Mass General Brigham

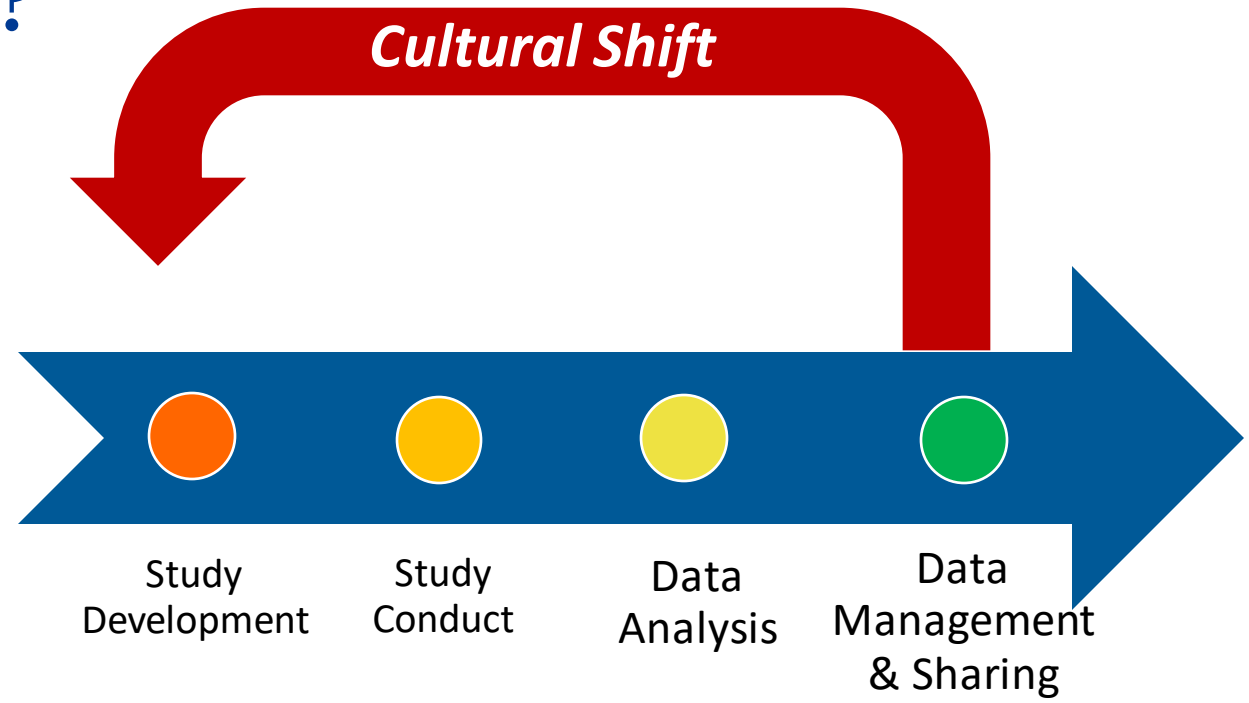
NIH Policy for Data Management and Sharing

Effective January 25, 2023
NIH Data Management and Sharing Policy Basics

- Requires submission of a Data Management and Sharing Plan (DMS Plan) that outlines how scientific data and any accompanying metadata will be managed and shared, *taking into account any potential restrictions or limitations.*
- Defines specific timeframes within which data must be shared
- Identifies costs that may and may not be included in the budget
- Requires the PI to submit revisions to DMP during regular reporting intervals or sooner
- Includes NIH compliance approach

Why is this Required by NIH?

- Promote a cultural shift towards making management and sharing of scientific data the norm
  - Emphasis on importance of good data management practices
  - Establishes the expectation for maximizing the appropriate sharing of scientific data generated, with justified limitations or exceptions



Prospectively plan for how scientific data will be preserved and shared

Research that falls under the NIH DMS Policy

All research that results in the generation of scientific data, and is funded or conducted, in whole or in part by NIH.

