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 agency.

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 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 <u>not</u> 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)

Policy Effective Dates

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**

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

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

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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

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Elements of a DMS Plan
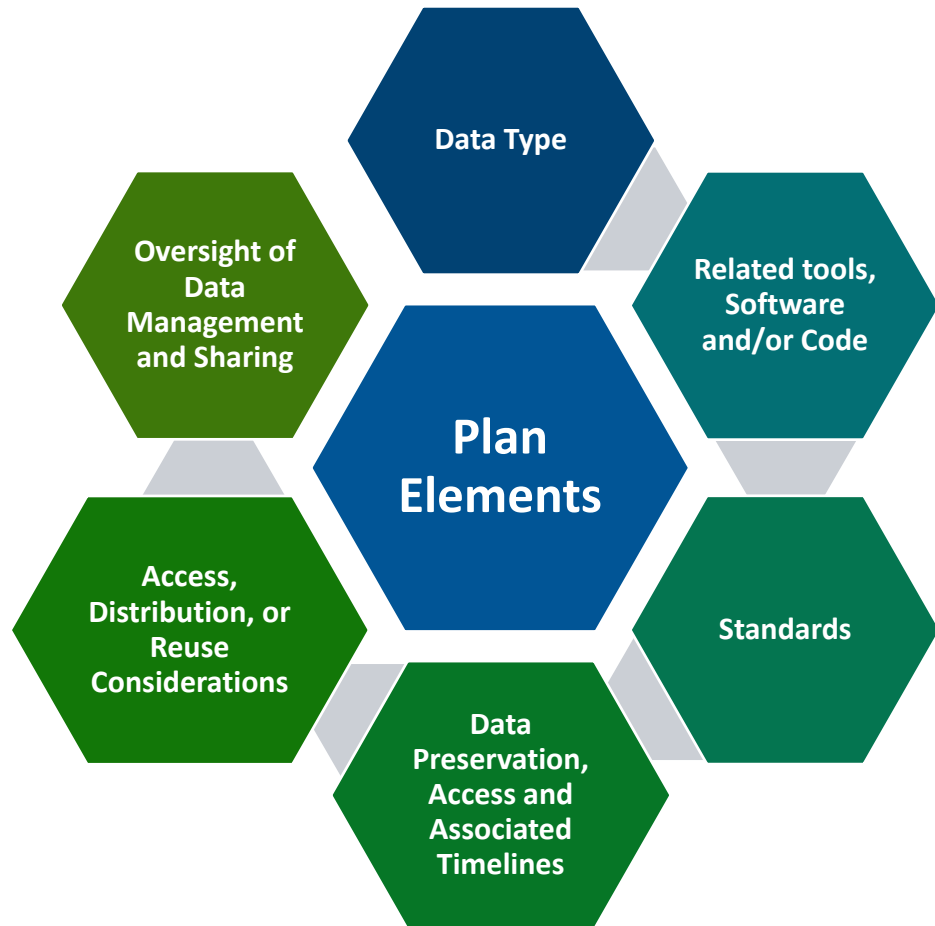
- **Data type**
  - Identifying data to be preserved and shared
- **Related tools, software, code**
  - Tools and software needed to access and manipulate data
- **Standards**
  - Standards to be applied to scientific data and metadata
- **Data preservation, access, timelines**
  - Repository to be used, 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

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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

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DMS Plan Submission

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

- Data Sharing Plans and Genomic Data Sharing Plans will no longer be submitted to the "Resource Sharing Plan(s)" field

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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

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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
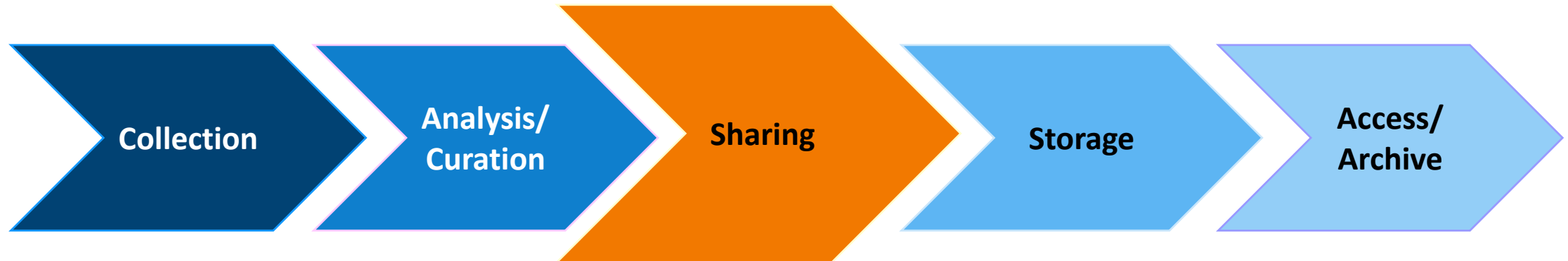
- Registry of Research Data Repositories

See **Repositories for Sharing Scientific Data**

When should I share my 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

Collection → Analysis/Curation → Sharing → Storage → Access/Archive

For how long should data be shared?

