RED
Research Education Development

Symposium for Research Administrators

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From Dodging to Drafting: NIH DMS Plans

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Meet the Presenters

Jennifer Ramsey, CRA

Research Administrator in the Department of Medicine (DOM) in the School of Medicine and Public Health (SMPH). She joined the DOM Office of Research Services in 2022 from the Florida State University, and they have 15 years of experience administering pre- and post-award at the college and department level.

Christy Schulz, MS

Research Administration Director in the School of Medicine and Public Health (SMPH). She oversees research and sponsored projects administration activities on behalf of SMPH. She coordinates monthly meetings for SMPH Research Administrators Network which includes 17 Clinical Departments, 10 Basic Science Departments, and 23 Institutes and Centers. She has been a research administrator for 23 years at UW.

Session Learning Objectives

- Learn about the NIH Data Management and Sharing (DMS) Policy and any related updates.
- Learn about the steps and content needed to create a DMS plan.
- Excel at DMS Plan related trivia.
- Participants will leave more confident in advising or assisting their faculty and researchers about NIH DMS Plans.

DMSP ≠ DSMP

Data Management and Sharing Plan

IS NOT THE SAME as the

Data Safety and Monitoring Plan.

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DMS Plan Policy Purpose

New Data Management & Sharing (DMS) Policy

Effective January 25, 2023; revised September 26, 2024.

"To promote the sharing of scientific data which accelerates biomedical research discovery, in part, by enabling validation of research results, providing accessibility to high-value datasets, and promoting data reuse for future research studies."

DMS Plan – Covered Data

- **Applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of scientific data.**

- **Includes:** data needed to validate and replicate research findings.
- **Excludes:** lab 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 lab specimens. See NOT-OD-21-013.

When do we need a DMS Plan?

Applies to research that generates scientific data:

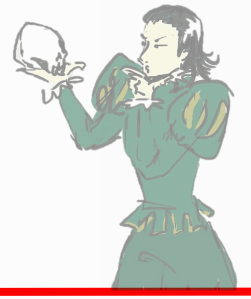
- Research Projects
- Some Career Development Awards (Ks)
- Small Business SBIR/STTR
- Research Centers

- Complete list of activity codes

Does not apply to activities that do not generate scientific data:

- Training (T)
- Fellowships (Fs)
- Construction (C06)
- Conference Grants (R13)
- Resource (Gs)
- Research-Related Infrastructure Programs (e.g., S06)

To include, or not to include…



Do you need a DMS Plan for training/fellowship (T/F) grants?

a. Always
b. No way
c. Maybe
d. This is confusing

Do you need a DMS Plan for early career (K) awards?

a. Yes
b. Definitely not
c. It depends
d. Please, stop asking

Requesting DMS Costs

- Investigators may request funds toward data management and sharing budget justification.

- **To request funds:**
  - Itemize the DMS costs in the budget justification under each category
  - Provide totals per category

- REMINDER: **Costs must be labeled Data Management and Sharing Plan costs**.

If your DMS Costs = $0?

- **If no funds are requested,** provide a statement in the justification AND don't forget the budget entry.
  - *R&R Budget Form*: enter Data Management and Sharing Plan costs $0 under "Section F8-17, Other Direct Costs."
  - *PHS 398 Modular Budget Form:* Use the Additional Narrative Justification attachment.
    - Same guidance as the R&R request for funds, but requires more information covered on the Justifying DMS Costs slide.

Budget & Justification Example

- ~~DMSP~~ Costs: **Data Management and Sharing Plan Costs:** ✓
  - Imaging data will be aggregated and stored in the Wisconsin ADRC database hosted on a backed-up system with RAID redundant storage. Current rates are $1.13/GB stored. For the retrospective image reconstruction and derived images storage, 12 GB ($13.56) per 4D-Flow scan is requested for a total cost of ~4265 * $13.56 = $57,833.40 ($11,567/year in years 1-5).

F. Other Direct Costs	Funds Requested ($)*
7. Alterations and Renovations	
8. Tuition Remission	12,000.00
9. Data Management and Sharing Plan Costs	11,567.00
Total Other Direct Costs	**27,587.00**

Allowable DMS Costs

- Curating data
- Developing supporting documentation
- De-identifying data
- Preparing metadata
- Local data management considerations
- Formatting data
- Data deposit/storage fees
- Costs associated with multiple repositories are allowable

Allowable DMS Costs Cont'd

- **Note:** Allowable costs *must be incurred during the performance period*, even for scientific data and metadata preserved and shared beyond the award period.
  - **Ex:** If proposing to preserve and share scientific data for 10 years, the cost for the entire 10-year period must be paid before the end of the period of performance (even if the award is 5 years).

