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NIH Updated Guidelines - Data Management and Sharing (DMS) Policy

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NIH Updated Guidelines - Data Management and Sharing (DMS) Policy

Michele Gibney, University Libraries
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Introductions

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And you?

Department

How long at Pacific

Experience with applying for external funding

Data Management and Sharing Policy website

https://sharing.nih.gov/data-management-and-sharing-policy

New Data Management & Sharing Policy Effective January 25, 2023!

The DMS Policy applies to all NIH funding mechanisms

Extramural	<u>Competing</u> applications submitted for Jan 25, 2023, and subsequent receipt dates - Non-competing awards will not immediately become subject to Policy
Contracts	Proposals submitted on or after Jan 25, 2023
Intramural	Projects conducted on or after Jan 25, 2023
Other funding agreements (e.g., Other Transactions)	Executed on or after Jan 25, 2023, unless otherwise stipulated by NIH

Culture Shift

Making the practice of data management and responsible data sharing the norm

Maximizing the availability of scientific data can...

TEST VALIDITY OF RESEARCH FINDINGS

STRENGTHEN ANALYSIS THROUGH COMBINED DATA SETS

ALLOW FOR REUSE OF HARD TO GENERATE DATA

OPEN NEW FRONTIERS OF DISCOVERY

FOSTER TRUST IN PUBLICLY FUNDED RESEARCH

NIH

Policy Requirements

1. **Submission** of Data Management & Sharing Plan with all applications for funding beginning January 25, 2023

2. **Compliance** with the Data Management and Sharing Plan approved by the funding NIH Institute, Center, or Office

DMS Policy: Scope

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

"Scientific data" is defined as:

"the recorded factual material 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."

Potential Examples of Scientific Data

Scientific data will vary depending on the project and the context.

Scientific data might include:

Single-cell RNA sequencing (scRNA-seq) of T lymphocytes or other immune cells in a study of HIV/AIDS	
Electrophysiological recordings and fMRI images in a study of a rodent model of PTSD	
Step activity from a wearable device in a study of cardiovascular health	

Exclusions from the DMS Policy

Scientific data do <u>not</u> 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, or
- Physical objects, (e.g., laboratory specimens)

Activities Subject to the DMS Policy

APPLIES TO...

All research generating scientific data, including but not limited to:

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

DOES NOT APPLY TO...

research projects <u>not generating</u> scientific data or non-research projects, including but not limited to:

- Training (Ts)
- Fellowships (Fs)
- Certain non-research Career Awards (e.g., KM1)
- Construction (C06)
- Conference Grants (R13)
- Resources (Gs)
- Research-Related Infrastructure Programs (e.g., S06)

Limitations on Sharing

DMS Plans should maximize appropriate sharing

Justifiable ethical, legal, and technical factors for limiting sharing include:

- Informed consent will not permit or limits scope of sharing or use

- Privacy or safety of research participants would be compromised and available protections insufficient

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

- Restrictions imposed by existing or anticipated agreements with other parties

Limitations on Sharing: Other Considerations

Reasons NOT generally justifiable to limit sharing:

- Data are considered too small

- Researchers anticipate data will not be widely used

- Data are not thought to have a suitable repository

Recent Resources

NEW

- Supplemental Information: Protecting Privacy When Sharing Human Research Participant Data (NOT-OD-22-213)

- Supplemental Information: Responsible Management and Sharing of American Indian/ Alaska Native Participant Data (NOT-OD-22-214)

- Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023 (NOT-OD-22-198)

