

The NIH Policy for Data Management and Sharing (DMS) in Effect: Planning for Success

**NIH Grants Conference
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Are you a:
(1) Researcher
(2) Research Administrator
(3) Other?



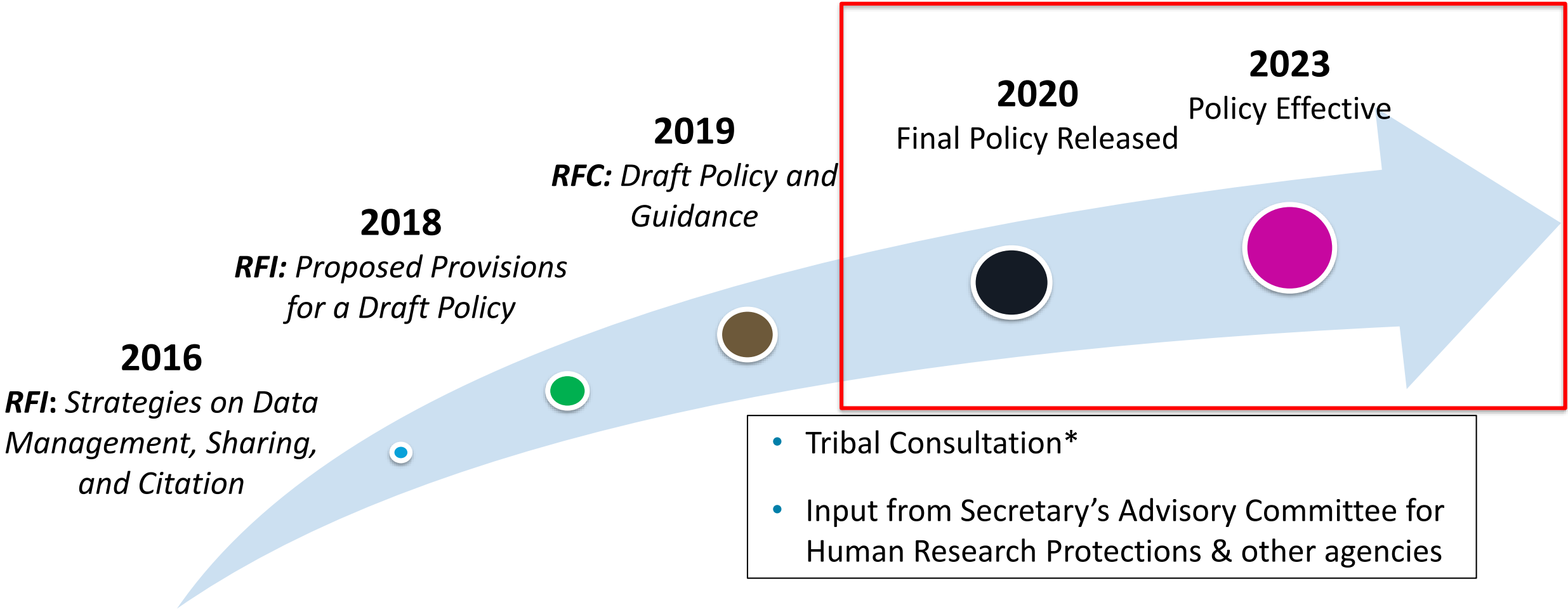
NIH Commitment to & Investment in Data Sharing

“Consistent with both the NIH mission to improve public health through research and its longstanding legislative mandate to make available to the public the results of the research activities that it supports and conducts....”

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-013.html>



Iterative Policy Development through Consistent Community Engagement



*See *“NIH Tribal Consultation Report: NIH Draft Policy for Data Management and Sharing”*

- **Advance rigorous and reproducible research**
 - Enable validation of research results
 - Make high-value datasets accessible
 - Accelerate future research directions
 - Increase opportunities for citation and collaboration



- **Promote public trust in research**
 - Foster transparency and accountability
 - Demonstrate stewardship over taxpayer funds
 - Maximize research participants' contributions
 - Support appropriate protections of research participants' data

- **Requirements (effective January 25, 2023):**
 1. **Submission** of Data Management & Sharing Plan
 2. **Compliance** with ICO-approved Plan (may affect future funding)
- **Scope:** All NIH-supported research generating scientific data
 - **What's in:** “Recorded factual material... of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications”
 - **What's out:** Lab notebooks, preliminary analyses, peer reviews, physical objects
- **Timelines:**
 - **When to share data:** No later than publication or end of award (for unpublished data), whichever comes first
 - **How long to share data:** Consider other relevant requirements and expectations (e.g., journal policies, repository policies)



'Which brings us to my next point.'

