



10-24-2022

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

Michele Gibney
University of the Pacific, mgibney@pacific.edu

Emily Novick
University of the Pacific, enovick@pacific.edu

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Recommended Citation

Gibney, M., & Novick, E. (2022). 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
Emily Novick, Office of Research and Sponsored Projects

Introductions

Michele Gibney, University Libraries, mgibney@pacific.edu

Emily Novick, Office of Research and Sponsored Programs, enovick@pacific.edu

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>

 An official website of the United States government [Here's how you know](#) ▼

[U.S. Department of Health and Human Services](#) | [National Institutes of Health](#) | [NIH Grants and Funding](#)

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DATA MANAGEMENT AND SHARING POLICY

GENOMIC DATA SHARING POLICY

OTHER SHARING POLICIES

ACCESSING DATA

ABOUT

Data Management and Sharing Policy

NIH has a longstanding commitment to making the results of NIH-funded research available. Responsible data management and sharing has many benefits, including accelerating the pace of biomedical research, enabling validation of research results, and providing accessibility to high-value datasets.

[About the Data Management and Sharing Policy](#) →



Planning and Budgeting for Data Management & Sharing

Find out what NIH expects in a Data Management & Sharing plan and what costs are allowed in a request.



Data Management

Proper data management is crucial for maintaining scientific rigor and research integrity. Learn about best practices for scientific data management.



Sharing Scientific Data

Under the NIH Data Management & Sharing Policy, investigators are empowered to choose the most appropriate methods for sharing scientific data. Learn more about methods for data sharing and selecting data repositories.

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

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

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 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, 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 not generating 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

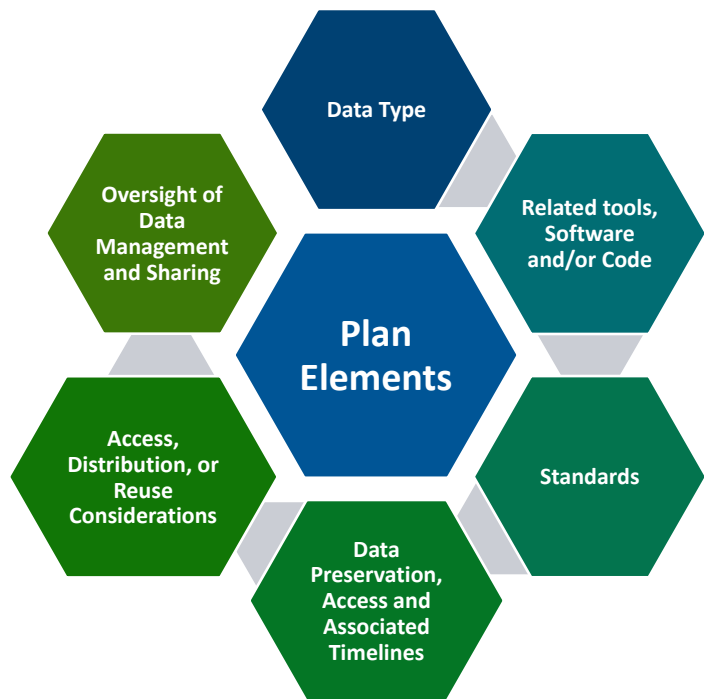


Recent Resources

- 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
<small>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.</small>
Element 1: Data Type
A. Types and amount of scientific data expected to be generated in the project: <i>Summarize the types and estimated amount of scientific data expected to be generated in the project,</i>
B. Scientific data that will be preserved and shared, and the rationale for doing so: <i>Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.</i>
C. Metadata, other relevant data, and associated documentation: <i>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.</i>
Element 2: Related Tools, Software and/or Code: <i>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</i>

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

- or -

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

* Select the primary funding organization

Funder

- or -

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

Which DMP template would you like to use?

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

Research Plan Section			
5. Vertebrate Animals	<input type="text"/>	<button>Add Attachment</button>	<button>Delete Attachment</button> <button>View Attachment</button>
6. Select Agent Research	<input type="text"/>	<button>Add Attachment</button>	<button>Delete Attachment</button> <button>View Attachment</button>
7. Multiple PD/PI Leadership Plan	<input type="text"/>	<button>Add Attachment</button>	<button>Delete Attachment</button> <button>View Attachment</button>
8. Consortium/Contractual Arrangements	<input type="text"/>	<button>Add Attachment</button>	<button>Delete Attachment</button> <button>View Attachment</button>
9. Letters of Support	<input type="text"/>	<button>Add Attachment</button>	<button>Delete Attachment</button> <button>View Attachment</button>
10. Resource Sharing Plan(s)	<input type="text"/>	<button>Add Attachment</button>	<button>Delete Attachment</button> <button>View Attachment</button>
11. Other Plan(s)	<input type="text"/>	<button>Add Attachment</button>	<button>Delete Attachment</button> <button>View Attachment</button>
12. Authentication of Key Biological and/or Chemical Resources	<input type="text"/>	<button>Add Attachment</button>	<button>Delete Attachment</button> <button>View Attachment</button>

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

Institute or Center	Repository Name	Repository Description
NCI		Keyword Filter
NCI	Cancer Nanotechnology Laboratory (caNanoLab)	caNanoLab is a data sharing portal designed to facilitate sharing in the biomedical nanotechnology research community. It expedite and validate the use of nanotechnology in the laboratory. caNanoLab provides support for the annotation of nanotechnology characterizations resulting from physico-chemical, in vitro assays and the sharing of these characterizations and associated data.

