requires submission of a Data Management and Sharing Plan. If the proposed research in the application will generate large-scale genomic data, the Genomic Data Sharing Policy also applies and should be addressed in this Plan. Refer to the detailed instructions in the application guide for developing this plan as well as to additional guidance on sharing.nih.gov. The Plan is recommended not to exceed two pages. Text in italics should be deleted. There is no "form page" for the Data Management and Sharing Plan. The DMS Plan may be provided in the format shown below.

Public reporting burden for this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0001 and 0925-0002). Do not return the completed form to this address.

Element 1: Data Type

A. Types and amount of scientific data expected to be generated in the project:
Summarize the types and estimated amount of scientific data expected to be generated in the project.

B. Scientific data that will be preserved and shared, and the rationale for doing so:
Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.

C. Metadata, other relevant data, and associated documentation:
Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.

Element 2: Related Tools, Software and/or Code:
State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they can be accessed.

Element 3: Standards:
State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources, and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by



Creating a DMS Plan in DMPTool.org

- DMPTool is a free, open-source, online application that helps researchers create data management plans
- NIH works with DMPTool.org to disseminate their DMS Plan templates and requirements
- DMPTool is easy to use, a webinar about its use was made available on the UTSW NIH DMS Policy web page

UTSW created an institutional account with [DMPTool.org](https://dmp-tool.org)!

- Single Sign-On (SSO)
- Template language for UTSW PIs to use in their DMS plans was added to DMPTool.org

Selecting an Acceptable Data Repository

NIH Preference on Repositories:

- In general, NIH does not endorse or require sharing data in any particular repository, although some initiatives and funding opportunities will have individual requirements. **Overall, NIH encourages researchers to select the repository that is most appropriate for their data type and discipline.**
- NIH strongly encourages the use of *established NIH-supported repositories* to the extent possible for preserving and sharing scientific data.
 - NIH-supported repository information can be found at sharing.nih.gov

Can't find a repository that suits your data?

- When investigators cannot locate a repository for their discipline or the type of data they generate, a *generalist repository* or *institutional repository* can be used to share data.

[Selecting a Data Repository](#) | [Data Sharing \(nih.gov\)](#)

NIH's Data Repository Preference

- For some programs and types of data, NIH and/or Institute, Center, Office (ICO) policy(ies) and Funding Opportunity Announcements (FOAs) identify particular data repositories to be used.



Designated Data Repository

- For data for which no data repository is specified by NIH, researchers are encouraged to select a data repository that is appropriate for the data generated from the research project.



Discipline or Data Type Specific
([NIH-supported Scientific Data Repositories](#))

PubMed Central
(Small datasets as supplementary material)

Generalist Repositories

Institutional Repositories

[Selecting a Data Repository](#) | [Data Sharing \(nih.gov\)](#)

A large, semi-circular graphic with a gold-to-brown gradient background. The text "UTSW Institutional Repository" is written in white, bold, sans-serif font, centered within the shape.

UTSW Institutional Repository

- UTSW joined the Texas Data Repository Dataverse and developed the UT Southwestern Research Data Repository.
- This institutional repository gives UTSW investigators an open-access **generalist repository option** that meets NIH's data sharing expectations.
- The repository consists of datasets generated by the University community, available for public access and reuse.
- Each dataset includes citation information and a Digital Object Identifier (DOI), facilitating attribution, usage tracking, and linking data to research publications.

<https://dataverse.tdl.org/dataverse/utswmed>

UT Southwestern Research Data Repository

Texas Data Repository

Search ▾ About User Guide Support Log In

UT Southwestern Medical Center

UT Southwestern Research Data Repository
(UT Southwestern Medical Center)

[Click here for instructions on how to use the Research Data Repository.](#)

Texas Data Repository >

[Contact](#) [Share](#)

The UT Southwestern Research Data Repository is an open access data repository for researchers affiliated with the UT Southwestern Medical Center. The repository consists of datasets produced by the University community, available for public access and re-use. Each dataset includes citation information and a Digital Object Identifier (DOI), facilitating attribution, usage tracking, and linking of data to research publications.

