

Welcome to Session 1 – Train-the-Trainer Data Management Sharing Plans



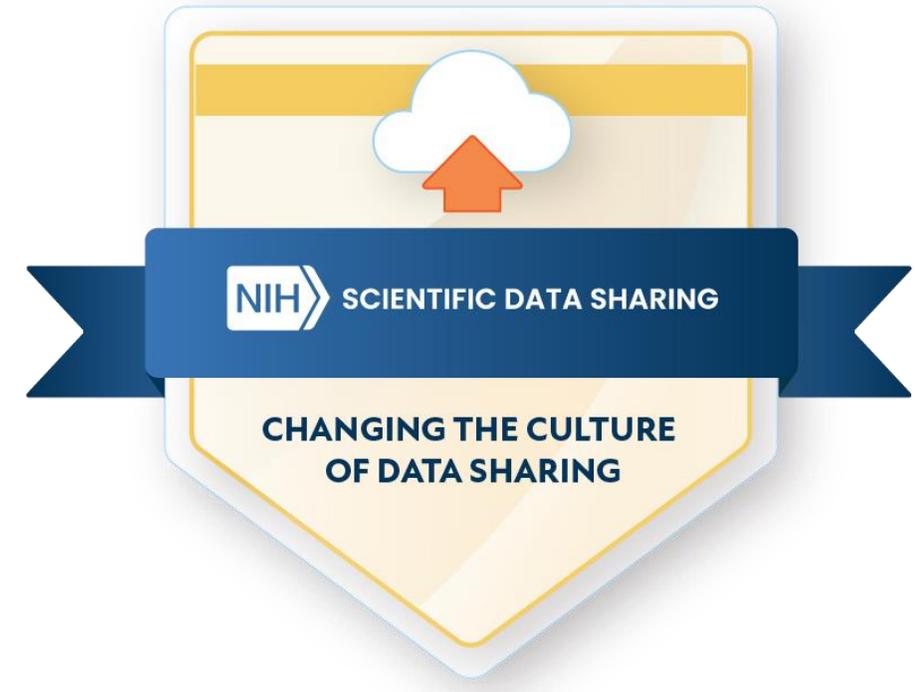
**Please take this short survey
while we wait for everyone to
settle in**

**You may scan the QR code or
open the link below in your web
browser:**

pollev.com/hibahawwad318

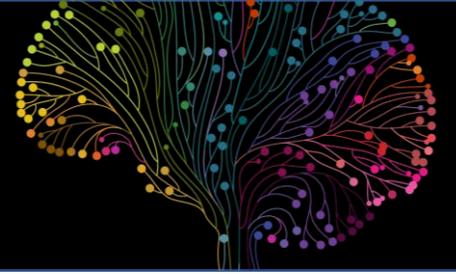


NIH has a longstanding commitment to making the results of research available.



Data Management and Sharing Policy will create a **consistent minimum expectation** for all research supported by NIH agency.

Scope of Data Management Sharing Policy

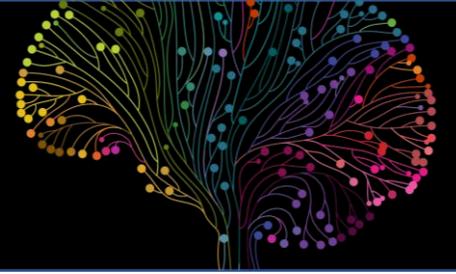


- Applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of "**scientific data**".
- Applications received after Jan. 25, 2023 must include a plan for sharing both published and non-published scientific data

"**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."

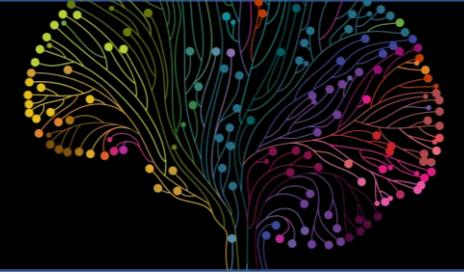
Exclusions from Data Management Sharing Policy



Scientific data do not include:

- Data **not** necessary for or of sufficient quality to validate & 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)

Research activities subject to DMS Policy



APPLIES TO...