Unallowable DMS Costs

- Infrastructure costs included in institutional overhead (for instance, Facilities and Administrative costs).
- Costs associated with the routine conduct of research, including costs associated with collecting or gaining access to research data.
- Costs that are double charged or inconsistently charged as both direct and indirect costs.

True or False?

You can pay for data storage fees after the end date of the project.

Justifying DMS Costs

- Include the following:
  - Brief justification of the proposed DMS activities that will incur costs.
  - Summary of type and amount of scientific data to be preserved and shared.
  - Name of the established repository(ies) to be used
  - General cost categories.

- NOTE: *DMS justification should be no more than half a page.*

Data Retention & Maintenance

- Grantee institutions are required to *keep the data for 3 years following closeout* of a grant or contract agreement per Section 8.4.2 of the NIH Grants Policy Statement.
- Grantee institutions may have additional policies and procedures regarding the custody, distribution, and required retention period for data produced under research awards.

NIH R01:
7/1/21 - 6/30/26

Earliest compliant data disposal date?

a. 10/30/29
b. 11/1/33
c. 6/30/29
d. 11/1/29

Human Subjects Data Sharing

INCLUSIONS

- NIH respects and recognizes Tribal sovereignty and American Indian and Alaska Native (AI/AN) communities' data sharing concerns.
- NIH has proposed additional considerations when working with Tribes and AI/AN communities.
- UW-Madison rests on ancestral land of the Ho-Chunk Nation, the People of Sacred Voice and the institution respects the inherent sovereignty and unique legal status, as affirmed and set forth in state and federal law, of the First Nations of Wisconsin. To learn more visit https://tribalrelations.wisc.edu/

EXCLUSIONS

- Examples of reasons that would generally not be justifiable factors limiting scientific data sharing include:
  - Data that are considered too small
  - Data that will not be widely used
  - Data are not thought to have a suitable repository

Human Genomic Data Sharing

- Investigators are expected to submit data to a repository acceptable under the Genomic Data Sharing Policy.
- **Data is to be shared** according to NIH's Data Submission and Release Expectations, but **no later than the end of the performance period,** ***whichever comes first***.
- Sample informed consent language and other resources can be found at Informed Consent for Secondary Research with Data and Biospecimens.
- NIH expects that informed consent for research use and data sharing be obtained per the Common Rule.

Non-Human Genomic Data Sharing

- Investigators may submit data to any repository.
- Data is expected to be shared as soon as possible, but no later than the time of publication, or end of the performance period, *whichever is first*.
- **Genomic Summary Results:**
  - Investigators conducting research subject to the GDS Policy should indicate in their DMS Plan if a study should be designated as "sensitive" for the purposes of access to Genomic Summary Results (GSR) as described in NOT-OD-19-023.

If you have a tiny data set, do you have to share your data?

Certifications & Limitations

- NIH expects researchers will attempt to maximize scientific data sharing, but may acknowledge that certain factors (i.e., ethical, legal, or technical) may necessitate limiting sharing to some extent.
- DMS Plans should address limitations on sharing by anticipating difficulties according to the criteria of the Institutional Certification (IC).
- If Institutional Certification criteria might not be met, investigators should reference the criteria and explain why in their DMS Plan.
  - Specify the element that cannot be met
  - Indicating what data can be shared
  - How to enable sharing to the maximal extent possible

Drafting a DMS Plan - Format

- Length – 2 pages or less unless using an NIH template.
- *Should be updated during the course of the award/support period* to reflect any changes in the management and sharing of scientific data.
- Do not include hypertext (e.g., hyperlinks and URLs) in the DMS Plan.
- Samples that align with the elements of a DMS Plan.
- Official UW-Madison DMP Tool & usage instructions.

Drafting a DMS - Data Specifics

- Data types
- Amount/size of data expected to be collected and used
- Indicate data modality (e.g., imaging, genomic, mobile, survey)
- Level of aggregation (e.g., individual, aggregated, summarized)
- Degree of data processing (i.e., how raw or processed)
- Which data from the project will be preserved and shared
- Listing of the metadata, other relevant data, or associated documentation

Additional details can be found in NOT-OD0-21-014

Tools, Software & Standards

- Are specialized tools or software needed to access or manipulate shared scientific data? ***Name them!***
- Specify how these tools can be accessed, and whether such tools are likely to remain available for as long as the scientific data remain available.
- What standards will be applied to the scientific data and associated metadata?
  - Your field has no common data standards? Indicate that no consensus data standards exist for the scientific data and metadata.