Search this dataverse... [Advanced Search](#)

☒ [Dataverses \(0\)](#)

☒ [Datasets \(0\)](#)

☐ [Files \(0\)](#)

This dataverse currently has no dataverses, datasets, or files. Please [log in](#) to see if you are able to add to it.

Advantages

- Log in with UTSW credentials
- Allow other collaborators to work on dataset before it is published
- Encourage including researcher identifiers (e.g., ORCID)

Limitations

- File upload limit
- No private, confidential, or other legally protected information
- De-identify any personally identifiable information

<https://dataverse.tdl.org/dataverse/utswmed>

Protecting Privacy: Best Practices

Supplemental Information to the NIH Policy for
Data Management and Sharing: Protecting Privacy
When Sharing Human Research Participant Data

Notice Number:
NOT-OD-22-213

De-identify data

De-identification mechanisms:

- Common Rule (identity cannot “readily be ascertained by the investigator”)
- HIPAA (safe harbor or expert determination)

*Warning: information in deidentified datasets **may** allow participants to be identified. Consider modifying information or sharing via controlled access.*

Standardized Data Sharing Agreements

Oversight

- Include assurances that institutional oversight body has reviewed and **considered the risks** of data sharing, ensure that sharing is **consistent with informed consent** (as applicable), and that the **protections in place** are appropriate (such as de-identification, including the standards and methods used).

Responsibilities

- Outline responsibilities of all parties having access to the data and any **data use limitations** including those required by Certificates of Confidentiality, as applicable.

Restrictions

- Outline **sharing limitations**
- **Prohibit attempts to re-identify and/or recontact** participants or their family members unless there is explicit consent to do so

Understand Legal Protections (Disclosure and Misuse)

Consider relevant laws

- Federal, Tribal, state, and local laws may apply to the disclosure and use of data

Understand NIH Certificates of Confidentiality (COC) Policy

- COC **prohibits disclosure** of protected information for non-research purposes except in specific situations (e.g., with consent)
- Data and all copies are covered by Certificates in **perpetuity**

Choosing a Repository: Points to Consider

Supplemental Information to the NIH Policy for
Data Management and Sharing: Protecting Privacy
When Sharing Human Research Participant Data

Notice Number:
NOT-OD-22-213

Controlled Access

*Data requesters must verify their identity and the appropriateness of their proposed research use to access data (*Gold Standard)*

1. There are **explicit limitations** on subsequent use (laws, regulations, policies, informed consent, and/or data use agreements)
2. The data are **sensitive**
 - Potentially stigmatizing traits, illegal behaviors, or other information that could cause harm or be used for discriminatory purposes.
 - If data are sensitive, it may be possible to de-identify the data in ways that would allow appropriate sharing.
3. The data **can't be fully de-identified**
 - Some de-identified datasets contain enough information that may allow reidentification of participants
4. There are **unknown risks to participant privacy** if released without controls.
 - Unanticipated approaches or technologies that become known.

Open Access

Available to data requesters without additional restriction

1. Scientific data are **de-identified** AND institutional review has determined that they **pose very low risk** when shared and used.
2. **Participants explicitly consent** to share data openly without restrictions

Enterprise Box Account

UTSW created an Enterprise Box Account, which provides researchers with an institutional repository option:

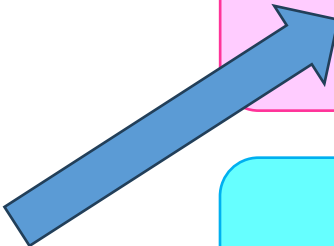
- Controlled access
- No limit on storage
- Single Sign-On



<https://www.box.com/>

Learning Objectives

1. List the administrative infrastructure and resources needed to support investigator compliance with the new NIH Data Management and Sharing Policy