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

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

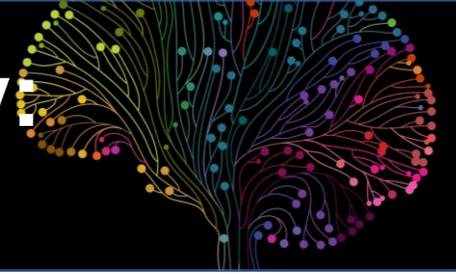
DOES NOT APPLY TO...

Research projects not generating scientific data or non-research projects, including but not limited to:

- Training (Ts)
- Fellowships (Fs)
- Construction (C06)
- Conference Grants (R13)
- Resources (Gs)
- Research-Related Infrastructure Programs (e.g., S06)

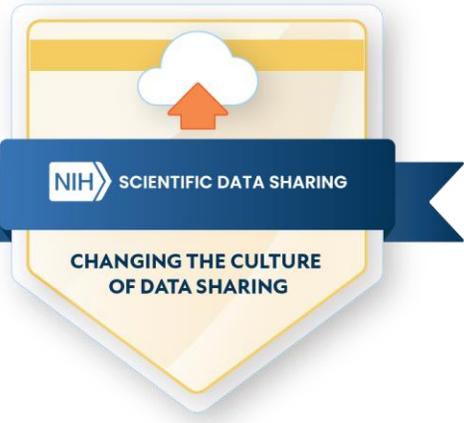
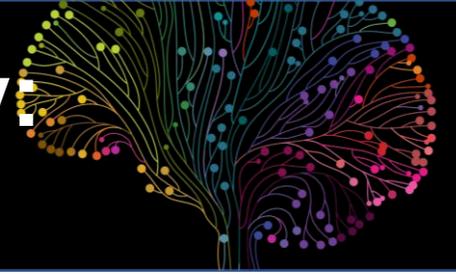
See [Research Covered Under the Data Management & Sharing Policy](#)

New NIH Data Management & Sharing Policy: DMSP



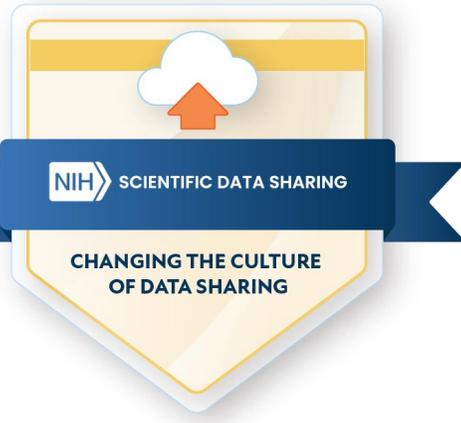
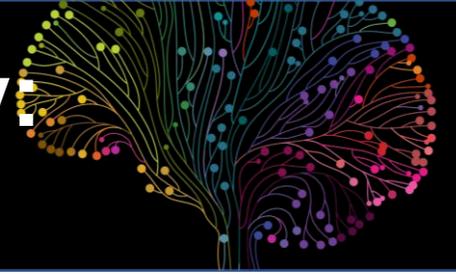
- **Planning & Budgeting for Data Sharing**
 - Determine if proposed research requires DMSP
 - Identify methods/approaches and repositories
 - Develop a plan – includes Genomic Data Sharing Policy (GDS) where applicable
 - Estimate budget and request funds for DMS
- **Submission & Review of the DMSP**
- **Implementing the DMSP**

New NIH Data Management & Sharing Policy: DMSP



- **Planning & Budgeting for Data Sharing**
- **Submission & Review of the DMSP**
 - DMSP format, budget request and budget justification.
 - For funded applications, NIH staff will reach out to work on making plans acceptable.
- **Implementing the DMSP**