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

Scientific Data Definition:
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.*

Scientific Data Does Not Include

- Laboratory notebooks
- Preliminary analyses
- Completed case report forms
- Drafts of scientific papers
- Plans for future research
- Peer reviews
- Communications with colleagues
- Physical objects, such as laboratory specimens.

NOTE: The definition of Scientific Data and what is not included only applies to the NIH DMS Policy and does not apply to institutional requirements for data retention.

NIH DMS Policy Does NOT Apply

Research projects and other activities that do not generate scientific data, or non-research projects

- 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)

Implementation of the Effective Date

Includes:

Funding Type	Effective Date
Competing grant applications and Contract proposals	Submitted to NIH for deadlines starting January 25, 2023, and subsequent receipt dates
Other funding agreements (e.g., Other Transactions)	Executed on or after January 25, 2023, unless otherwise stipulated by NIH

NOTE: The Policy is NOT retroactive to currently funded projects. However, if you submit a competitive renewal on/after Jan 25, 2023, then the policy applies.

A few more definitions…

Data Management and Sharing Plan (Plan): A plan describing the data management, preservation, and sharing of scientific data and accompanying metadata.

Data Management: The process of validating, organizing, protecting, maintaining, and processing scientific data to ensure the accessibility, reliability, and quality of the scientific data for its users.

Metadata: Data that provide additional information intended to make scientific data interpretable and reusable (e.g., date, independent sample and variable construction and description, methodology, data provenance, data transformations, any intermediate or descriptive observational variables).

Key Differences: 2003 Policy vs 2023 Policy

2003 Data Sharing Policy

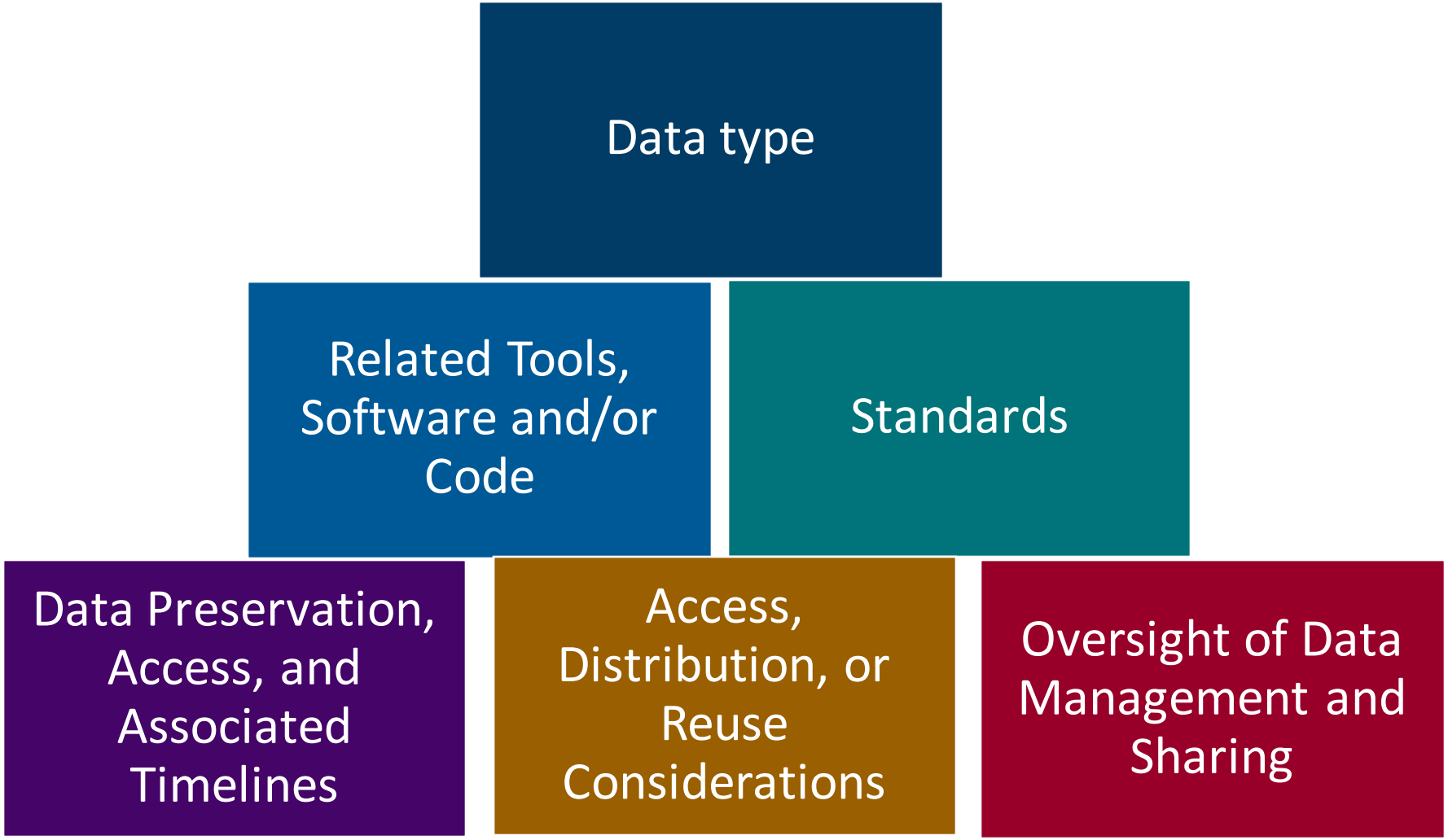
- Applied to awards of $500,000 or more per year
- Plan for data sharing
- Could be 1 paragraph