2. Analyze the latest developments with the NIH Data Management and Sharing Policy including NIH's feedback and suggestions on initial DMS Plans

3. Identify the challenges and potential avenues for compliance monitoring, allowable costs, and data sharing timelines

Communications Campaign

Prior to January 25th

- Two All Faculty Emails
 - Invite to Informational Session
 - Prior to Implementation
- Faculty Informational Session
- Today@UTSW Newsletter
- Announcements in *Academic Connections*
- SPA Research RoundUp Meeting
- Lab Managers Forum Listserv
- IACUC Listserv
- HRPP Research Matters Meeting
- Provosts & Business Affairs Meeting
- Administrators Meeting
- Clinical Research Update
- HRPP Updates Meeting

After January 25th

- Faculty Senate Meeting
- Institutional Compliance Research and Academics Virtual Office Hours
- IM Department Informational Session
- Executive Compliance Committee Meeting
- SPA Research RoundUp Meeting

Announcements in Campus Newsletters and Listservs

Upcoming Data Management and Sharing Plans

Beginning Jan. 25, 2023, the National Institutes of Health (NIH) will require the submission of Data Management and Sharing (DMS) plans for all new or competing renewal grant applications, for all research that generates scientific data.

The new policy requires that PIs deposit their scientific data in publicly accessible data repositories at or before publication or at the completion of a research project; and that they explicitly describe their plans for how and where their data will be deposited.

An informational session for faculty will be held on Dec. 2 at 9 a.m. in NG3.112. More information is [available online](#) (VPN required). Send questions to DataSharing@utsouthwestern.edu.



RESEARCH

Faculty: Attend upcoming data management and sharing plans informational session

Beginning Jan. 25, 2023, the National Institutes of Health will require the submission of Data Management and Sharing (DMS) plans for all new or competing renewal grant applications for all research that generates scientific data.

The new policy requires that principal investigators deposit their scientific data in publicly accessible data repositories **at** or before publication or **at** the completion of a research project, whichever comes first; and that they explicitly describe their plans for how and where their data will be deposited.

A faculty-focused [informational session](#) will be held on Friday **at** 9 a.m. in NG3.112. More information is [available online](#) (VPN required). For questions, email DataSharing@utsouthwestern.edu.

Data Management and Sharing Policy

Beginning Jan. 25, the National Institutes of Health will require the submission of a Data Management and Sharing Plan (DMP) for all new or competing renewal grant applications for all research that generates scientific data.

The recording of an informational session for faculty about the new policy, held last month, is now [available online](#) (VPN required). Send questions to DataSharing@utsouthwestern.edu.

UT Southwestern
Medical Center

CLINICAL RESEARCH UPDATE

CURRENT CLINICAL RESEARCH NEWS ROUNDUP

To: IACUC-Researchers-lists

Retention Policy No Auto Deletion (50 years)

Dear Investigators:

As previously announced, beginning January 25, 2023, the NIH will require the submission of Data Management and Sharing (DMS) plans for all new or competing renewal grant applications for all research that generates scientific data.

The NIH has partnered with [DMPTool.org](#) to help researchers create institutional account with DMPTool.org. Also, UTSW has established

NIH DATA MANAGEMENT & SHARING POLICY



Beginning January 25, 2023, the NIH requires the submission of a Data Management and Sharing Plan (DMP) for all new or competing renewal grant applications for research that generates scientific data, and data must be shared the time of publication or at the end of the award, whichever comes first.