- Not one size fits all. Appropriate time frame varies across disciplines.

- Consider relevant requirements and expectations:
  - Data repository policies
  - Award record retention requirements
  - Journal policies

Collection → Analysis/Curation → Sharing → Storage → Access/Archive

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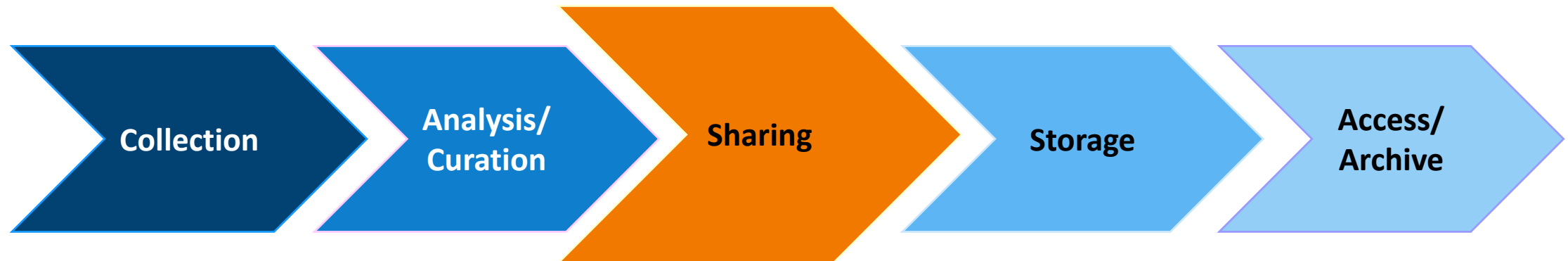
Data Management and Sharing Costs

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)

See **[Budgeting for Data Management & Sharing](#)** for details

Submitting DMS Budgets

- Direct costs to support the activities proposed in the 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.	
10.	

  - **PHS 398 Modular Budget Form:** <u>within</u> Additional Narrative Justification

2. Budget Justifications				
Personnel Justification		Add Attachment	Delete Attachment	View Attachment
Consortium Justification		Add Attachment	Delete Attachment	View Attachment
Additional Narrative Justification		Add Attachment	Delete Attachment	View Attachment

Justifying DMS Budgets

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

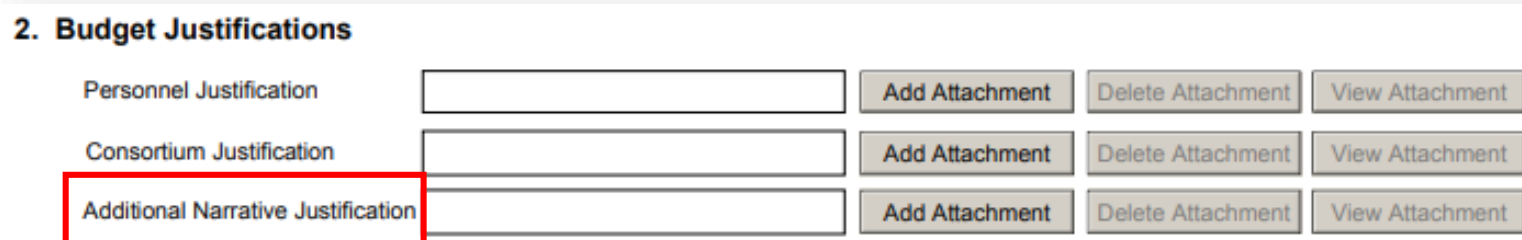 - **R&R Budget Form:** section L. Budget Justification

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

DMS Plan Assessment

- NIH program staff determine **if DMS Plan** is acceptable or unacceptable

- Peer reviewers ONLY consider if **budget** is reasonable

Resolving Issues Before Award

- DMS Plan must be approved prior to award

- If additional details are needed, it may be necessary to communicate with NIH staff to resolve issues with DMS Plan
  - Will occur through standard Just-In-Time (JIT) process
  - Provide additional information and potentially a revised DMS Plan

Incentives for Good Sharing Practices

- Data citation to incentivize data sharing
- Shared data can be cited as products of awards and claimed as products of NIH funding
    - Data can be cited anywhere other research products are cited, e.g., bibliography, biosketch, progress report
- Persistent unique identifiers to help track data reuse