New NIH Data Management & Sharing Policy: DMSP



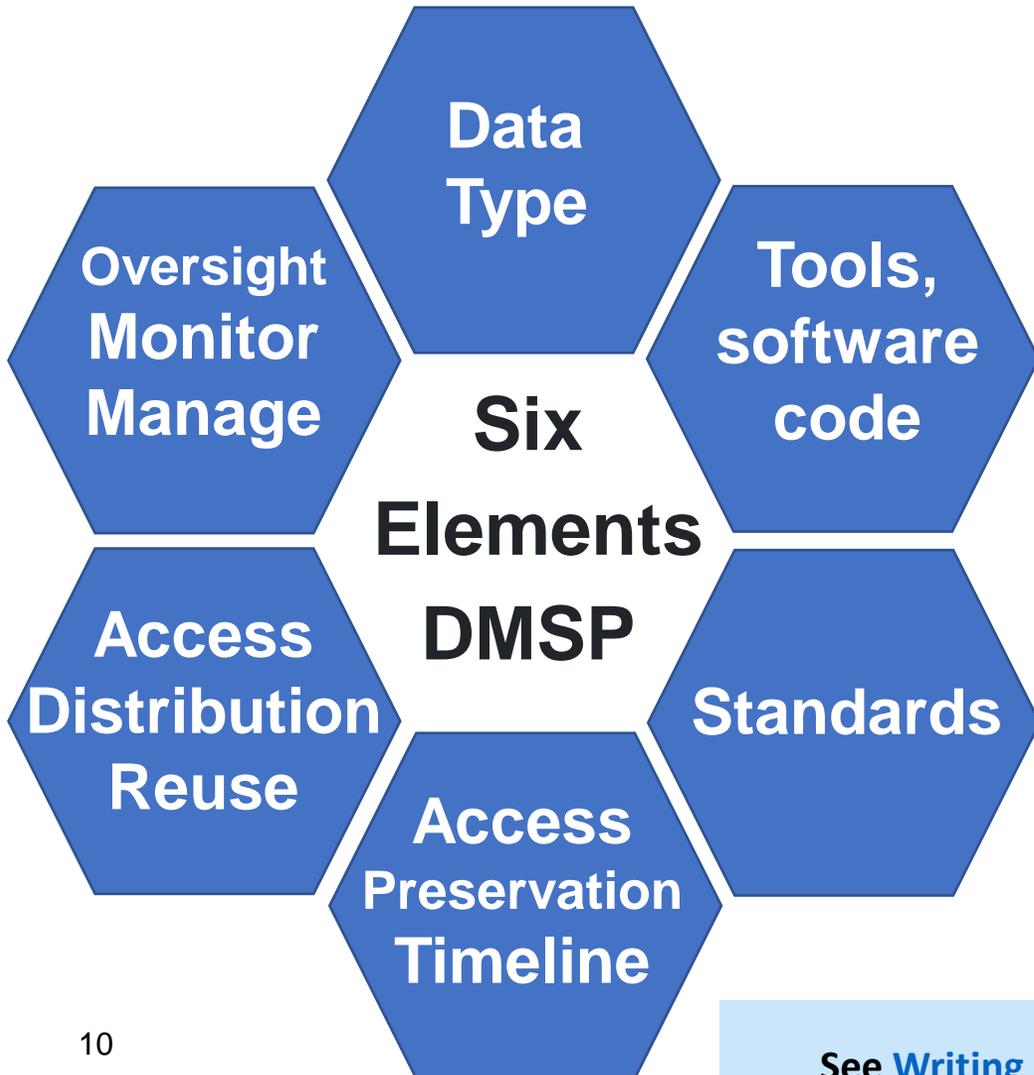
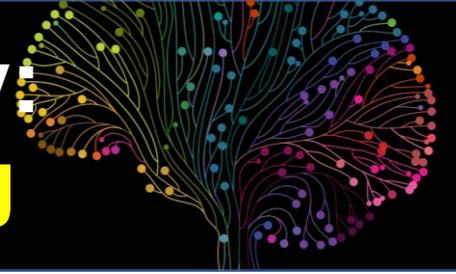
- **Planning & Budgeting for Data Sharing**
- **Submission & Review of the DMSP**
- **Implementing the DMSP**
 - Manage and share data as described in DMSP
 - Provide updates on DMS activities in annual progress reports (RPPRs)
 - Work with NIH staff to review and approve modifications to DMSP if plans change