2023 Data Management & Sharing Policy

- Applies regardless of funding level
- Adds management to the plan
- Requires more details, but limited to 2 pages

Plan Components

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


Data type
Related Tools, Software and/or Code
Standards
Data Preservation, Access, and Associated Timelines
Access, Distribution, or Reuse Considerations
Oversight of Data Management and Sharing

Data type

Section 1

Briefly describe the scientific data to be managed, preserved, and shared, including:

Types of data	*256-channel EEG data and fMRI images*
Amount of scientific data to be generated/used in the research	*from 50 research participants* Descriptions may include • Data modality (e.g., imaging, genomic, mobile, survey) • Level of aggregation (e.g., individual, aggregated, summarized) and/or degree of data processing
A description of which scientific data from the project will be preserved and shared.	• NIH does not anticipate that researchers will preserve and share all scientific data generated in a study. • Researchers should decide which scientific data to preserve and share based on ethical, legal, and technical factors and the reasoning for these decisions.
A brief listing of the metadata, other relevant data, and any associated documentation that will be made accessible to facilitate interpretation of the scientific data	*Study protocols and data collection instruments*

Section 2

Whether specialized tools are needed to access or manipulate shared scientific data to support replication or reuse, and name(s) of the needed tool(s) and software.

- If applicable, specify how needed tools can be accessed (e.g., open source and freely available, generally available for a fee in the marketplace, available only from the research team)
- If known, whether such tools are likely to remain available for as long as the scientific data remain available

Standards

An indication of what standards will be applied to the scientific data and associated metadata.

- Data formats, data dictionaries, data identifiers, definitions, unique identifiers, and other data documentation
- While many scientific fields have developed and adopted common data standards, others have not. In such cases, the DMS Plan may indicate that no consensus data standards exist for the scientific data and metadata to be generated, preserved, and shared.

Section 4

- The name of the repository(ies) where scientific data and metadata will be archived.

See Selecting a Data Repository)

- How the scientific data will be findable and identifiable

(i.e., via a persistent unique identifier or other standard indexing tools.)

- When the scientific data will be made available to other users and for how long
  - Identify any differences in timelines for different subsets of scientific data to be shared.

