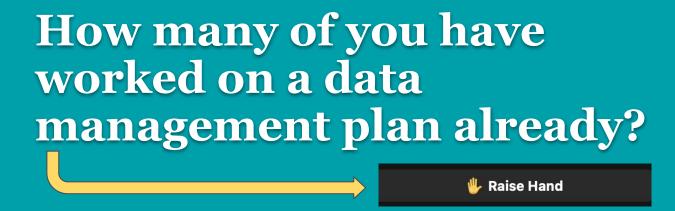
### **Fulfilling New Data Management** & Sharing Expectations: *NIH DMS Policy & Beyond*

Janeway Society Presentation June 2, 2023

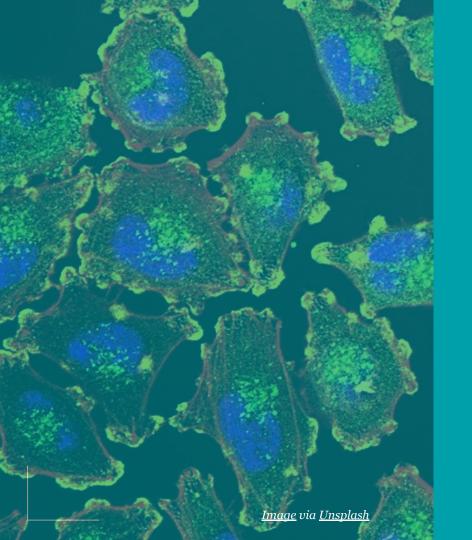
**Kaitlin Throgmorton, MLIS** Data Librarian for the Health Sciences

## Agenda

- NIH Data Management and Sharing (DMS) Policy overview
  - Plus: Quick Look at White House's Office of Science & Technology Policy (OSTP) Memo
- Advice for writing DMS plans
- Strategies for succeeding in this new policy landscape
- Q&A





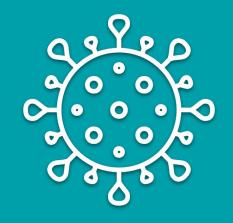


# **Policy Overview**





1





2, 3, 4

# Why?

 ★ Accelerate translation of results into *knowledge* ★ Maximize *value of* and *trust in scientific data* ★ Improve human health

P nubmed ncbi nlm nih gov

National Library of Medicine National Carter for Biotechnology Information

Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine Lindsev R Baden et al. N Engl J Med. 2021.

Background: Vaccines are needed to prevent coronavirus disease 2019 (Covid-19) and to protect persons who are at high risk for omplications. The mRNA-1273 vaccine is a pid nanoparticle-encapsulated mRNA-based

at encodes the prefusion stabilized

66 Cite

Show detail

Clinical Trial

Abstract



## **Two Main Parts of NIH 2023 Policy**



### Submit DMS plan



### **Implement DMS plan**

### NIH SCIENTIFIC DATA SHARING

Are you Ready for NIH's Data Management and Sharing (DMS) Policy?

NIH has issued the DMS Policy (effective for due dates on/after January 25, 2023) to promote the sharing of scientific data. See <u>sharing.nih.gov</u> for details and instructions.

#### Planning & Budgeting for Data Management and 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.

#### · Determine if 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 include in application or proposal. If subject to Genomic Data Sharing Policy, submit a single Plan that addresses genomic data considerations.

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

#### Submission & Review of DMS Plans

Applicants planning to generate scientific data will submit DMS Plans to NIH as part of the funding application or proposal.

Submit DMS Plans and budget requests as part of the funding application or proposal.

Note: Plans are reviewed by NIH program staff for completeness and acceptability. If Plan is not acceptable and complete, work with NIH staff to modify as appropriate.

#### Implementing DMS Plans

Awardees are expected to carry out data management and sharing as outlined in approved plans and as a term and condition of award.

· Manage and share data as described in the approved DMS Plan.

· Provide updates on data management and sharing activities in annual progress reports

· Work with NIH staff to obtain review and approval of modifications if plans change.

Learn more at https://sharing.nih.gov!

### **NIH: Elements of a DMS Plan**



- Data type(s)
- Data standards
- Related tools, software, code
  - Data preservation, access, and associated timeline
- Access, distribution, reuse considerations
- Oversight of DMS

 $\operatorname{Yale}$  Harvey Cushing/John Hay Whitney Medical Library

6

10 Simple Rules for Maximizing the Recommendations of the NIH Data Management and Sharing Plan	Elements of a NIH Data Management and Sharing Plan
1 Describe the data	
2 Choose documentation types	Data Type
3 Describe the tools and software	
	Related Tools, Software &/or Code
4 Use standard file types, identifiers, and descriptive elements	Standards
5 Understand the options (	Standards
5 Understand the options for preserving data	
6 Find a repository	Data Preservation, Access, & Associated Timelines
7 Coordinate timelines for data sharing	Data Preservation, Access, and a
8 Protect privacy and confidentiality prior to access	Access, Distribution, or Reuse Considerations
	Access, Distribution, or Reuse Com
9 Know the controls and approvals needed for data accessibility	Oversight of Data Management and Sharing
	Deta Management au
10 Plan for and outline oversight of data management and sharing	Oversight of Data in

7

### NIH: When & What to Share

• Timeliness in data sharing \*

- At time of associated publication
   OR:
- End of grant ("performance period")
   Whichever is <u>first</u>

 Covers all scientific data generated in grant

 "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."

## **NIH: Data Sharing Approaches**

- "NIH encourages investigators to use the sharing approaches most appropriate for their data": 8
  - Data repositories (and archives)
  - Data enclaves
  - "Under the auspices of the investigator"
  - Mixed modes

## **Additional NIH Policy Points**

- Plans are just <u>two</u> pages
- Plans are <u>NOT</u> part of scored peer review criteria (unless otherwise noted in funding announcement)
- Plans can be updated (via RPPRS)
- Budgeting is important (see resources)
- Policy may not apply in some cases (but it probably does)

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#### Learn more at https://sharing.nih.gov!