NIH Policy Requirements

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

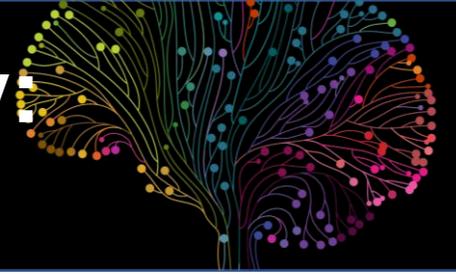
Compliance with the Data Management and Sharing Plan approved by the funding NIH Institute, Center, or Office

New NIH Data Management & Sharing Policy: DMSP - Planning & Budgeting for Data Sharing



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

New NIH Data Management & Sharing Policy: DMSP – Submission & Review of DMSP



DMSP Format (not to exceed 2 pages)

OMB No. 0925-0001 and 0925-0002 (Rev. 07/2022 Approved Through 01/31/2026)

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](https://www.nih.gov/sharing). The Plan is recommended not to exceed two pages. Text in italics should be deleted. There is no "form page" for the Data Management and Sharing Plan. The DMS Plan may be provided in the *format* shown below.

Public reporting burden for this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0001 and 0925-0002). Do not return the completed form to this address.

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 can be accessed.

Element 3: Standards:

State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources, and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist.

Element 4: Data Preservation, Access, and Associated Timelines

A. Repository where scientific data and metadata will be archived:

Provide the name of the repository(ies) where scientific data and metadata arising from the project will be archived; see [Selecting a Data Repository](#).

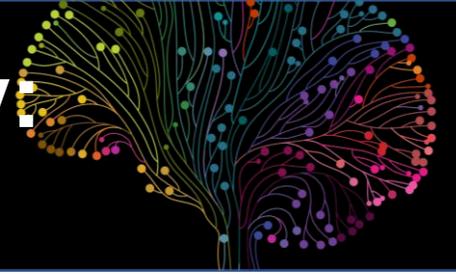
B. How scientific data will be findable and identifiable:

Describe how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools.

C. When and how long the scientific data will be made available:

Describe when the scientific data will be made available to other users (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) and for how long data will be available.

New NIH Data Management & Sharing Policy: DMSP – Submission & Review of DMSP



DMSP Format (not to exceed 2 pages)

Element 5: Access, Distribution, or Reuse Considerations

A. Factors affecting subsequent access, distribution, or reuse of scientific data:

NIH expects that in drafting Plans, researchers maximize the appropriate sharing of scientific data. Describe and justify any applicable factors or data use limitations affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, and any other considerations that may limit the extent of data sharing. See [Frequently Asked Questions](#) for examples of justifiable reasons for limiting sharing of data.

[NIH DMS Plan
Format Page](#)

B. Whether access to scientific data will be controlled:

State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval.)

[ODC-TBI sample
DMS Plan](#)

C. Protections for privacy, rights, and confidentiality of human research participants:

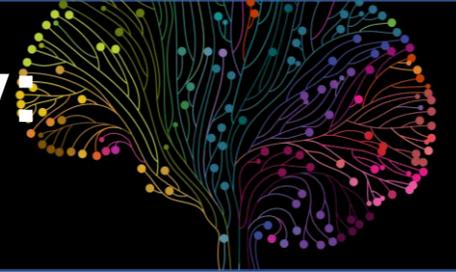
If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures).

Element 6: Oversight of Data Management and Sharing:

Describe how compliance with this Plan will be monitored and managed, frequency of oversight, and by whom at your institution (e.g., titles, roles).