What is the deadline for data sharing?

a. ~~Whenever the PI wants~~. *Hilarious, but no!*

b. When an associated article is published. ← **Yes!**

c. At the end of an award. ← **Also, yes!**

d. Whatever comes first. ← **Yes, to infinity!**

Preservation, Access & Timeline

- Include name of the repository(ies).
- How the scientific data will be findable and identifiable.
- When the scientific data will be made available to other users and for how long.
- Make scientific data available for as long as it might be useful for the larger research community, institutions, and/or the broader public.
- Identify any differences in timelines for different subsets of scientific data to be shared.

DMS Distribution & Oversight

- Describe factors affecting subsequent access, **distribution**, or reuse of scientific data related to:
  - Informed consent
  - Privacy and confidentiality protections
  - If access to scientific data derived from humans will be controlled
  - Any restrictions imposed by federal, Tribal, or state laws, regulations, or policies, existing/anticipated agreements or any additional considerations that may limit the extent of data sharing.
- **Oversight:** Indicate how compliance with the Plan will be monitored and managed, frequency of oversight, and by whom.

True or False?

The DMS Plan is a
set it and forget it document.

Proposal Stage DMS Plans

- FOAs or ICs may have specific expectations e.g. scientific data to share, relevant standards, repository selection. View a list of NIH Institute or Center data sharing policies.
- The DMS Plan attachment is maintained as a separate document in the grant folder viewable via the Status Information screen in eRA Commons.
  - This document is viewable by authorized users and is not part of the assembled e-Application.
  - Peer reviewers will only use information found in the budget justification to determine whether the requested DMS costs are reasonable and will not be provided with the separate DMS Plan attachment (see NOT-OD-22-189).

DMS Plan Assessment

- Program staff at the proposed NIH Institute or Center (IC) will assess DMS Plans.
- Applications selected for funding will only be funded if the DMS Plan is complete and acceptable.
- Peer reviewers will not be asked to comment on the DMS Plan nor factor it into the Overall Impact score (unless its integral to project design/specified in the FOA).
  - If integral, program staff will assess the DMS Plan adequacy, but peer reviewers will be able to view it and may factor the information into scores per the evaluation criteria.

Pre-award DMS Plan Revisions

- Applicants will be expected to communicate with their Program Officer and/or Grants Management Specialist to resolve any issues that prevent the funding IC from approving the DMS Plan.
- Before an award is made, applicants must use the "Data Management and Sharing Plan (DMSP) Revision" section of the Just in Time (JIT) Screen in eRA Commons, to submit a revised DMS Plan.
  - **Note:** SOs must no longer use the 'Other File' section in Just-in-Time to submit the revised DMS plan.
- If needed, applicants should submit a revised DMS Plan. Refer to NIH Grants Policy Statement Section 2.5.1 Just-in-Time Procedures for additional guidance.

Post-award DMS Plan Revisions

- Plans may require revision over the course of a project for a variety of reasons.
  - New scientific direction
  - Different data repository
  - Changes to how data is managed or shared
  - Timeline revision
- All requests for NIH awarding ICO prior approval must be submitted by the Authorized Organization Representative (Signing Official (SO) role in eRA Commons) at least 30 days in advance of the requested change, and the currently approved DMS Plan remains in effect for the award until the request is approved by the funding NIH ICO.

DMS Plans & RPPRs

RPPRs due on or after October 1, 2024, recipients must address the DMS Policy.

- For awards for which the NIH DMS Policy applies, recipients will be asked:
  - Whether data has been generated to date and what type of data it is;
  - Whether data has been shared for use by others;
  - If data has been shared, in what repository and under what unique digital identifiers;
  - If data has NOT been shared, what is the status of data sharing (e.g., being prepared for submission, submitted to repository, not yet expected to be shared); and
  - If data has not been generated and/or shared as outlined in an approved DMS Plan, what corrective actions have or will be taken to comply with the approved Plan.
- The updated NIH RPPR Instruction Guide is posted to the Research Performance Progress Report (RPPR) page.

Courtesy of Adobe Stock photos.

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