



FLORIDA STATE  
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# *NIH Data Management and Sharing (DMS) Policy: Overview*

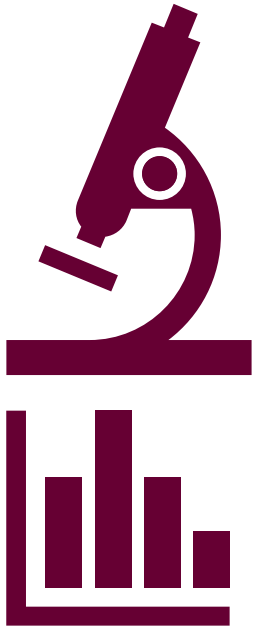
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FSU Office for Human Subjects Protection

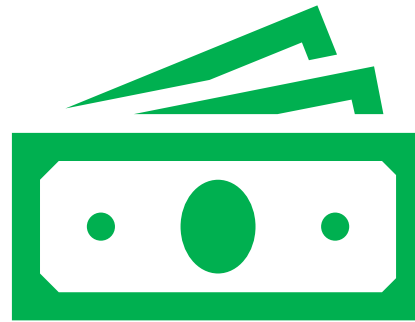
October 24, 2022

# NH

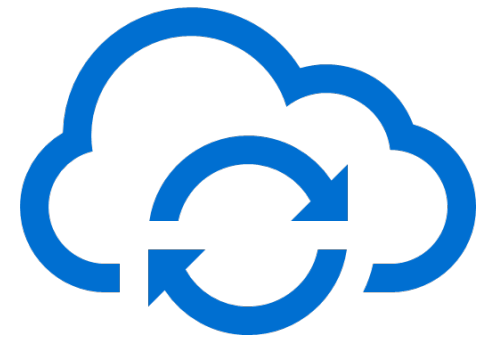
## **DATA MANAGEMENT AND SHARING POLICY**



Research  
generating  
scientific  
data



NIH  
application →



Data  
Management  
and Sharing  
(DMS) Plan



**1. Applies to NIH applications submitted on or after January 25, 2023 receipt dates**

**2. Requires submission of Data Management and Sharing (DMS) Plan with application**  
(Plan should outline how *scientific data* will be managed and shared)

**3. Policy includes compliance and enforcement of approved DMS Plans**



## 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*

## Examples—

...imaging data (MRI, CT);  
biological data (ECG, x-ray);  
phenotype (blood type,  
demographic, specimen  
information); genomic data;  
other (clinical trial results,  
questionnaires, epidemiology)

## Not included—

...laboratory 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 laboratory specimens



