Preparing for the New NIH Data Management & Sharing Plan Requirements: Part 1

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Session Outcomes

- Overview of the new NIH DMSP
- Identify the elements of the plan
- Recognize allowable costs
- Review of the DMPTool as a resource
- Other useful resources

Overview

- New policy is effective for applications due on or after January 25, 2023 (Replaces the 2003 Data Sharing Policy)

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

- Note that funding opportunities or Centers may have specific expectations (for example: scientific data to share, relevant standards, repository selection). View a list of NIH Institute or Center data sharing policies. Investigators are encouraged to reach out to program officers with questions about specific requirements

- **Does not** create a uniform requirement to **share** all scientific data, but does convey "an expectation that researchers will maximize appropriate data sharing when developing plans"

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Planning & Budgeting for Data Management & Sharing

Prospectively planning for how scientific data will be managed and ultimately shared is a crucial first step in optimizing the reach of data generated from NIH-funded research. Investigators and institutions are encouraged to consider these crucial elements early in research planning.

ⓘ Tip: Consider consulting institutional resources such as librarians and data managers to help plan effectively!

❓ Determine if your proposed research is subject to the DMS policy.

🔍 Identify appropriate methods/approaches and repositories for managing and sharing scientific data.

📄 Develop a Plan for managing and sharing scientific data and submit this Plan within the funding application or proposal.
Note that applications subject to both the DMS Policy and the GDS Policy will submit a single Plan.

💲 Estimate and request funds for data management and sharing activities if not already covered by institution or other sources.

NIH Data Management & Sharing Policy Overview

Overview (continued)

- Plan = two pages or less, long narratives not required

- DMS Plans must be submitted **at submission - <u>NOT</u> Just-in-Time**

- NIH Program Staff assesses merit of plan; Applications selected for funding will only be funded if the DMS Plan is complete and acceptable

- Peer reviewers may comment on the proposed budget for data management and sharing, although these comments will not impact the overall score (will not be provided with the separate DMS Plan attachment)

Scope of DMSP

https://neuroscienceit.medium.com/how-to-determine-if-a-research-lab-is-right-for-you-2d18ccbed44a

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

- **Scientific Data** is defined as data commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications

- **Does not apply to funding that does not generate data**

Scientific data does not include

- Data **not** necessary for or of sufficient quality to validate and replicate research findings,
- Laboratory notebooks
- Preliminary analyses
- Completed case report forms
- Drafts of scientific papers
- Plans for future research
- Peer reviews
- Communications with colleagues
- Physical objects (e.g., laboratory specimens)

Plan elements

Plan Elements		
	Data Type	Identify data and metadata to be preserved and shared
	Tools, Software, Code	Tools and software needed to access and manipulate data
	Standards	Standards to be applied to scientific data and metadata
	Data Preservation, Sharing, Timelines	Repository to be used, persistent unique identifier, and when/how long data will be available
	Access, Distribution, Reuse	Description of factors for data access, distribution, or reuse
	Oversight	Plan compliance will be monitored/managed and by whom

Element 1: Data Type

- General summary/description of data
  - Type
  - Amount/size
  - Modality (survey, wearable devices, etc..)
  - Level of aggregation (summarized, individual, aggregated)
  - Degree of data processing (how raw or processed)

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Data Type (cont'd)

- Description of which data will be preserved & shared
    - Not all; base on ethical, legal, technical factors
    - Provide rationale

- What else might be included to facilitate data interpretations and/or use
    - Metadata
    - Other relevant data
    - Associated documentation (protocols and instruments)

Element 2:
Related Tools, Software, and/or Code

- Names of any specialized tools needed to access or manipulate shared data to support replication or reuse

- How to access these tools:
  - Open source and freely available?
  - Generally available for a fee?
  - Available only from the research team?

- Are the tools likely to remain available as long as your data is available?

Element 3:
Standards

- What standards will be applied to the data and metadata to enable interoperability of datasets and resources?

  - Formats
  - Data dictionaries/ontologies
  - Definitions (NIH Common Data Elements (CDE) Repository)
  - Schemas

- If no common data standard in your field, indicate no consensus data standards exist

Element 4:
Data Preservation, Access, and Timelines

- Where and when the scientific data associated with your research will be made available

    - Name of repository(ies) where data will be archived

    - How data will be findable and identifiable (persistent unique identifier or other standard indexing tool)

    - When data made available to use & for how long

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Timing

- 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

- NIH encourages researchers to make scientific data available for as long as they anticipate it being useful

- Could be different timelines for different subsets of data to be shared

- If a no cost extension is granted for an extramural award, scientific data should be made accessible no later than the time of an associated publication, or the end of the no cost extension, whichever comes first

Data Sharing Limitations: Examples

- Existing consent (for previously collected data) prohibits sharing or limits the scope or extent of sharing and future research use

- Privacy or safety of research participants would be compromised or place them at greater risk of re-identification or suffering harm, and protective measures such as de-identification and Certificates of Confidentiality would be insufficient

- Explicit federal, state, local, or Tribal law, regulation, or policy prohibits disclosure

- Datasets cannot practically be digitized with reasonable efforts

Element 5:
Access, Distribution or Reuse Considerations

- Describe any applicable factors affecting subsequent access, distribution, or reuse

- Verbiage for human data but could relate to animal or other

- State if the access to scientific data will be controlled (through Data Use Agreement (DUA) for example vs repository)

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Element 6:
Oversight of Data Management and Sharing

- Plan Compliance: monitoring & management
  - How?
  - Frequency?
  - Who? (list titles/roles)

Submission Details

- Various submission details based on type (extramural grants vs contracts for example)

- Optional DMS Plan format (fillable format version in Word available)

- Implementation Details for the NIH Data Management and Sharing Policy (NOT-OD-22-189)

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.