Activities Subject to the DMS Policy

Applies to all research that generates scientific data, including:

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

Does not apply to research and other activities that *do not* generate scientific data, including:

- Training (Ts)
- Fellowships (Fs)
- Construction (C06)
- Conference Grants (R13)
- Resources (Gs)
- Research-Related Infrastructure Programs (e.g., S06, S10)

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



Sharing should be...

- **The default practice**
 - Maximize appropriate data sharing; Plans may justify limitations (e.g., ethical, legal, technical factors)
 - All scientific data should be managed; **not all must be shared**
- **Responsibly implemented**
 - Plans should outline protection of privacy, rights, and confidentiality
 - Existing laws, regulations, and policies continue to apply
- **Prospectively planned for at all stages of the research process**
 - During informed consent, including communicating how data will be used and shared
 - Data submission, including whether access to data, even if de-identified, should be controlled



- **Justifiable ethical, legal, and technical factors for limiting sharing of data include:**

Examples include:

- Informed consent will not permit or limits scope of sharing or use
- Explicit federal, state, local, or Tribal law, regulation, or policy prohibits disclosure

- **Reasons not generally justifiable to limit sharing include:**

Examples include:

- Dataset too small
- Researchers anticipate data will not be widely used
- Data are not thought to have a suitable repository

See [FAQ](#) for details

Policy Scope

- How does the DMS Policy fit in with other NIH data sharing policies and requirements?
- How does the DMS Policy interact with the data sharing expectations of other research partners (e.g., other funding agencies, collaborators)?
- Are projects establishing repositories or creating data infrastructure subject to the DMS Policy (i.e., establishing a data coordinating center with no research question proposed)?

Managing and Sharing Scientific Data

- Does the timeline for sharing scientific data change in the event of a no cost extension?
- What are justifiable reasons for limiting sharing of data?
- Do SBIR/STTR projects have to share scientific data under the DMS Policy?

Considerations for Scientific Data Derived from Human Participants

- What steps does the DMS Policy take to ensure institutions and researchers protect research participants?
- Does the DMS Policy expect that when consent is obtained for research involving human participants, it must be for broad sharing and the future use of data?

Compliance and Enforcement

- How will noncompliance with the NIH DMS Policy be handled?

See [DMS Policy FAQs](#)

- August 11 and September 22, 2022: 2-part public webinar series, *A Conversation with NIH: Implementing the new Data Management and Sharing Policy*
 - 4,900+ attendees at each event
 - 300+ questions at each event
 - Recording and materials posted publicly
<https://sharing.nih.gov/about/learning>
- Upcoming events <https://sharing.nih.gov/news-events>

Elements of a Data Management and Sharing 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
 - Plan compliance will be monitored/ managed and by whom

See [Writing a Data Management & Sharing Plan](#) for details



Format of a Data Management and Sharing Plan

- ✓ Recommended to be no more than 2 pages
- ✓ Optional format page available and incorporated into FORMS-H application instructions
- ✓ Federal Demonstration Partnership (FDP) pilot project to test structured templates and tools for DMS Plan submission

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.

DMS Plan format page added to list of Format Pages and incorporated into FORMS-H application instructions



Sample NIH DMS Plans Available

- Several sample NIH DMS Plans available for educational purposes, including:
 - Human clinical and/or MRI data (NIMH)
 - Human genomic data (NIMH & NHGRI)
 - Human & non-human genomic data (NIMH)
 - Secondary data analysis (NIMH)
 - Human clinical and genomics data (NICHD)
 - Human survey data (NICHD)
 - Model organism (Zebrafish) data (NICHD)
 - Technology development (NHGRI)

DATA MANAGEMENT AND SHARING PLAN

An example from an application proposing to collect single cell genomic data from mice and humans.

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 (**but this has not been done in the sample below**). There is no "form page" for the Data Management and Sharing Plan. The DMS Plan may be provided in the *format* shown below.

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.

As detailed in the Research Strategy Section, we propose the generation of a spatially mapped single-cell atlas of the developing mouse brain and include specific deliverables. Our primary deliverable for each modality will be a matrix of cells \times (counts in peaks for ATAC, UMIs in genes for RNA, or methylation status for DNAm) along with a dense metadata table with information for each cell. This includes the animal sex, developmental time point, punch of origin with x,y,z coordinates, assigned cluster and inferred cell type, assigned subcluster and inferred cell type, as well as a number of QC metrics (total reads, passing reads, reads in peaks, TSS enrichment, cell barcode combination, date of preparation for each stage, sequencing platform, likelihood of being a doublet, and any other relevant metrics that arise during the project).

The amount and type of data from human cells will depend on the results from the mouse studies. Data sharing plans will be updated when appropriate (likely at the start of year 4 of the grant award).