### A Policy & A Memo





### open.science.gov

### **NIH DMS Policy Draft Released**

An update to its 2003 policy, NIH releases a draft plan for public comment of its new data management and sharing policy.

### - OSTP Nelson Memo Released

2020

2022

2023

2023

2025

White House releases <u>memo</u> stating that U.S. federal agencies must update their public access plans by 2025 — includes removal of publication embargos and more open data sharing.

### [JAN] <u>NIH DMS Policy</u> In Effect

NIH DMSP in effect — now applies to all research generating scientific data and requires DMS plans to be submitted with grants and implemented post-award. Data sharing timelines are more aggressive.

### [FEB] <u>NIH Response</u> to OSTP Memo

NIH releases for public comment a <u>draft public access</u> <u>plan</u> to comply with new OSTP memo. Essentially, it points to its new DMS Policy as how it will comply.

### [DEC] OSTP Memo In Effect

All U.S. federal agencies must release plans to comply with memo's expectations.

NIH = National Institutes of Health DMS = Data Management & Sharing OSTP = Office of Science & Technology Policy

### <u>OSTP Memo</u> – Data Implications (Section 3b)

• For those with federally funded research:

- Share data freely and publicly at time of publication — unless subject to limitations
- Share other data, even data without publications
- Repositories used for data deposits should align with <u>these guidelines</u>

 According to the policy, federal agencies should create guidance, policies, and recommendations to facilitate this process

## Strategies for Success

<u>Image</u> via <u>Unsplash</u>

## Using tools and templates

- Use **DMPTool** (see resources)
- Review sample plans from NIH and others <sup>10</sup>
- Consult with **colleagues** 
  - In future, consider the <u>YSM</u>
     <u>Grant Library</u> (see resources)



## **Contextualizing data**

 Documenting data
 Using metadata standards
 Adhering to data standards and best practices (see resources)



<u>Image</u> via <u>Unsplash</u>

## **Protecting participants**

 Outlining participant consent (and opt-out) for data sharing early on
 Planning for data de-identification 11



Image via Unsplash

## **Maintaining research integrity**

 Adding access controls
 Utilizing data licensing and/or data use agreements
 Tracking data reuse with persistent identifiers and data citation



### **Taking advantage of repositories**

 May simplify long-term data preservation
 NIH lists repositories and characteristics to look for <sup>12</sup>



datadryad.org



icpsr.umich.edu





### CENTER FOR GLOBAL CLINICAL RESEARCH DATA

### vivli.org

### **Repositories for Sharing Scientific Data** In general, NIH does not endorse or require sharing data in any particular repository, although some initiatives and funding opportunities

will have individual requirements. Overall, NIH encourages researchers to select the repository that is most appropriate for their data type and discipline. See Selecting a Data Repository.

Browse through this listing of NIH-supported repositories to learn more about some places to share scientific data. Note that this list is no exhaustive. Select the link provided in the "Data Submission Policy" column to find data submission instructions for each repository.

Can't find a repository that suits your data? Here are several more resources

· A listing of generalist repositories that accepts all data types

Nature's Data Repository Guidance<sup>®</sup>

The Registry of Research Data Repositories

#### NIH-supported Scientific Data Repositories\*

Institute or Center	•	Repository Name	٠	Repository Description
All	~			Keyword Filter
CIT, NINDS		Federal Interspeco, Tournalis, Brain Joiury Research, JETTBHS Informatics, Sostem		The Federal Interagency Traumatic Brain Injury Research (FTBR) developed to share data across the entities TBI research field and between laberaciticaties, a well as interconcivity with their find data, methodologies, and associated tools, rather than summarie information, can accelerate research progress by allowing re-sail aggregation, integroom, and repress comparison with other data community-wide sharing requires common data definitions and si comprehensiva and coherent informatics approaches.

## National Library of Medicine National Center for Biotechnology Information

### Submission Portal

Submit to the world's largest public repository of biological and scientific information

### submit.ncbi.nlm.nih.gov

osf.io

Additional repositories of note

### **Intentions & Future Directions**

- NIH wants "investigators to benefit from *first and continuing use* but not from prolonged exclusive use" 8
- Goal: Treating datasets as primary research outputs



# **Summing Up**

 Data management and sharing expectations increasing at NIH and elsewhere

 Many resources and strategies available





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- Nelson, A. (2022). Memorandum: Ensuring Free, Immediate, and Equitable Access to Federally Funded Research. White House Office of Science and Technology Policy. <u>https://www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-Access-Memo</u>.<u>pdf</u>
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- 11. NIH. Protecting Participant Privacy When Sharing Scientific Data. Scientific Data Sharing. https://sharing.nih.gov/data-management-and-sharing-policy/protecting-participant-privacy-w hen-sharing-scientific-data
- 12. NIH. Selecting a Data Repository. Scientific Data Sharing. <u>https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/selecting-a-data-repository</u>



### **Library Resources**









DMP Email Course

Other Trainings <u>& Info</u>

Images via <u>Unsplash</u>

## **Resources: NIH DMS Plan Preparation**



Main policy website



Build your Data Management Plan Plan generator with templates



Resource compendium for data management



FAIRsharing.org

The "Google" of data standards



## **Resources: NIH DMS Plan Budgeting**



Budgeting for DMS

Yale Office of Sponsored Projects (OSP)

Yale budgeting tip sheet

### **Get in touch!**

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osphelp@yale.edu Subject line: NIH Data Mandate/DMP