(i.e., the larger research community, institutions, and/or the broader public)

Note: NIH encourages

- Making scientific data available for as long as they anticipate it being useful for the larger research community, institutions, and/or the broader public

- To consider relevant requirements and expectations as guidance for the minimum time frame scientific data should be made available. (e.g., data repository policies, award record retention requirements, journal policies)

Section 5

NIH expects researchers will maximize the appropriate sharing of scientific data generated consistent with privacy, security, informed consent, and proprietary issues.

Describe any applicable factors affecting subsequent access, distribution, or reuse of scientific data related to:

- Informed consent restrictions (e.g., disease-specific limitations, particular communities' concerns)
- Privacy or safety of human participants at risk even with protections such as de-identification
- Whether access to scientific data derived from humans will be controlled (i.e., made available by a data repository only after approval)
- Any restrictions imposed by federal, Tribal, or state laws, regulations, or policies, or existing or anticipated agreements
  - May include de-identification requirements, restrictions under Certificates of Confidentiality, and other protective measures
  - Consider agreement terms from third party funders, with partners, with Health Insurance Portability and Accountability Act (HIPAA) covered entities that provide Protected Health Information under a data use agreement, through licensing limitations attached to materials needed to conduct the research, etc.

Do NOT propose these as limitations:

- Data are too small
- Data are not likely to be used very widely
- There's not an appropriate repository for deposition

From webinar: *Understanding the New NIH Data Management and Sharing (DMS) Policy*
August 11, 2022
NIH Office of Extramural Research
NIH Office of Science Policy

Section 6

Indicate how compliance with the DMS Plan will be monitored and managed, frequency of oversight, and by whom (e.g., titles, roles).

NOTE: This is requesting information on how the DMS Plan will be monitored/managed *internally*

Sharing Timeline

- As soon as possible
- No later than the time of publication in a peer-reviewed journal OR the end of performance period, *whichever comes first*.
  - If no-cost extension, then at time of first publication or end of extended performance period, whichever comes first
  - SBIR/STTR may withhold applicable data for 20 years after the award date, as stipulated in the specific SBIR/STTR funding agreement and consistent with achieving program goals
  - Other policies or funding awards may require earlier sharing

Sharing is expected even if null or negative results or no publication

Choosing a Repository

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

Funding Mechanism Designated

For some programs and types of data, the funding mechanism may identify particular data repositories (or sets of repositories) to be used to preserve and share data. When this is the case, researchers should use the designated data repository(ies).

If not designated by funder

Use Established Repositories

NIH encourages the use of established data repositories

- Compliance with FAIR (Findable, Accessible, Interoperable, and Re-usable)
- NIH does not necessarily support repositories for all data that are to be share under the policy
- Researchers may need to use repositories supported by other organizations, both public and private

What if No Repository is Specified by Funding Mechanism?

Select a data repository that is appropriate for the data generated and is in accordance with the desired characteristics.

Considerations:

- Primary consideration should be given to data repositories that are discipline or data-type specific to support effective data discovery and reuse.
  - NIH makes a list of such data repositories available (https://www.nlm.nih.gov/NIHbmic/domain_specific_repositories.html).

Resources to Find Appropriate Repositories

[Repositories for Sharing Scientific Data | Data Sharing (nih.gov)]

NIH-supported Scientific Data Repositories*

Institute or Center	Repository Name	Repository Description	Open Data Submission	Data Submission Policy	Open Time Frame for Data Deposit
All		nhgri			
NHGRI	The NHGRI Genomic Data Science Analysis, Visualization, and Informatics Lab-space (AnVIL)	The NHGRI Genomic Data Science Analysis, Visualization, and Informatics Lab-space (AnVIL) is a scalable and interoperable resource for the genomic scientific community, that leverages a cloud-based infrastructure for democratizing genomic data access, sharing and computing across large genomic, and genomic-related data sets.	Yes	How to submit data to AnVIL	Yes