See [Writing a Data Management & Sharing Plan](#) for details



Harmonization of Genomic Data Sharing (GDS) and DMS Policies

- NOT-OD-22-198: Implementation Changes for GDS Plans
 - **Single Plan** for applications subject to both DMS and GDS Policies

For more information about the GDS Policy and other NIH sharing Policies, please attend tomorrow's 11:00 am presentation:

- Overview of the NIH Genomic Data Sharing (GDS) Policy, Other Sharing Policies, and Open Q&A



Have you explored the resources on sharing.nih.gov?



- Expectations for writing a Data Management & Sharing Plan
- Includes instructions and optional format for submitting Plans
- Addresses Genomic Data Sharing Policy expectations
- Recent FAQs that address Plans

[Home](#) > [Data Management and Sharing Policy](#) > [Planning and Budgeting for Data Management & Sharing](#)

Planning and Budgeting for Data Management & Sharing

NIH expects applicants to submit a plan for how they will manage and share their data and allows applicants to include certain costs associated with data management and sharing in their budget.



Writing a Data Management & Sharing Plan

Learn what NIH expects Data Management & Sharing plans to address.



Budgeting for Data Management & Sharing

Find out what data sharing related costs may be requested in an application for funding.

Changes to DMS Plan Submission

- Updates made to FORMS-H version of grant application forms – updated instructions available now
- New “**Other Plan(s)**” field added to PHS 398 forms to collect a single DMS Plan PDF attachment
 - Separate “Data Sharing Plan” and “Genomic Data Sharing Plan” attachments will no longer be collected as Resource Sharing Plan(s)
 - Plans for sharing genomic data will be included as part of the DMS Plan in Other Plan(s)

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



DMS Plan will NOT be visible to peer reviewers.

**except for certain FOAs with a data sharing focus*

What About the Resource Sharing Plan(s) Field?

- Existing “**Resource Sharing Plan(s)**” field will remain to support Research Tools and Model Organism Sharing Policy
 - “Resource Sharing Plan(s)” attachment will continue to be visible to peer reviewers and included as an Additional Review Consideration
- eRA validations to ensure DMS Plans are attached to appropriate form 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
11. Other Plan(s)	<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

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



Supplemental Information: Repository Selection

- Encourages use of established repositories
 - Generally improves FAIRness of data
- Helps investigators identify appropriate data repositories
 - E.g., use of persistent unique identifiers, attached metadata, facilitates quality assurance
- NIH ICs may designate specific data repository(ies)



Supplemental Information: Repository Selection

Specialized Data Repositories

- Prioritizes data-type and discipline-specific data repositories
- Refers to NIH-supported data repository list outlining:
 - Repository description (e.g., data-types accepted, research community served, tools available),
 - Supportive NIH IC(s),
 - Whether and when new data are accepted, and
 - How to submit data

- Examples include:

dbGaP

GenBank

NIMH Data Archive

BioData Catalyst

ImmPort

BioLINCC



- Direct costs to support 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.		
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
Additional Narrative Justification	<input type="text"/>	Add Attachment	Delete Attachment View Attachment

- Brief summary of DMS Plan and description of DMS costs (recommended $\leq \frac{1}{2}$ page) must be **included within the budget justification attachment**; peer reviewers may comment on requested DMS costs based on this information
 - **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"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
Consortium Justification	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
Additional Narrative Justification	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>

See Instructions in [FORMS-H Application Guide](#)

- In preparation for an award, program staff ensure the Elements of a DMS Plan have been **adequately addressed** and assess the **reasonableness** of those responses
- Applications will only be funded when DMS Plan is **complete** and **acceptable**
 - Any issues with a DMS Plan will need to be resolved through the Just-in-Time (JIT) process
- DMS Plans may be updated throughout award lifecycle if revisions are necessary (e.g., new scientific direction, a different data repository, or a timeline revision)
 - Revised DMS Plans must be assessed and approved by the NIH ICO

- Approved DMS Plan becomes Term and Condition of Award
- Recipient reports progress on implementing approved DMS Plan in Research Performance Progress Report (RPPR)
 - RPPR instructions will be updated
- 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

Steps for preparing for the DMS Policy:

- **Identify existing resources within your institution** that may be able to assist you, such as data librarians
- Review examples of relevant sample plans on sharing.nih.gov
- 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 DMS Policy
- **Read FOA** for any ICO or program-specific DMS requirements

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NIH SCIENTIFIC DATA SHARING

Search

NIH Staff | FAQ

DATA MANAGEMENT AND SHARING POLICY GENOMIC DATA SHARING POLICY OTHER SHARING POLICIES ACCESSING DATA

Expediting the Translation of Research Results

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.

Featured Webinar: Data Management Understanding

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 quality. Learn about best practices for scientific data management.

Learning

Find resources and training opportunities for NIH sharing policies. We will continue to post additional resources, so check back frequently.