**Data sharing is NOT required . . . but submitting a plan IS!**

**Plans reviewed by ICO Staff\***

**Plan must protect subjects' confidentiality, rights, & privacy**

**PIs must explain legal, ethical and technical limits**

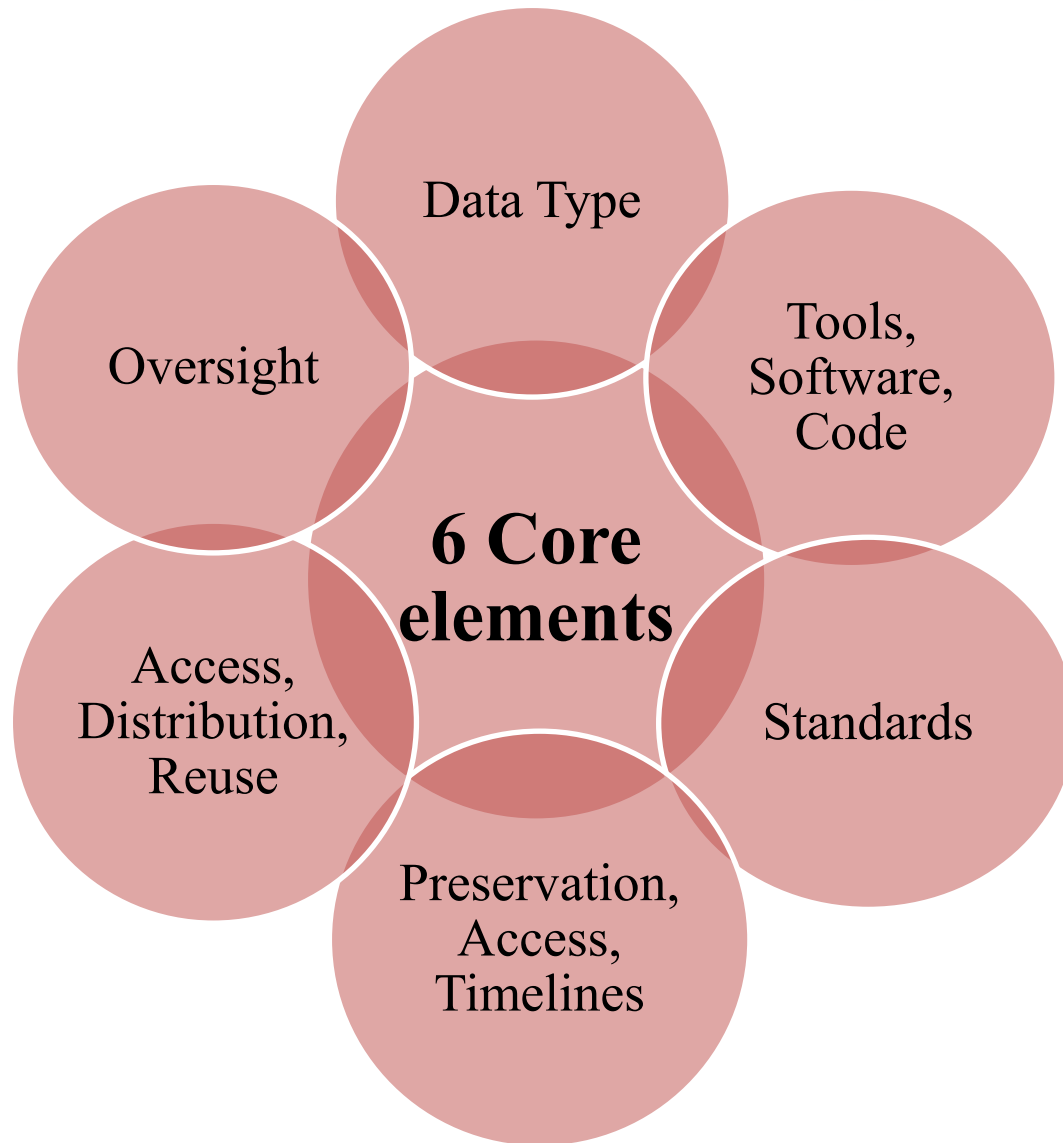
**ICO Staff determine if Plans are complete & acceptable\*\* (JIT)**

**Peer review of DMS Plan budget**



*\*IF a DMS plan is integral to FOA and scoreable, peer reviewers may score the DMS plan*

*\*\*NOT FUNDED if otherwise*



- Data type
  - e.g., types, amount, aggregation/individual, documentation available
- Tools, software, code
  - e.g., open source, freely available or fee, how tools may be accessed
- Standards
  - e.g., format, dictionaries, identifiers, vocabularies, whether common data standards apply
- Preservation, access, timelines
  - e.g., repository, persistent unique identifier to find data, when & for how long data are available
- Access, distribution, reuse
  - e.g., controls or restrictions due confidentiality protections, HIPAA, DUAs
- Oversight
  - e.g., how compliance will be monitored, managed and by whom



# NIH Scientific Data Sharing

<https://sharing.nih.gov/>

DATA MANAGEMENT AND SHARING POLICY tab

## NIH DMS Policy Webinar series

<https://sharing.nih.gov/about/learning>

## NOT-OD-22-189

DMS Policy Grant-related Implementation Details

[\[link\]](#)





- New Other Plan(s) field to be added to the PHS 398 form to attach DMS Plan as pdf attachment (see image)
- DMS and Genomic data sharing plans no longer submitted via Resource Sharing Plan(s) field

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



- Direct DMS-related costs allowed as “**Data Management and Sharing Costs**” [[link](#)]
  - **Research & Related Budget Form:** line item in section F (Other Direct Costs)

F. Other Direct Costs		Funds Requested (\$)
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. <b>Data Management and Sharing Costs</b>		
9.		
10.		