See **Statements & Notices**

Elements of a DMS Plan
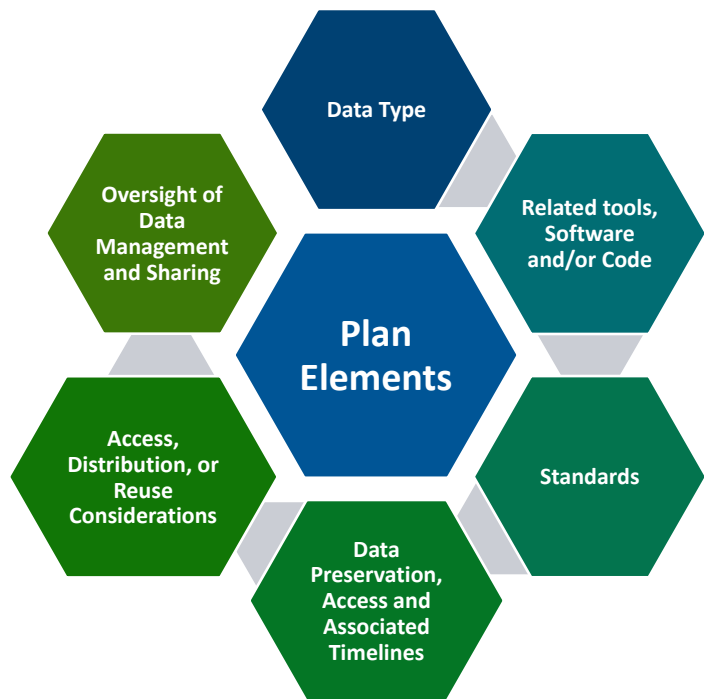
- **Data type**
  - Identifying data to be preserved and shared
- **Related tools, software, code**
  - Tools and software needed to access and manipulate data
- **Standards**
  - Standards to be applied to scientific data and metadata
- **Data preservation, access, timelines**
  - Repository to be used, persistent unique identifier, and when/ how long data will be available
- **Access, distribution, reuse considerations**
  - Description of factors for data access, distribution, or reuse
- **Oversight of data management and sharing**
  - Plan compliance will be monitored/ managed and by whom

See Writing a Data Management & Sharing Plan for details

Format of a DMS Plan

- Plans should be no more than 2 pages in length

- Optional format page will be available

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

DMS Plan format page will be added to list of Format Pages and incorporated into FORMS-H application instructions by Fall 2022

DMP Tool

https://dmptool.org/

DMP Tool

Create a new plan

Before you get started, we need some information about your research project to set you up with the best DMP template for your needs.

* What research project are you planning?

☐ mock project for testing, practice, or educational purposes

* Select the primary research organization

Research organization

University of the Pacific

- or - ☐ No research organization associated with this plan or my research organization is not listed

* Select the primary funding organization

Funder

National Institutes of Health (nih.gov)

- or - ☐ No funder associated with this plan or my funder is not listed

Which DMP template would you like to use?

NIH-GEN DMSP (Forthcoming 2023)   ⌄

We found multiple DMP templates corresponding to your funder.

Create plan   Cancel

DMS Plan Submission

- A new "**Other Plan(s)**" field will be added to the PHS 398 form to collect a single PDF attachment

National Institutes of Health

Sharing Data

Encourages use of established repositories

Depositing data in a quality repository generally improves the FAIRness of data – Findable, Accessible, Interoperable, Reusable

NIH ICs may designate specific data repository(ies)

See [Selecting a Data Repository](#) for details

Finding and Selecting a Repository:
Desirable Characteristics for All Data Repositories

✔ Unique Persistent Identifiers

✔ Long-Term Sustainability

✔ Metadata

✔ Curation and Quality Assurance

✔ Free and Easy Access

✔ Broad and Measured Reuse

✔ Clear Use Guidance

✔ Security and Integrity

✔ Confidentiality

✔ Common Format

✔ Provenance

✔ Retention Policy

Finding and Selecting a Repository:
NIH & Other Resources

NIH-Supported Repositories

- Filterable list of 70+ NIH Repositories

Other Repository Resources

- Generalist repositories

- Nature's Data Repository Guidance

- Registry of Research Data Repositories

See **Repositories for Sharing Scientific Data**

Data Repositories - Scholarly Commons

Pacific branded
Unlimited storage
Any file type
Excellent SEO
Customizable display & metadata
FAIR Principles