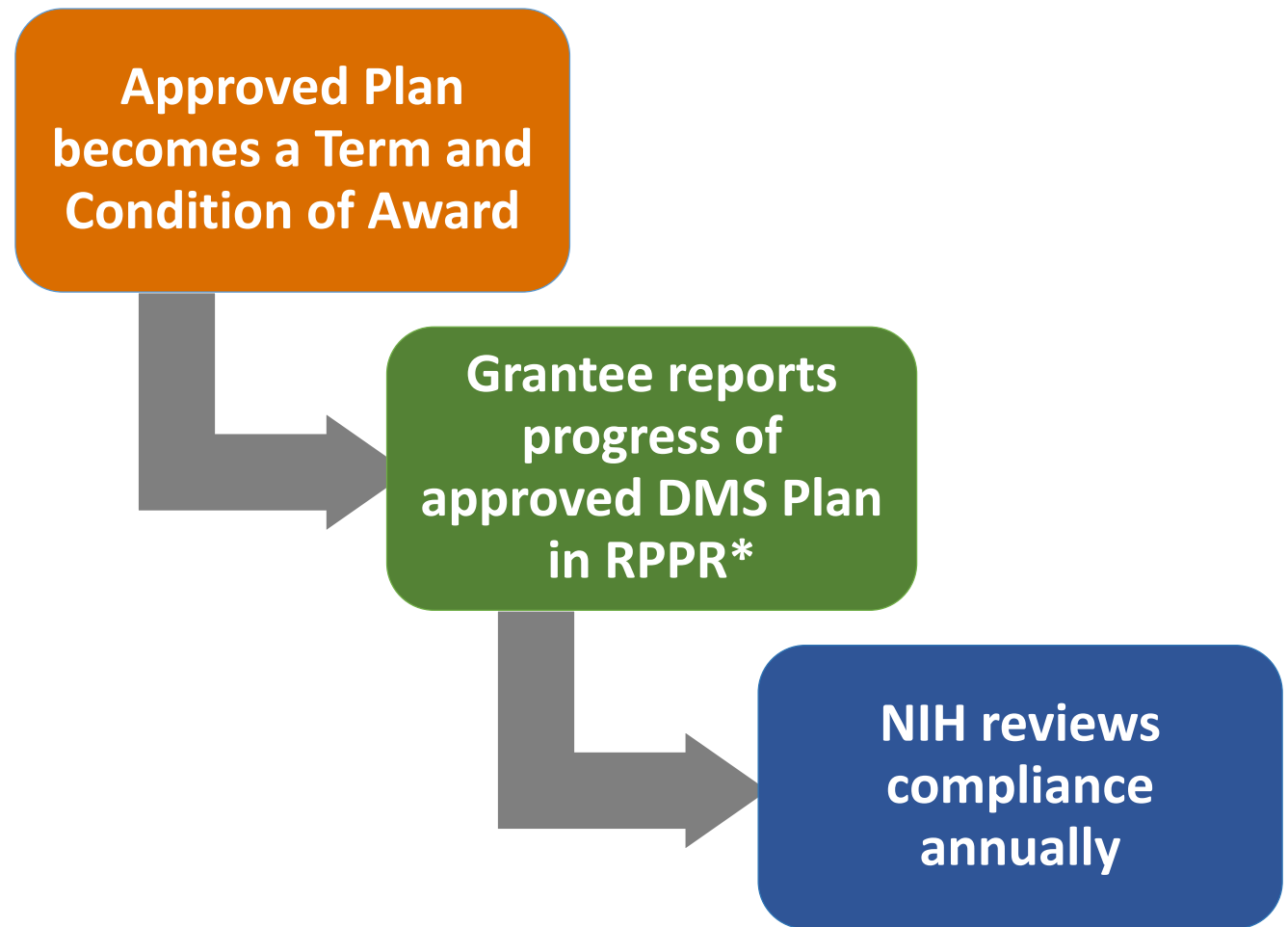# Is the use of a Unique Persistent Identifier (PID) required?

Definition: A Unique Persistent Identifier assigns datasets a citable, unique persistent identifier, such as a digital object identifier (DOI) or accession number, to support data discovery, reporting, and research assessment.

The use of PIDs is encouraged and their use is a desirable characteristic of data repositories.

Monitoring Compliance

*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.

Is my research also subject to other NIH data sharing policies?

DECISION TOOL

Which Policies Apply to My Research?