The new NIH DMS policy applies to all new projects which meet the following criteria:

- All applications received on or after January 25, 2023
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- NIH strongly encourages the use of established NIH-supported repositories to the extent possible for preserving and sharing scientific data.
- NIH-supported repository information can be found at sharing.nih.gov

RESOURCES

- UTSW Readiness Group includes SPA, RSRM, HRPP, RIO, & the Library
- New web page on MyUTSW: [NIH DMS Policy Readiness Page](#)
- Dedicated Data Sharing email: DataSharing@utsouthwestern.edu
- SPA's web page on [Regulatory Updates](#)

To: lab-managers-foru
Subject: [Lab-managers-for
Attachments: Informational Sessi
ATT00001.txt

Good Morning Lab Managers,

The Office of Research Support and Regulatory Management is hosting a *Faculty Informational Session* regarding the new NIH DMS event with live broadcasting and recording. You may



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NIH Data Management and Sharing Policy The Simplest Possible FAQs

Please visit the [UTSW NIH Data Management and Sharing Policy web page](#). This page will be updated to try to keep up with changes from the NIH.

1. What is it?

The Data Management and Sharing Policy is a new NIH mandate that data obtained using NIH support must be deposited in a publicly accessible data repository. Every new NIH grant application for a project that may generate data must contain a new section describing the PI's Data Management Plan. Some types of grants are excepted, including meeting, training, and equipment grants.

2. Who has to submit the new and expanded Data Management Plan (DMP)?

Anyone submitting an application for a project that will produce data must include a DMP according to the new requirements as of January 25, 2023.

3. When?

The policy becomes effective January 25, 2023.

4. Is it only for new grants?

The policy includes new grants and COMPETING RENEWALS. Annual non-competing renewals are not included.

5. What does a DMP contain?

The DMP is a new two-page section in the NIH grant application. A current draft template for the two-page plan is available [here](#), but changes are likely, possibly as late as January 1. UTSW is preparing a customized template that includes UTSW-specific boilerplate. It will be available on our intranet site when it is ready. Please note that NIH expects to make changes to the current policy and requirements in 2023 and 2024.

6. What is meant by "data"?

The NIH definition of "data" is broad and potentially inconsistent. Read the NIH definition [here](#). UTSW will try to provide more guidance as the time approaches.

7. What is a data repository?

A publicly accessible, on-line data storage facility that will be permanently maintained (or at least until the policy or technology changes). Familiar examples are GenBank and Protein Data Bank. Repositories must be searchable, implicitly by subject and depositor, and must be able to assign Digital Object Identifiers (DOIs) to individual bodies of data. NIH lists their preferred data repositories [here](#). These include so-called generalist repositories that can accommodate diverse data types. UTSW is negotiating access to trusted repositories for its researchers. Details will be available in the near future.

8. When must data be deposited?

Data must be deposited at the time a related manuscript is published. Other data that has not been published must be made available at the end of the project period or earlier, depending on NIH's requirements for your DMP.

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9. What about data on human subjects and animals?

HRPP and IACUC will be providing guidance and DMP boilerplate regarding confidentiality of human subject research and animal research.

10. Will my grant be scored on its data management plan?

No. If the grant is to be funded, the plan will be evaluated for adequacy by program staff and any needed changes will be negotiated at that time. This is a work in progress for NIH: don't sweat the details.

Impact on Animal Research Subjects Data

- No specific guidance on what type of data must be shared, other than data that is “necessary to validate or replicate research findings.”
- To assist animal researchers, we created suggestions on how to meet NIH’s data sharing expectations while maintaining confidentiality regarding animal research data.
- If data is obtained from images or recordings, the best consideration is to share the quantified data rather than the images and recordings.

Office of Research Support and Regulatory Management
DataSharing@UTSouthwestern.edu
214-648-0456

IACUC
Tip Sheet

Suggestions for Data Management and Sharing Plans for Animal Study

This tip sheet provides researchers with suggestions about what animal related data should be considered for inclusion in data management and sharing plans (DMPs) based on the [NIH Data Management and Sharing Policy](#).

The use of animals in research can be a sensitive issue and under no circumstances should photographic equipment be taken into UT Southwestern animal facilities without prior approval of the ARC Assistant VP. For additional guidance, please refer to the [ARC Photographing Policy](#).