Data Repositories - External

Figshare: https://figshare.com/

OSF: https://osf.io/

Re3data: https://www.re3data.org/

Monitoring Compliance

POLICIES COMPLIANCE TRANSPARENCY RULES LAW REQUIREMENTS STANDARDS REGULATIONS
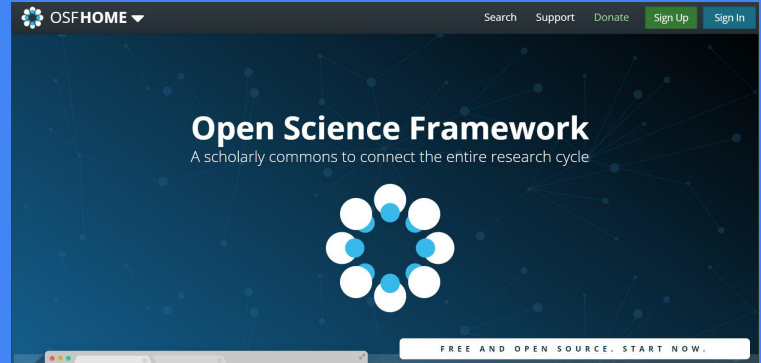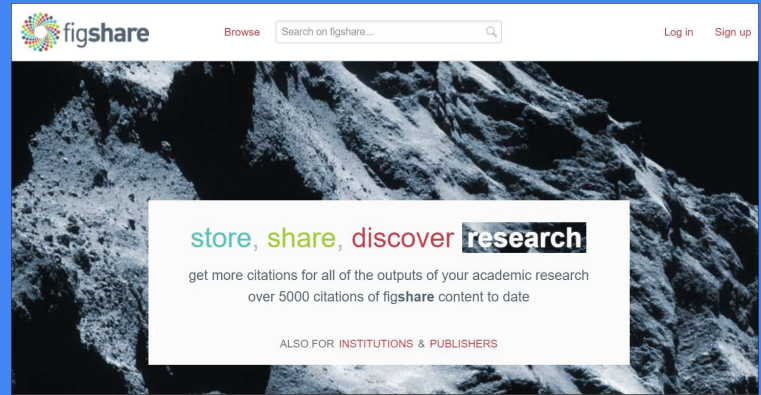
*RPPR: Research Performance Progress Report (RPPR) - Annual, Interim, and Final

Approved Plan becomes a Term and Condition of Award

Grantee reports progress of approved DMS Plan in RPPR*

NIH reviews compliance annually
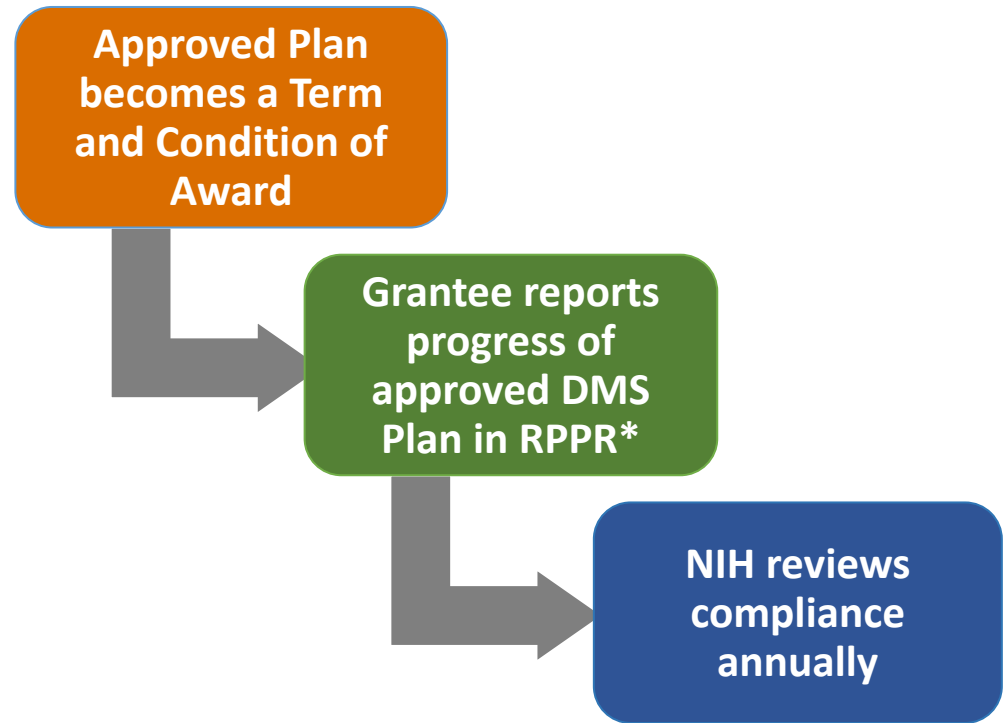
Failure to comply…. may result in an enforcement action, including additional special terms and conditions or termination of award, and may affect future funding decisions.

White House OSTP Memo

- Directs all Federal agencies to develop plans to ensure:
  - Publications resulting from federally funded research are made freely available and publicly accessible without embargo
  - Scientific data underlying publications should be made accessible at time of publication
  - Approaches for sharing scientific data not underlying publications

- Initial agency plans due February 2023

- No change anticipated for the NIH DMS Policy

White House Memo

Resources

NIH Data Management & Sharing Policy website:
https://sharing.nih.gov/data-management-and-sharing-policy

NIH Webinar Series: https://sharing.nih.gov/about/learning/DMS-Update

2023 DMS Frequently Asked Questions:
https://sharing.nih.gov/faqs#/data-management-and-sharing-policy.htm

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QUESTIONS?