New NIH Data Management & Sharing Policy: DMSP – Submission & Review of DMSP



DMSP Submission in PHS398 form

Research Plan Section

5. Vertebrate Animals

Add Attachment

Delete Attachment

View Attachment

6. Select Agent Research

Add Attachment

Delete Attachment

View Attachment

7. Multiple PD/PI Leadership Plan

Add Attachment

Delete Attachment

View Attachment

8. Consortium/Contractual Arrangements

Add Attachment

Delete Attachment

View Attachment

9. Letters of Support

Add Attachment

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View Attachment

10. Resource Sharing Plan(s)

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View Attachment

11. Other Plan(s)

Add Attachment

Delete Attachment

View Attachment

12. Authentication of Key Biological and/or
Chemical Resources

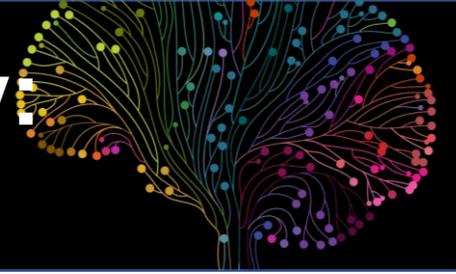
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New NIH Data Management & Sharing Policy:

DMSP – Submission & Review of DMSP



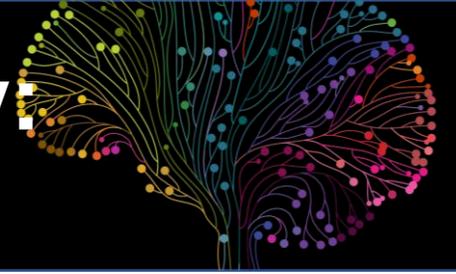
ALLOWABLE COSTS

- Curating data/developing supporting documentation
- Preserving/sharing data through repositories
- Local data management considerations
- **IMPORTANT:** Must be incurred during the performance period

UNALLOWABLE COSTS

- Infrastructure costs typically included in indirect costs
- Costs associated with the routine conduct of research (e.g., costs of gaining access to research data)

New NIH Data Management & Sharing Policy: DMSP – Submission & Review of DMSP



SUBMITTING THE DMSP Budget

Direct costs to support the activities proposed in DMS Plan must be indicated as “Data Management and Sharing Costs”

R&R 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. Data Management and Sharing Costs	
9.	

PHS 398 Modular Budget Form:
within Additional Narrative Justification

2. Budget Justifications

Personnel Justification

Add Attachment

Consortium Justification

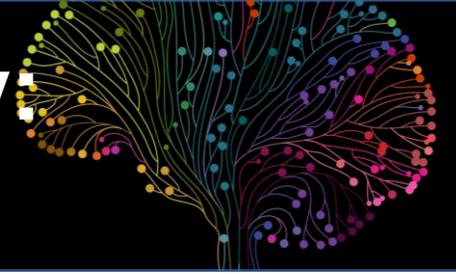
Add Attachment

Additional Narrative Justification

Add Attachment

New NIH Data Management & Sharing Policy

DMSP – Submission & Review of DMSP



SUBMITTING THE DMSP Budget justification

Brief summary of DMS Plan and description of DMS costs must be **included within the budget justification attachment**

R&R Budget Form: section L.
Budget justification

L. Budget Justification

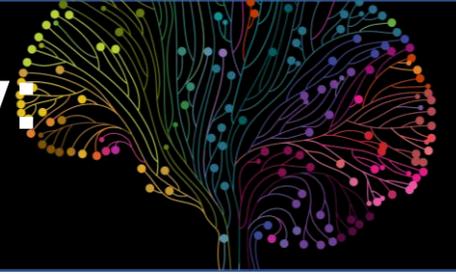
(Only attach one file.)

PHS 398 Modular Budget Form:
Additional Narrative Justification

2. Budget Justifications

Personnel Justification	<input type="text"/>	<input type="button" value="Add Attachment"/>
Consortium Justification	<input type="text"/>	<input type="button" value="Add Attachment"/>
Additional Narrative Justification	<input type="text"/>	<input type="button" value="Add Attachment"/>

New NIH Data Management & Sharing Policy: DMSP – Submission & Review of DMSP



DMSP Review

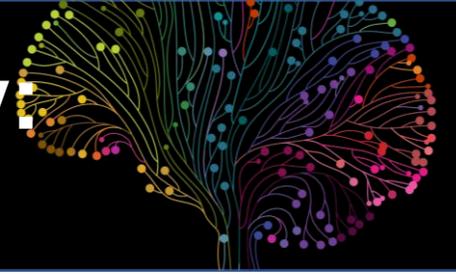
NIH Program staff:

- Ensure 6 elements of DMSP have been adequately addressed
- Applications will only be funded when DMSP is complete & acceptable

Peer reviewers:

Consider if budget is reasonable

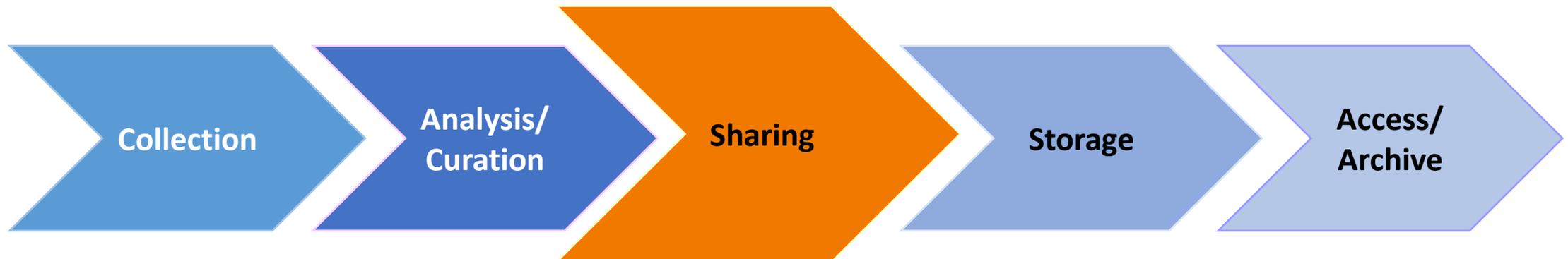
New NIH Data Management & Sharing Policy: DMSP – **Implementing the DMSP**



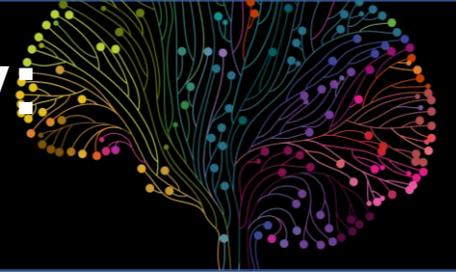
Timeline for sharing data

As soon as possible!

No later than the time of a **publication of findings** in a peer-reviewed journal OR at the **end of the award**, whichever comes first



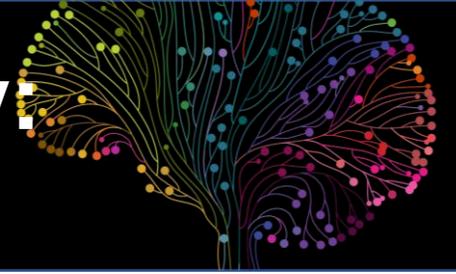
New NIH Data Management & Sharing Policy: DMSP – **Implementing the DMSP**



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



New NIH Data Management & Sharing Policy: DMSP – **Implementing the DMSP**



1. **New & Updated DMSP is required when there is a change in:**

- Change in Timeline
- Change in Repository
- Change in Scope



2. **Use NIH resources & interagency resource center:** Work with NIH Program staff - We're here to help you

New NIH Data Management and Sharing Policy: Use the resources



- Applications received after Jan. 25, 2023 must include a plan for sharing both published and non-published scientific data
- NIH and NINDS have developed resources to help researchers prepare their applications and encourage thoughtful, effective planning



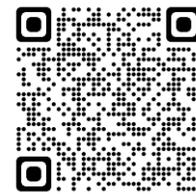
**NINDS Data Sharing:
Information for
Applicants and Awardees**



**Protecting Privacy When
Sharing Human Research
Participant Data**



**NIH DMS Plan Guidance
and Sample Plans**



**Justifiable Reasons for
Limiting Sharing of Data**

Slides from this workshop will be posted to link on NINDS TBI website



<https://www.ninds.nih.gov/current-research/focus-disorders/focus-traumatic-brain-injury-research>