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

Data Management and Sharing Plan Format Page

DMP Tool

https://dmptool.org/

Budgeting for Data Management and Sharing

- NIH recognizes that making data accessible and reusable for other researchers may incur costs

- Funds toward data management and sharing allowable in the budget and budget justification sections of applications

- To request funds toward DMS costs:

  – A line item in the budget form

  – A brief summary of the DMS Plan and a description of the requested DMS costs in the budget justification

Allowable Costs

- Curating data & developing supporting documentation
- De-identifying data
- Local data management considerations
- Preserving & sharing data through established repositories

  – fees for long-term data preservation and sharing are allowable, but funds for these activities must be spent during the performance period, even for scientific data and metadata preserved and shared beyond the award period

Allowable Costs (continued)

- Personnel costs required to perform any of the data management and sharing tasks are allowable

- Budget requests must **not include infrastructure costs that are included in institutional overhead** (e.g., facilities and administrative costs) or costs associated with the routine conduct of research (data collection or access fees fall into this)

Updating a Plan after Funding

- Although the plans are submitted before research begins, if any changes occur during the award or support period that affects how data is managed or shared, investigators should update the plan to reflect the changes

- It may be helpful to discuss potential changes with the Program Officer

- The funding institute or center will need to approve the updated plan

DMSP Subject Guide

Managing Research Data from Start to Finish: Home

This subject guide provides information on how to manage research data.

| Home | Data Management Plans | DMPTool | Data Repositories | Budgeting | Human Data | Data Capture with REDCap |
| Training Videos for the USA Community | Contact Information |

Overview

This subject guide highlights information and resources to help you use best practice in managing your research data throughout it's life cycle, including developing data management and sharing plans, file naming and cataloging conventions, metadata standards, proper storage and security, and determining where to archive your data in order to comply with accessibility mandates.

These topics are increasingly important, as NIH's new **Data Management and Sharing Policy** (DMSP) goes into effect on January 25, 2023, with the expectation that investigators and institutions with research funded or conducted in whole or in part by NIH that results in the generation of scientific data will:

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

https://libguides.southalabama.edu/research_data_mgt

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Resources

- [Final Data Management & Sharing (DMS) Policy](#)
- [Scientific Data Sharing website](#) with [FAQs](#)
- [Elements of an NIH Data Management and Sharing Plan](#)
- [Selecting a Repository for Data Resulting from NIH-Supported Research](#)
- [Allowable Costs for Data Management and Sharing](#)
- [Managing Research Data from Start to Finish](#)

Data Management Plans:
Tools and Resources

NIH > National Institutes of Health
Office of Extramural Research

NIH > National Library of Medicine
Network of the National Library of Medicine

COGR
Council On Governmental Relations
An Association of Research Universities and Affiliated Medical Centers and Independent Research Institutes

DMPTool

LIBGUIDES AT USA
Managing Research Data from Start to Finish:

Why are Data Management and Sharing Important?

- Reproducibility

- Facilitates data reuse

- Helps make Data FAIR

FAIR Principles

Findable
- Descriptive keywords
- Persistent Identifier (DOI)

Accessible
- Easy to retrieve by machines and humans
- Data in a repository

Interoperable
- Open formats
- Consistent vocabulary

Re-Usable
- Clear reuse licenses
- Good documentation

DMPTool

Free, online application managed by the [California Digital
Library](#) that helps researchers create data management
plans specific to their funder's requirements.

Provides a click-through wizard for creating a DMP that
complies with funder requirements.

Used by many institutions around the world (83,000+users).

The DMPTool has funder-specific templates for both private
and public funders; current community focus is on the new
NIH DMSP Policy

Why Use the DMPTool

- Guidance: Quick links to relevant resources, both from funder and from the institution
- Receive Feedback: from collaborators or your institution's DMPTool administrator
- View Example Public Plans: List of plans that creators chose to make public, including featured plans
- Machine actionable DMP – allows for automated exchange of information about your research. Also known as networked DMP
  - Connect to ORCHID ID – has the ability to automatically add your DMP to your profile

https://dmptool.org/

https://libguides.southalabama.edu/research_data_mgt

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- Comply with the approved DMSP

Other funding agencies, including the National Science Foundation, also have **policies** that impact the management and sharing of data and require DMPs be included with grant applications.

DMS Demonstration Pilot: Implementation
Source: NIH Policy for Extramural Research Administration

Phase 1: Test Standardized DMS Plan Templates and DMPTool: 12/22-12/23
 • Pilot participants will test the effectiveness of new web-based (DMPTool) templates to support the generation of a DMS Plan that is compliant with the new NIH policy and meets the varying needs of ICs.

Phase 2: Cost Policies: 1/23-12/23
• Establish common cost principles.
• Identify types of costs required.
• Determining how to identify additional/unforeseen costs that may be required to meet the spirit of the data sharing policy.

Timeline for Implementation (tentative):
• Initial Planning: September 1, 2022 - November 30, 2022
• December 1, 2022 – January 25, 2023: sharing templates, evaluation criteria, pilot guidelines with relevant participants
• **January 26, 2023 – December 31, 2023: data collection** – feedback to NIH and community
    - FDP collaborate with NIH to plan a pilot of DMSP templates. Phase 1 test the effectiveness/usability of two DMSP templates.
    - Researchers and NIH program

DMS Training Series

Session 2: Where to Share Data
January 18th 2:00 pm

Session 3: Metadata and the "How" of Data Sharing
January 25th, 2:00 pm

Jana Hermann, Institutional Repository Coordinator
University Libraries