- **PHS 398 Modular Budget Form:** within Additional Narrative Justification

2. Budget Justifications			
Personnel Justification	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
Consortium Justification	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
<b>Additional Narrative Justification</b>	<input type="text"/>	Add Attachment	Delete Attachment View Attachment



1

- NIH webinars, policy, [sharing.nih.gov](http://sharing.nih.gov)

2

- Identify FSU resources, expertise

3

- Follow FOAs, PHS 398/other funding application requirements

4

- Practice drafting DMS Plans using templates

5

- Visit other web resources (DMPTool, FASEB DataWorks)



# NIH Data Management and Sharing (DMS)

The National Institutes of Health (NIH) has issued a new **NIH Data Management & Sharing Policy** which will go into effect for proposals for NIH funding that are submitted for due dates on or after January 25, 2023. The policy is intended to "promote the management and sharing of scientific data generated from NIH-funded or conducted research" in the interest in part of ensuring improved public access to publicly funded research and enabling data reuse for future studies.

*In brief and relevant to proposals involving human research, researchers must include a data management and sharing plan in their proposals, and the plan must describe how IRBs as well as human subjects (study participants) will be provided with information about how such data may be shared and protected.*



Click on one or more of the panels below to learn more and what to do if the NIH DMS Policy may apply to your human research!

▼ **How will the NIH DMS Policy Apply to FSU Research?**

▼ **Data Management & Sharing Plan Requirement**

▼ **How to Inform Human Subjects about Your Data Management & Sharing**

▼ **Resources**



▼ Resources

## Office for Human Subjects Protection Resources

Below are some templated language for use in preparing DMS Plan Element 5 (pertaining to Access, Distribution, or Reuse Considerations for human research informed consent, confidentiality and privacy); the templated language may also be used when preparing protocols submitted for IRB review. Additional resources, including template consent language regarding data management and sharing, are forthcoming.

- Human Research Protections-Related Template Language for DMS Plans (Element 5) [[link](#); opens a Word document for ease of use]

## Florida State University Libraries Resources

The FSU Libraries provide a wide range of Research Data Management guidance, including guidance for planning and creating data management plans as well as suggested best practices, list of data repositories, agencies/sponsors' data sharing requirements, and sample data management plans. Researchers planning NIH funding applications are strongly advised to access these resources and to contact the FSU Libraries Research Data Management Librarian for further information and additional resources or support:

- [FSU Libraries Research Data Management page](#)
- [FSU Libraries List of Data Repositories](#)



[OHSP NIH DMS link](#)



# Other Resources



## General DMS Policy-related Resources

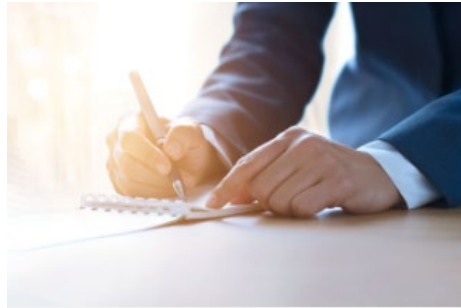
- **NIH Policy for Data Management and Sharing** (NOT-OD-21-013) (includes link to related announcements)
- NIH Office of Extramural Research and Office of Science Policy-hosted **webinars** for understanding the new NIH DMS policy
- **NIH Scientific Data FAQs**
- NIH links for **managing** and **sharing scientific data**
- DHHS Secretary's Advisory Committee on Human Research Protections, *Attachment A - NIH Data Sharing Policy Implications of the NIH Draft Policy for Data Management and Sharing on Data Derived from Human Participants* (identifying challenges and providing guidance to the research community) [\[link\]](#)

## Preparing a DMS Plan

- **Writing a Data Management & Sharing Plan** (find out what NIH expects should be addressed in Data Management & Sharing Plans)
- NIH Supplemental Information: **Elements of an NIH DMS Plan**
- **DMPTool** (University of California service for creating DMPs; easy sign up for accessing templates and tools)
- National Institute of Mental Health Data Sharing for Applicants and Awardees ([link](#); includes links to sample DMS plans)

## Data Sharing Repositories

- List of **NIH-supported Repositories**
- National Library of Medicine's **Open Domain-specific Repositories** (note that NIH encourages the use of domain-specific repositories where possible)



**SPONSORED RESEARCH ADMINISTRATION**



**RESEARCH COMPLIANCE**



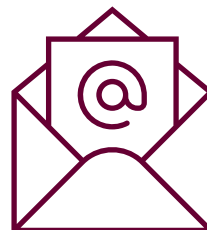
**HUMAN SUBJECTS / IRB**



**UNIVERSITY LIBRARIES**



# Contact us for IRB-related DMS issues



**Click an icon above to contact or find us**

**For questions about this slide deck:**

T. Howard Stone, Director

[thstone@fsu.edu](mailto:thstone@fsu.edu)

<https://ohsp.fsu.edu>