Webinars

- **REGISTER NOW!** A Conversation with NIH: Implementing the New Data Management and Sharing Policy
 - Webinar I: Understanding the New NIH Data Management and Sharing Policy - August 11, 2022
 - Resource Slide Deck **NEW**
 - Webinar Recording **NEW**
 - Webinar II: Diving Deeper into the New NIH Data Management and Sharing Policy - September 22, 2022
 - Register

A recording of each webinar will be available on this page approx. 5-7 business days after the live event.

Website: [NIH Scientific Data Sharing](#)

FAQs: [DMS Policy FAQs](#)

Email Box: Sharing@nih.gov

Budget/Costing Questions:
grantspolicy@nih.gov

Webinar Series: [NIH DMS Policy Implementation](#)

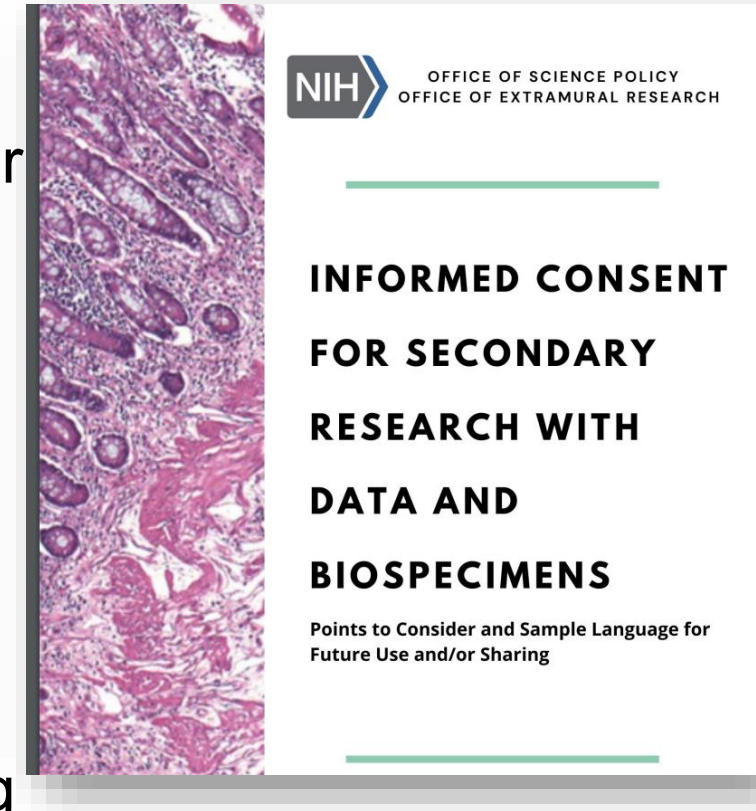
Extra Slides



- **NOT-OD-21-013** – Final NIH Policy for Data Management and Sharing
- **NOT-OD-21-014** – Supplemental Information to the NIH Policy for Data Management and Sharing: Elements of an NIH Data Management and Sharing Plan
- **NOT-OD-21-015** – Supplemental Information to the NIH Policy for Data Management and Sharing: Allowable Costs for Data Management and Sharing
- **NOT-OD-21-016** – Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research

- **NOT-OD-22-189** – Implementation Details for the NIH Data Management and Sharing Policy (August 5)
- **NOT-OD-22-195** – New NIH "FORMS-H" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2023 (August 8)
- **NOT-OD-22-198** – Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023 (August 31)
- **NOT-OD-22-213** – Supplemental Information to the NIH Policy for Data Management and Sharing: Protecting Privacy When Sharing Human Research Participant Data (September 21)
- **NOT-OD-22-214** – Supplemental Information to the NIH Policy for Data Management and Sharing: Responsible Management and Sharing of American Indian/Alaska Native Participant Data (September 21)

- Policy encourages researchers and institutions to establish robust consent processes, but:
 - Does not establish additional consent expectations
 - Does not require consent be obtained any particular way (e.g., broad consent)
- Policy recognizes limitations on data sharing based on the informed consent process
- Informed Consent Resources:
 - Points to consider
 - Sample language for future use and/or data sharing



[Informed Consent Resource](#)

Supplemental Information for Protecting Privacy When Sharing Human Research Participant Data

- Provides a basic **framework for considering how to protect privacy** when sharing data from human participants
- Not intended as a guide for regulatory compliance
- **Broadly applicable** to different research contexts
- Establishes shared principles, provides best practices, and offers considerations for determining **whether to control access to data**

NOT-OD-22-213



Supplemental Information: Responsible Management and Sharing of American Indian/ Alaska Native Participant Data

- Information to assist in developing appropriate DMS Plans
- Best Practices for Responsible Management and Sharing of AI/AN Participant Data
- Emphasizes:
 - ✓ Respect for Tribal Sovereignty
 - ✓ Partnerships and mutual agreements
 - ✓ Building trust
- Developed through Tribal Consultation and stakeholder engagement beginning in 2019

NOT-OD-22-214