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

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PACIFICUniversity
Libraries

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SEARCH

Enter search terms:

in this repository ▾

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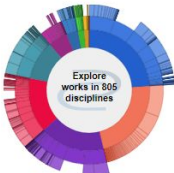
Submit Research

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At a Glance

Top 10 Downloads
All time

Recent Additions
20 most recent additions
Activity by year

Item of the Day

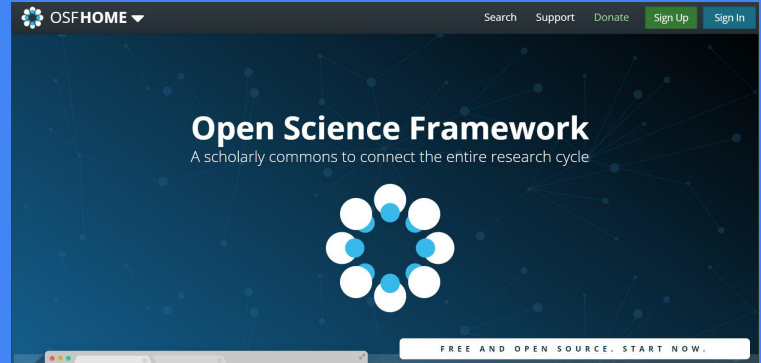
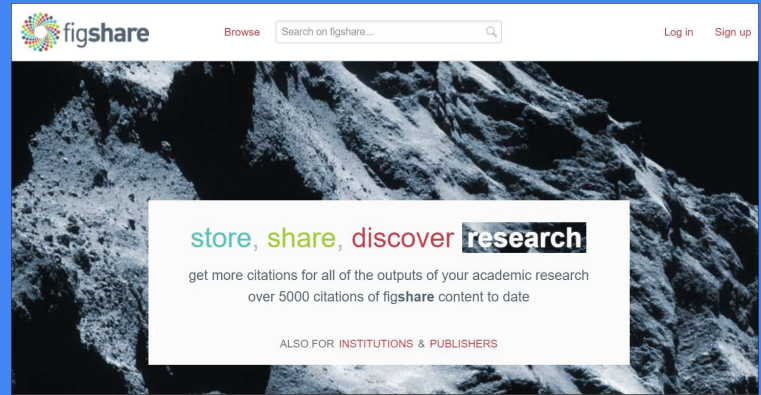


Data Repositories - External

Figshare: <https://figshare.com/>

OSF: <https://osf.io/>

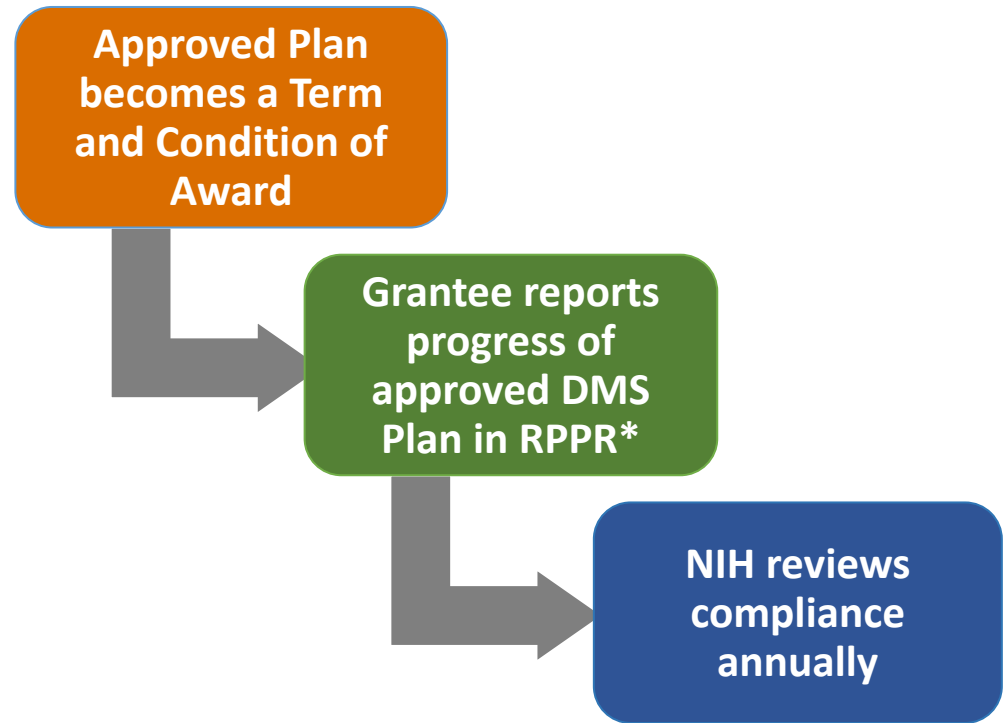
Re3data:
<https://www.re3data.org/>



Monitoring Compliance



***RPPR**: Research Performance Progress Report (RPPR) - Annual, Interim, and Final



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?