NIH has a variety of sharing policies in place for research that it funds. This tool will assist in helping you determine which of the following NIH policies apply to a particular project:

- Genomic Data Sharing Policy
- 2003 Data Sharing Policy
- Data Management & Sharing Policy (in effect January 25, 2023)
- Model Organism Sharing Policy
- Research Tools Policy

START HERE

NIH INSTITUTE AND CENTER DATA SHARING POLICIES

Institute or Center	Data Sharing Policy Name	Description of Data Sharing Policy
NCI ⌄		
NCI	NCI Clinical Trial Access Policy	NCI believes that the full value of NCI-suppo[rted] Clinical Trials can be realized only if the resul[ts are] published as rapidly as possible. The Clinical [...] at ensuring public availability of results from [...] trials from all NCI-funded research grants, co[...] and/or contracts that support covered interve[...]

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You Can Prepare Now

❑ **Familiarize yourself** with the DMS Policy and resources available at sharing.nih.gov

❑ **Identify existing resources and expertise within your institution** that may be able to assist you, such as data librarians

❑ Try **drafting a Data Management and Sharing Plan** for your work based on the recommended elements (NOT-OD-21-014)

❑ **Review your past data sharing practices** to meet other funder or publisher expectations and consider what you may need to update for the new Policy in the future

❑ **Get involved:** see FASEB DataWorks! for challenges and prizes

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For More Information...

- **Website:** [NIH Scientific Data Sharing](#)

- **FAQs:** [DMS Policy FAQs](#)

- **Email Box:** [Sharing@nih.gov](#)

- **Webinar Part II:** [Diving Deeper into the New NIH Data Management and Sharing Policy](#) - September 22

Stay in the loop!

BLOGS

- **Under the Poliscope**
- **Open Mike**

LISTSERVS

- **Extramural Nexus**
- **NIH Guide to Grants & Contracts**
- **Office of Science Policy News**
- **NIH Scientific Data Sharing News & Events**

SOCIAL MEDIA

- **@NIHGrants**
- **@NIH_OSP**

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Virtual NIH Grants Conference & PreCon Events

August 2022 – February 2023

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Interact with NIH experts!
Engage and network with your peers!
Gather resources to use and share with colleagues!

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Grants.nih.gov/learning-center/conference

PreCon Events
August 25:   NIH Loan Repayment Programs: Supporting the Next Generation of Researchers
September 15:   Navigating Early Career Funding Opportunities
October 14:   Research Misconduct & Integrity
November 9:   Foreign Collaborations: Policies, Processes, & Partnerships
December 6 & 7:   Human Subjects: Policies, Clinical Trials, & Inclusion
January 12, 2023: Making the Most of the 2023 NIH Grants Conference

2-Day Conference
February 1 & 2, 2023:   2023 *Virtual* NIH Grants Conference: Funding, Policies, & Processes

Resources from Webinar

- [Research Covered Under the Data Management & Sharing Policy | Data Sharing (nih.gov)](#)

- FAQ on Scientific Data ([Frequently Asked Questions (FAQs) | Data Sharing (nih.gov)](#))

- [Data Management & Sharing Policy Overview | Data Sharing (nih.gov)](#)

- FAQ on Justifiable Reasons to Limit Data Sharing ([Frequently Asked Questions (FAQs) | Data Sharing (nih.gov)](#))

- [Informed-Consent-Resource-for-Secondary-Research-with-Data-and-Biospecimens.pdf (nih.gov)](#)

- Sharing Data From Human Participants ([Data Sharing Approaches | Data Sharing (nih.gov)](#))

- FAQ on Reusing, Existing Shared Data ([Frequently Asked Questions (FAQs) | Data Sharing (nih.gov)](#))

- [Writing a Data Management & Sharing Plan | Data Sharing (nih.gov)](#)

- Data Management and Sharing Plan Format Page ([NIH Forms & Applications | grants.nih.gov](#))

- [Selecting a Data Repository | Data Sharing (nih.gov)](#)

Resources from Webinar (cont.)

- Repositories for Sharing Scientific Data | Data Sharing (nih.gov)

- FAQ on When to Share Data: Frequently Asked Questions (FAQs) | Data Sharing (nih.gov)

- FAQ on Data Sharing Timelines When a No Cost Extension is Granted: Frequently Asked Questions (FAQs) | Data Sharing (nih.gov)

- Budgeting for Data Management & Sharing | Data Sharing (nih.gov)

- NOT-OD-22-189: Implementation Details for the NIH Data Management and Sharing Policy

- FAQ on Noncompliance: Frequently Asked Questions (FAQs) | Data Sharing (nih.gov)

- Which Policies Apply to My Research? | Data Sharing (nih.gov)

- NIH Institute and Center Data Sharing Policies | Data Sharing

- Home Page | Data Sharing (nih.gov)