# The New NIH Data Management & Sharing Policy

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# New NIH Data Management & Sharing Policy

- Goals:
  - Advance rigorous and reproducible research
  - Promote public trust in research
  - Promote data stewardship
- Developed with public input, released in 2020.
- Takes effect January 25, 2023.

NIH Data Sharing Policy

# New NIH Data Management & Sharing Policy

- All NIH-supported research generating scientific data is required to have a **Data Management and Sharing Plan**.
- Plans are submitted with **application**.
- Researchers should **maximize** appropriate data sharing.
- **Compliance** is expected and is **monitored** at regular reporting intervals.
- Encourages the use of **established data repositories**.
- Data shared no later than the **time of an associated publication** or the end of the performance period.

NIH Data Sharing Policy

# Make a Plan.

# Follow the Plan.

# Applies **only** to NIH-funded research that will produce scientific data

"The DMS Policy does not apply to research and other activities that do not generate scientific data, including training, infrastructure development, and non-research activities."

Research Covered Under the Data Management & Sharing Policy

*Note: ICs may have additional data sharing requirements*

# Elements of a DMS Plan

- Data Type
- Related Tools, Software and/or Code
- Standards
- Data Preservation, Access, and Associated Timelines
- Access, Distribution, or Reuse Considerations
- Oversight of Data Management and Sharing

**Recommended to be 2 pages or less**

*NOT-OD-21-014: Supplemental Information to the NIH Policy for Data Management and Sharing*
*Writing a Data Management & Sharing Plan*

# What's different?

- Applies to ALL projects that will produce scientific data, not just those research proposals seeking $500,000 or more in direct costs.
- Provides more guidance regarding the contents of the plan.
- Recommends depositing the data into an established repository if choosing to share the data.
- Explicitly states that there are allowable costs which should be written into the budget.
- Compliance will likely be more rigorously monitored.

**Data = valuable research product**

# What does this mean for researchers?

- Plan for sharing data **before** starting project
  - Informed consent
  - Study design
  - Connect with repository
  - Ensure plan is able to be implemented.
- Add data management and sharing costs to budget
  - Supplemental Information: Allowable Costs
- Thoroughly document research
  - Share data = also share context
  - Accurate and detailed descriptions

# Looking at the Format Page

OMB No. 0925-0001 and 0925-0002, DMS Plan Format Page

OMB No. 0925-0001 and 0925-0002 *(Rev. 07/2022 Approved Through TBD)*

**PREVIEW – DRAFT**

## 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.

**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.*

DRAFT

**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 the research proposed in this project. If applicable, indicate that no consensus standards exist.*

DRAFT

**Element 4: Data Preservation, Access, and Associated Timelines**

A. **Repository where scientific data and metadata will be archived:**
*Provide the name of the repository(ies) where scientific data and metadata arising from the project will be archived; see Selecting a Data Repository).*

B. **How scientific data will be findable and identifiable:**
*Describe how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools.*

C. **When and how long the scientific data will be made available:**
*Describe when the scientific data will be made available to other users (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) and for how long data will be available.*

**Element 5: Access, Distribution, or Reuse Considerations**

**A. Factors affecting subsequent access, distribution, or reuse of scientific data:**

*NIH expects that in drafting Plans, researchers maximize the appropriate sharing of scientific data. Describe and justify any applicable factors or data use limitations affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, and any other considerations that may limit the extent of data sharing. See Frequently Asked Questions for examples of justifiable reasons for limiting sharing of data.*

**B. Whether access to scientific data will be controlled:**

*State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval).*

**C. Protections for privacy, rights, and confidentiality of human research participants:**

*If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures).*

**Element 6: Oversight of Data Management and Sharing:**

*Describe how compliance with this Plan will be monitored and managed, frequency of oversight, and by whom at your institution (e.g., titles, roles).*

# Exploring an Example Plan

Converting a resource sharing plan into a DMS Plan: https://osf.io/euaty

# Frequently Asked Questions (FAQs)

Frequently Asked Questions (FAQs) - 2023 Data Management & Sharing Policy

# Am I expected to share all data generated during my research?

No.

Researchers are expected to **maximize the appropriate sharing** of **scientific data**.

Not all data generated during NIH-supported research will constitute scientific data under the DMS Policy.

Importantly, not all scientific data may be appropriate to share.

# What are justifiable reasons for limiting sharing of data?

NIH expects that researchers will take steps to maximize scientific data sharing, but may acknowledge in Plans that **certain factors (i.e., ethical, legal, or technical) may necessitate limiting sharing** to some extent.

Reasons that are NOT justifiable include:

- data are considered to be too small
- data that researchers anticipate will not be widely used
- data are not thought to have a suitable repository

# When should scientific data be shared?

Scientific data should be made accessible **as soon as possible**, and **no later than the time of an associated publication or the end of the performance period** of the extramural award that generated the data.

Associated publication: peer-reviewed journal articles; no later than the date on which the article is first made available in print or electronic format.

# Who will review DMS Plans?

**Program officers** will evaluate the completeness (all elements of a plan are addressed) and reasonableness of DMS Plans.

Each plan will be assessed within the context of the proposed project.

**Peer reviewers will not look at DMS Plans**, but will see data management related items within the budget.

# How will compliance be monitored?

**RPPR will be updated** to include questions about compliance with DMS Plan.

Researchers are expected to **communicate with their Program Officers** to reconcile any issues and get back into compliance, if needed.