As a general rule, only share images/videos when the images/videos are the data. If data is obtained from images/videos and documented separately from those images/videos, then share that documented data and not the images/videos.

When sharing images of animals that provide data, only share the component of the image relevant to the research.

Example: If a tumor image is data, ensure that the image only shows the tumor and not the entire animal.

You do not need to share the following:

- Animal ID numbers, tattoos, names, or other identifying information. Data can be identified as from “#1,” or “Group 2, An. 3,” etc.
- Images of laboratory notebooks and cage cards. Data found in these items can be transcribed into other documents, e.g. Word or excel documents, and then shared.
- Animal health records, unless they represent research data. This would include room logs, veterinary records, surgery records (including post-op monitoring), and veterinary necropsy reports.
 - Images or information related to incidental health findings, such as hair loss or fighting injuries in rodents, do not need to be shared.

Do not provide:

- Contact information
- Room or building numbers
- Images of researchers
- IACUC correspondence, including protocol numbers and documents
- Other personal information

December 2022

INSIDE the IACUC

In case you haven't heard yet, the National Institutes of Health (NIH), which is the single largest funder of biomedical research in the United States, has focused on the need for transparency and the ability to reproduce research results so that results from funded research can be maximized. As a culmination of a multi-year effort, the NIH recently implemented a policy to require data management and sharing plans for all NIH grant submissions for research that generates data.

Over the next couple of years, the NIH is expected to provide clarification and additional guidance for what is expected in these plans. But, it behooves laboratory animal professionals to be familiar with the NIH's new requirements so that we can best support our researchers and offer assistance when it comes to sharing data generated by the use of laboratory animals.

For this month's issue, Dr. Torres-Altoro gives us an overview of the newly implemented policy and how it will impact researchers. Additionally, she outlines practical advice that the laboratory animal community can give researchers when they are developing their plans to submit their grant applications.

We urge everyone within laboratory animal science to become familiar with this new NIH policy. It promises to become an integral part of how biomedical research can continue to advance further to improve the health of both humans and animals.

Stacy and Claire

Stacy Pitt, DVM, MS, MBA, CPHA, CHRC, DACAV is the Associate Vice President of Research Support and Regulatory Management and Assistant Professor in Psychiatry at the University of Texas Southwestern Medical Center in Dallas, TX.

F. Claire Hankenson, DVM, MS, DACLAM, is the Associate Vice President for Research and Attending Veterinarian and Executive Director, University Laboratory Animal Resources, at the University of Pennsylvania in Philadelphia, PA.

Suggestions for Data Management and Sharing (DMS) Plans for Animal Study Data: Navigating the 2023 NIH DMS Policy

By Melissa I. Torres-Altoro, PhD, CPA

Effective January 25, 2023, the NIH implemented their new Data Management and Sharing (DMS) policy to promote the sharing of scientific data.¹ The intent of the DMS policy is to enhance access to biomedical research outcomes, with the aim to improve reproducibility and promote data reuse for future research studies.

Importantly, this new DMS policy will not be retroactive and does not impact ongoing grant work. Instead, the policy only applies to all new or competing renewal grant applications which meet the following criteria:

- Applications for receipt dated on or after January 25, 2023.
- NIH-supported research regardless of funding level.
- Research that results in the generation of scientific data.

The policy requires that Principal Investigators (PIs) deposit their scientific data in publicly accessible data repositories at or before the data is included in peer-reviewed publications or at the completion of a research project, whichever comes first. Further, PIs should explicitly describe their plans for how and where their data will be deposited.⁴

What animal research data should be shared?