NIH-supported Scientific Data Repositories*

Institute or Center	Repository Name	Repository Description	Open Data Submission	Data Submission Policy	Open Time Frame for Data Deposit
All		genomic			
NCI	Genomic Data Commons (GDC)	The mission of the GDC is to provide the cancer research community with a unified data repository that enables data sharing across cancer genomic studies in support of precision medicine. The GDC contains clinical, biospecimen, and molecular data from several cancer research programs.	Yes	How to submit data to GDC	Yes
NCI	Proteomic Data Commons (PDC)	The Proteomic Data Commons hosts mass spectra and process data from cancer proteomic experiments. Many datasets have corresponding genomic and/or imaging data available in other nodes of the Cancer Research Data Commons.	Yes	How to submit data to PDC	Yes
NCI	The Cancer Imaging Archive (TCIA)	TCIA is a service which de-identifies and hosts a large archive of medical images of cancer accessible for public download. The data are organized as "Collections", typically patients related by a common disease (e.g. lung cancer), image modality (MRI, CT, etc) or research focus. DICOM is the primary file format used by TCIA for image storage. Supporting data related to the images such as patient outcomes,	Yes	How to submit data to TCIA	Yes

What if No Repository is Specified by Funding Mechanism?

If no appropriate discipline or data-type specific repository is available, researchers should consider a variety of other potentially suitable data sharing options:

- Small datasets (up to 2 GB in size) may be included as supplementary material to accompany articles submitted to PubMed Central (https://www.ncbi.nlm.nih.gov/pmc/about/guidelines/#suppm).
- Data repositories, including generalist repositories (https://www.nlm.nih.gov/NIHbmic/generalist_repositories.html) or institutional repositories, that make data available to the larger research community, institutions, or the broader public.
- Large datasets may benefit from cloud-based data repositories for data access, preservation, and sharing.

Additional Repositories and Guidance

- Generalist repositories
- Nature's Data Repository Guidance
- Registry of Research Data Repositories

Also available on the NIH Repository search page at
Repositories for Sharing Scientific Data | Data Sharing (nih.gov)

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

Additional Considerations for Repositories Storing Human Data

- Exhibit the *Desirable Characteristics for All Repositories*, particularly with respect to confidentiality, security, and integrity.
  AND
- Exhibit the following *Additional Considerations*:

  - ✓ Fidelity to Consent
  - ✓ Restricted Use Compliant
  - ✓ Privacy
  - ✓ Plan for Breach
  - ✓ Download Control
  - ✓ Violations
  - ✓ Request Review

Additional Considerations apply even when repositories store only **de-identified** human data because…

Re-identification is always a risk making the protection of privacy and security additionally important