NIH is still coming up with additional compliance monitoring processes.

# What should the budget look like?

Uncertainty right now around specific amounts. All allowable costs submitted in budget requests **must be incurred during the performance period**.

Consider costs for:

- Setup: preparing to collect data during the project
- Management: caring for and storing data during the project
- Clean up: assemble data to be shared
- Deposit: putting data into a repository

# What are allowable costs?

Reasonable, allowable costs may be included in NIH budget requests for:

- Curating data
- Developing supporting documentation
- Formatting data
- De-identifying data
- Preparing metadata
- Local data management considerations, such as unique and specialized information infrastructure
- Preserving and sharing data through established repositories

Budgeting for Data Management & Sharing

# What if the researcher is collecting sensitive information or is nervous about sharing?

Emphasis is on **prospectively planning** for data.

Research using sensitive data or working with populations that are small or vulnerable **may be justifiable reasons to not share**. [Some uncertainty here]

Consider a repository that can provide appropriate security measures.

NIH is recommending that researchers “do what they need to do” with data before the end of award period. **No cost extensions could accommodate some concerns**.

# Will researchers be able to share their data on Deep Blue?

It depends. **The best place to share is an appropriate disciplinary repository, if it exists.**

Deep Blue Data meets the NIH's list of desired characteristics of a data repository.

But **researchers will need to ensure the data are able to be freely shared with the public**. (Consider informed consent, PHI, etc.)

From NIH: Repositories for Sharing Scientific Data

# Is there a connection to the recent OSTP memo?

- The Nelson memo, released on Aug 25, 2022 requires all federal agencies to develop a plan for making all federally-funded research manuscripts and data openly available, with plans to be implemented by Dec 2025.
- NIH already has a Public Access Policy for manuscripts.
- NIH anticipates that there will be no changes to the new data management and sharing policy.
- NIH will be working to address the requirements of the memo.

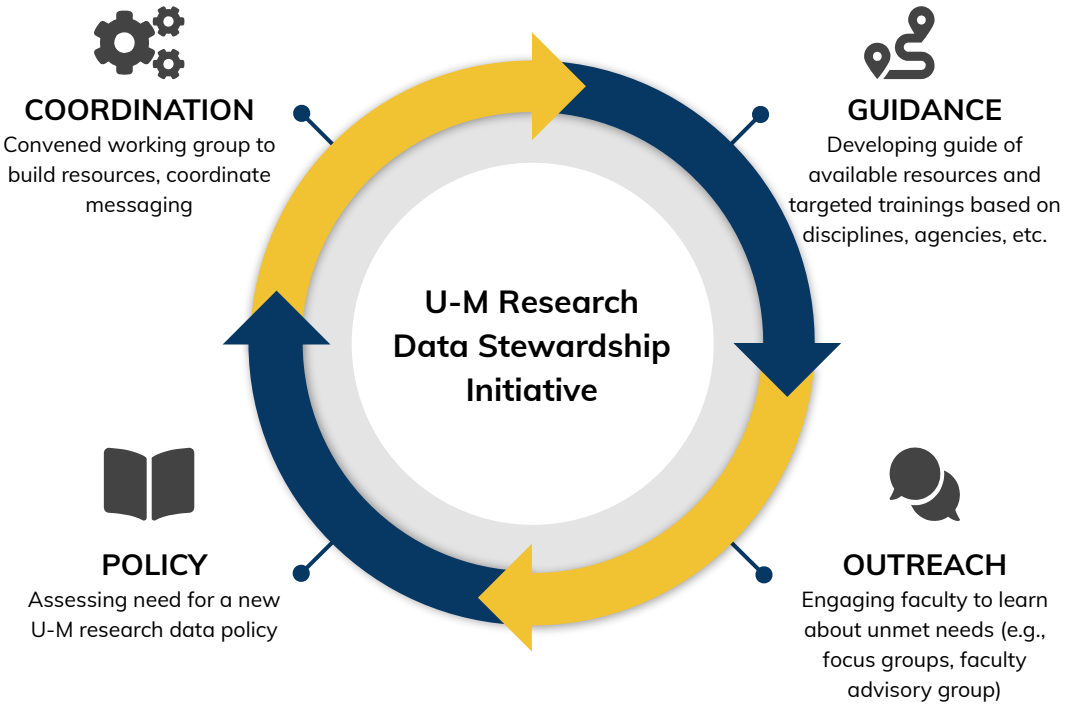
# How can I advise researchers on their DMS Plans?

1. Recommend that they review the resources provided directly from NIH on Writing a Data Management & Sharing Plan
2. Point them toward the NIH DMSP page on the Research Data Management guide from the library
3. Encourage them to:
    a. Start early! Don't wait until the last minute to start writing their DMS Plan
    b. Connect with the repository they want to use for sharing their data
    c. Reach out for a consultation to THLResearchDataCore@umich.edu or researchdataservices@umich.edu

# Data management and sharing is hard

# ...and so is writing a plan

# Research Data Stewardship Initiative (RDSI)




https://research.umich.edu/research-data-stewardship/

# Resources

- Resources from NIH
  - Overview of the policy
  - FAQ page
  - Preview/Draft of DMS Plan format page (PDF)
- Resources from U-M
  - RDSI Website
  - U-M Library expertise
    - Data Services
    - Research Data Management (Health Sciences) Guide
  - Electronic Research Notebook

# Thanks!
# Questions?

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