The cornerstone of the new policy is the requirement that a proposed data management plan (DMP) be included in all grant applications where the research will result in scientific data. In the DMP, the investigator must review the data that will be generated and how it will be managed and shared. The DMPs will be reviewed by NIH staff at the institute or center funding the award, and they will not be included in the grant review materials sent to the peer reviewers. NIH has posted some example data management plans, a few of which include animal research.⁴ Beyond this, no specific guidance has yet been released as to exactly what type of data must be shared, other than data that is “necessary to validate or replicate research findings.”⁴

Obviously, this will have an impact on scientists performing animal research. Planning for how animal study data will be managed and ultimately shared is an important step in avoiding misinterpretation or misunderstanding of the animal-based research data that will be shared via the DMS Policy. At UT/UTSW, we have created suggestions on how to meet NIH's data-sharing expectations for animal research, and these recommendations may prove useful to you as well.

In general, when collecting images or video recordings of animals, do not include personnel contact information, animal facility rooms or building numbers, images of employees/researchers, IACUC correspondence, IACUC protocol documents/identifiers, or any other personal information. Animal images and recordings (audio and video) could be shared when these are

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IRB Updates and Resources in Light of Latest Developments



- The IRB informed consent template was updated to account for the new NIH policy.
- The IRB is developing a Tip Sheet with further information specific to human research.
 - IRB web page
 - Dedicated NIH DMS MyUTSW site
- A new email address was created to handle ***all*** human research data sharing requests:
datasharingIRB@utsouthwestern.edu.

Two Pilot DMS Templates Now Available in DMPTool

- As of June 1, 2023, two Pilot DMS templates have been added to DMPTool.org.
- When researchers log into DMPTool.org, they have a choice of three templates for NIH DMS plans:
 - *NIH-Default DMSP*
 - *NIH-FDP Pilot Template Alpha* - Alpha is a prescriptive template designed to limit the need for free text entry.
 - *NIH-FDP Pilot Template Bravo* - Bravo aims to provide detailed prompts as well as more options to include free text responses as necessary.
- The pilot templates are available for **all** to use and not just organizations participating in the FDP NIH DMS pilot project.
- This information was made available on our dedicated [NIH DMS Policy](#) web page on MyUTSW.

A screenshot of the DMPTool web interface. At the top, it says "* Select the primary funding organization". Below this, there is a text input field labeled "Funder" containing the text "National Institutes of Health (nih.gov)". Further down, it asks "Which DMP template would you like to use?". There are three radio button options: "✓ FDP Pilot Template Alpha" (which is selected), "FDP Pilot Template Bravo", and "NIH-GEN DMSP (2023)". At the bottom of the selection area, there are two buttons: "Clear selection" and "Cancel". A green arrow points from the text "NIH-FDP Pilot Template Alpha" in the list to the selected option in the screenshot.

Single Budget Line Item Requirement for DMS Costs Rescinded

NIH Application Instruction Updates – Data Management and Sharing (DMS) Costs

Notice Number:

NOT-OD-23-161

Key Dates

Release Date:

July 31, 2023

Related Announcements

- **August 5, 2022** - Implementation Details for the NIH Data Management and Sharing Policy. See Notice [NOT-OD-22-189](#).

Issued by

NATIONAL INSTITUTES OF HEALTH (NIH)

Purpose

This notice updates the NIH application instructions for submitting requests for Data Management and Sharing costs in a single line item. As outlined in the [Final NIH Policy on Data Management and Sharing \(DMS\)](#), costs associated with data management and data sharing may be allowable under the budget for the proposed project. Currently, the [NIH How to Apply - Application Guide](#) states that costs to support activities described in the DMS plan, including personnel costs, must be noted on the R&R Budget Form as a single line item titled "Data Management and Sharing Costs." The line item must be used only for DMS costs and cannot be combined with any "Other" costs. If no costs will be incurred, the applicant must enter "0" in the funds requested column. These previous instructions will be rescinded effective October for due dates on or after October 5, 2023.

Effective for applications submitted for due dates on or after October 5, 2023, NIH will no longer require the use of the single DMS cost line item. NIH recognizes that DMS costs may be requested in many cost categories. Therefore, in line with our standard budget instructions, DMS costs must be requested in the appropriate cost category, e.g., personnel, equipment, supplies, and other expenses, following the instructions for the R&R Budget Form or PHS 398 Modular Budget Form, as applicable. While the single cost line item is no longer required, NIH will require applicants to specify estimated DMS cost details within the "Budget Justification" attachment of the R&R Budget Form or "Additional Narrative Justification" attachment of the PHS 398 Modular Budget Form, pursuant to the instructions.

Updates to the [NIH How to Apply – Application Guide](#) will be published prior to the October 5, 2023, effective date.

- NIH issued a guidance notice [NOT-OD-23-161](#) to update the NIH application instructions for submitting request for DMS costs in a single line item.
- Effective for applications submitted for due dates on or after October 5, 2023, NIH will no longer require the use of the single DMS cost line item.



Single Budget Line Item Requirement for Data Management and Sharing Costs Rescinded

By NIH Staff

Posted August 15, 2023

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1 Comments

Currently, grant applicants submitting detailed budgets must request costs to support Data Management and Sharing (DMS) Plan activities as a single line item on the R&R Budget Form titled "Data Management and Sharing Costs." **This requirement will be rescinded for due dates on or after October 5, 2023 ([NOT-OD-23-161](#)).**

For applications with due dates on or after October 5, 2023, DMS costs must be included with other costs in the appropriate cost categories (e.g., personnel, equipment, supplies, other expenses), following standard form instructions. For example, personnel costs associated with data management and sharing activities, must be entered in section A. Senior/Key person or section B. Other Personnel. Supporting details, including a breakdown of any personnel effort, and the estimated associated total direct costs must be included in the budget justification.

The application form instructions on the [How to Apply – Application Guide](#) page and the [Budget/Costs FAQs](#) on the [Scientific Data Sharing](#) site have been updated to reflect this change.

NIH's Feedback on Initial DMS Plans

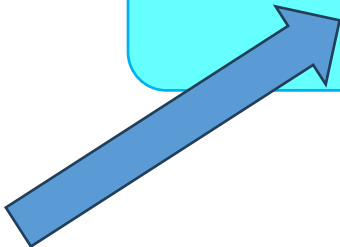
- The only comments we know of at UTSW, which came at JIT, were:
 - PI who failed to include the funding institute's specific repository in his plan and also needed to provide clarification on the data sharing timeline.
 - No request to change content
 - PI who was asked to revise the DMS plan recently, but it is not clear at this time what changes the NIH wants to see
- NIH will share feedback, comments, and suggestions on initial DMS Plans in late October.
- NIH will be updating their FAQs for some challenges researchers are facing but are not addressed in the policy.
- NIH is gathering data and feedback through a **Pilot Project** of selected institutions.
 - Goals of Pilot Project:
 - Test structured templates and tools for DMS Plan submission
 - Establish cost policies and identify types of cost required
- NIH is also considering an RFI after the Pilot Project to gather comments from wider audience and beyond the two foci for the pilot study.

Learning Objectives

1. List the administrative infrastructure and resources needed to support investigator compliance with the new NIH Data Management and Sharing Policy

2. Analyze the latest developments with the NIH Data Management and Sharing Policy including NIH's feedback and suggestions on initial DMS Plans

3. Identify the challenges and potential avenues for compliance monitoring, allowable costs, and data sharing timelines



Compliance Monitoring for Institutions



- NIH has yet to provide succinct guidance regarding oversight and monitoring by an institution
 - No structure exists
 - No suggested institutional corrective actions from NIH
 - No reporting mechanism for institutions
 - RPPR?
- Do institutions need to identify potential avenues for compliance monitoring?
- UTSW suggested language for Compliance & Oversight: *“The contact PI for the project is Dr. X at the University of Y. Dr. X will meet regularly with members of the research project team to ensure that data collection, management, and submission to the repositories occur in a manner compliant with this Data Management and Sharing Plan.”*

Survey of Institutional Compliance Monitoring Plans

Institution	FY 22 NIH Funding	Current Plan	Responsibility Institutional Entity (If Provided)
Large University with a Medical School	\$650-700M	Periodic audits of DMS Plans, no current structure for the audit plan	Same group as IACUC/IRB
Large University with a Medical School	\$200-250M	PI or other investigative personnel must be identified on DMS Plan to take responsibility for compliance and oversight	N/A
Academic Medical Center	\$250-300M	PI responsible	N/A
Academic Medical Center	\$150-200M	No guidance	N/A
Academic Medical Center	\$150-200M	No guidance	N/A
Large University with a Medical School	\$50-100M	Post-Approval Monitoring or PI	Human Research – IRB Animal Research – IACUC Other Research – PI
Medium University with a Medical School	\$50-100M	Deferred any oversight/compliance questions to the Library	Library
Medium University with no Medical School	\$10M	PI is ultimately responsible but will implement a risk-based audit approach	Sponsored Projects
Large University with a Medical School	\$<10M	No institutional guidance	Individual academic departments
Large University with a Medical School	\$<10M	PI responsible	N/A

Many institutions indicate that they are in a “holding pattern” and not implementing any compliance monitoring without further NIH guidance

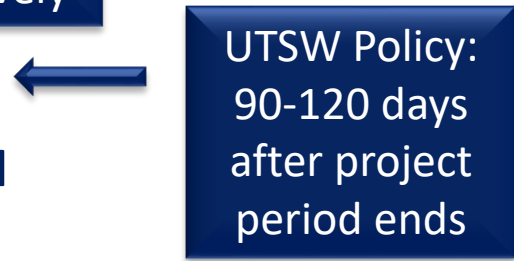
Monitoring Components for an Institutional Process

- What is being shared
 - Appropriate data from the relevant studies identified in DMS Plan
- When is it being shared
 - Shared on or before publication
 - Non-published data shared before award close-out
 - Other time points in the DMS Plan – **Not encouraged**
- Justifications for not sharing data followed
- How is data shared
 - Repositories identified in DMS Plan
- Appropriate reporting of data sharing progress in RPPRs

Difficult to do
prospectively



UTSW Policy:
90-120 days
after project
period ends



Monitoring Components for the HRPP

- What is being shared
 - Appropriate data from the relevant studies identified in DMS Plan
- When is it being shared
 - Shared on or before publication
 - Non-published data shared before *protocol* close-out
 - Other timepoints in the DMS Plan?
- Justifications for not sharing data followed
- How is data shared
 - Repositories identified in DMS Plan
- Appropriate reporting of data sharing progress in RPPRs



Consistent
with informed
consent and
IRB
requirements



May not
correspond to
award close-
out

Potential Institutional Monitoring Options (in order of effort/burden)

1. No monitoring by the institution, PI completely responsible
2. *Ad hoc* monitoring at close-out or at other triggers (e.g. first manuscript publication)
3. *Ad hoc* monitoring during award period and review at all close-outs
4. Reviews at RPPR (annual)
5. Reviews at RPPR (annual) and close-out
6. Reviews at RPPR, manuscript review, and close-out
7. Reviews at RPPR, timepoints in the DMS Plan, manuscript publication, triggers, & close-out

Additional options:

- IRB reviews as part of QA
- IACUC reviews with PAM

Our Challenges

- Access to DMS Plans and RPPRs in eResearch
- Changes expected to NIH policy guidance in 2024 and beyond
- Resources with appropriate expertise and increased workload (e.g. HRPP)
- Need for a closed repository for human research data
 - Institutional agreements may be needed for external closed repositories
- No institutional policy on data sharing
 - Many institutions implemented a policy on data sharing at prior to the NIH policy
- Administrative burden for PIs
 - The more involved the monitoring by the institution, the more PI time will be needed
- Changes to DMS Plans during the award

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Questions?