Other Policies may apply in addition to the DMS

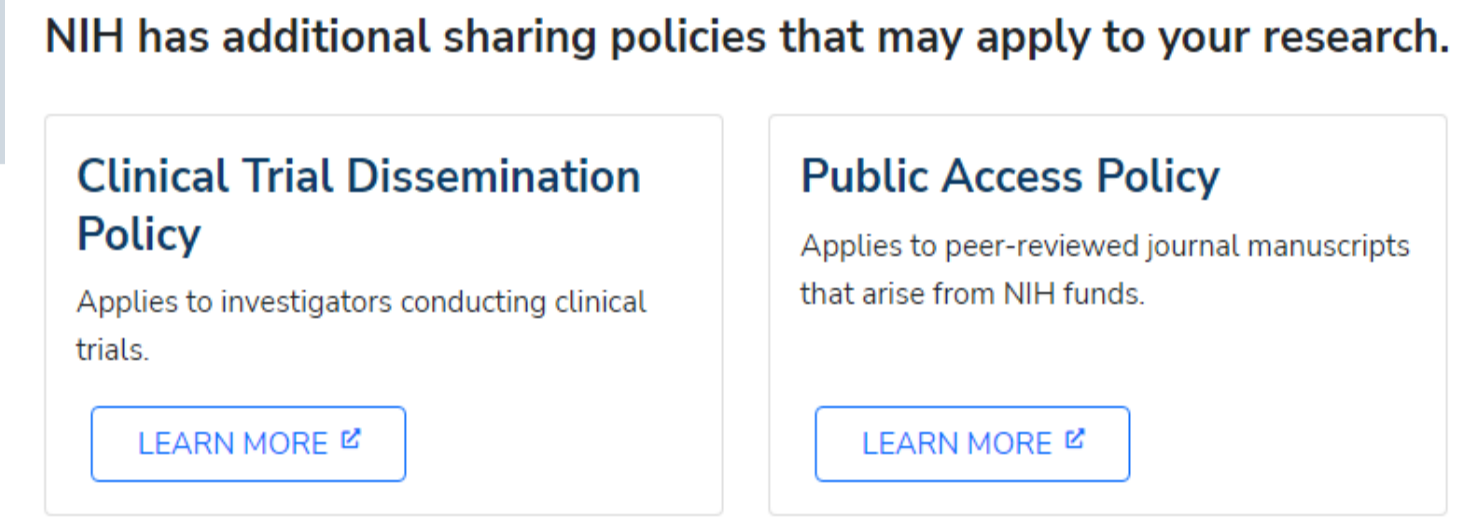
Additional Considerations

- Plans may be publicly available
  - Do not include proprietary or private information
  - NIH is still assessing when/how this may be enacted
- Be aware you may need to comply with other sharing policies in addition to the NIH DMS Policy
  - NIH DMS Policy is the foundation, ICOs and programs may build on policy
  - Other policies may apply and be have more detailed requirements
  - When more than one policy applies, you are obligated to comply with all requirements

Resources to Identify Other Policies that Apply

Which Policies Apply to My Research?

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



Resources to Identify Other Policies that Apply

NIH Institute and Center Data Sharing Policies | Data Sharing

NIH Institute and Center Data Sharing Policies

Data sharing is a priority across NIH. To this end, many institutes, centers, and research programs have instituted specific data sharing policies in addition to the trans-NIH policies. These policies are listed in the table below. Note that individual funding opportunities may specify other requirements or expectations, so be sure to read all instructions carefully.

Institute or Center	Data Sharing Policy Name	Description of Data Sharing Policy	Repositories
NHLBI	NHLBI Policy for Data Sharing from Clinical Trials and Epidemiological Studies	Encourages all applicants to include a plan to address data sharing or to state why data sharing is not possible. For studies that meet the the following criteria, applicants are are required to provide a data sharing plan, which will be reviewed and approved by the relevant NHLBI program official: a) research applications/proposals requesting $500000 direct costs; b) research studies that have 500 or more participants c) ancillary studies based on NHLBI-funded parent studies d) applications/proposals submitted in response to FOAs that specify includsion of data sharing plans; or e) other research studies deemed appropriate for data sharing by NHLBI program official investigators.	NHLBI data repository, BioLINCC

Proposal Submission and Award Management

NIH, AHRQ, and FDA Proposals: Summary of Changes

For all proposals with a submission deadline of January 25, 2023 or later, all proposals will be submitted using new form set, **Forms-H**.

Data Management & Sharing Plan

- New required attachment with a two-page limit uploaded under "Other Plan(s)"
- Data sharing plans and genomic data sharing plans will no longer be submitted under Resource Sharing Plan(s)
- Optional NIH format page will be available

Budgeting for Data Management & Sharing

- Direct Costs to support activities proposed in the DMS Plan must be included in the R&R budget
- Brief description of the plan and direct costs must be included in the appropriate Budget Justification attachment

New NIH “Forms-H” Grant Application Forms

NOT-OD-22-195: New NIH "FORMS-H" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2023

Due Dates on or before January 24, 2023	Dues Dates on or after January 25, 2023
FORMS-G	FORMS-H
• Applications submitted for due dates on or before January 24, 2023 • Applications submitted under NIH Late Policy 2-week window of consideration for intended due dates on or before January 24, 2023 • Applications submitted by February 1, 2023 under NIH Continuous Submission Policy for the January 7, 2023 AIDS intended due date	• Applications submitted for due dates on or after January 25, 2023 • All application types (New, Resubmission, Renewal, Revision) • Applications submitted early for intended due dates on or after January 25, 2023

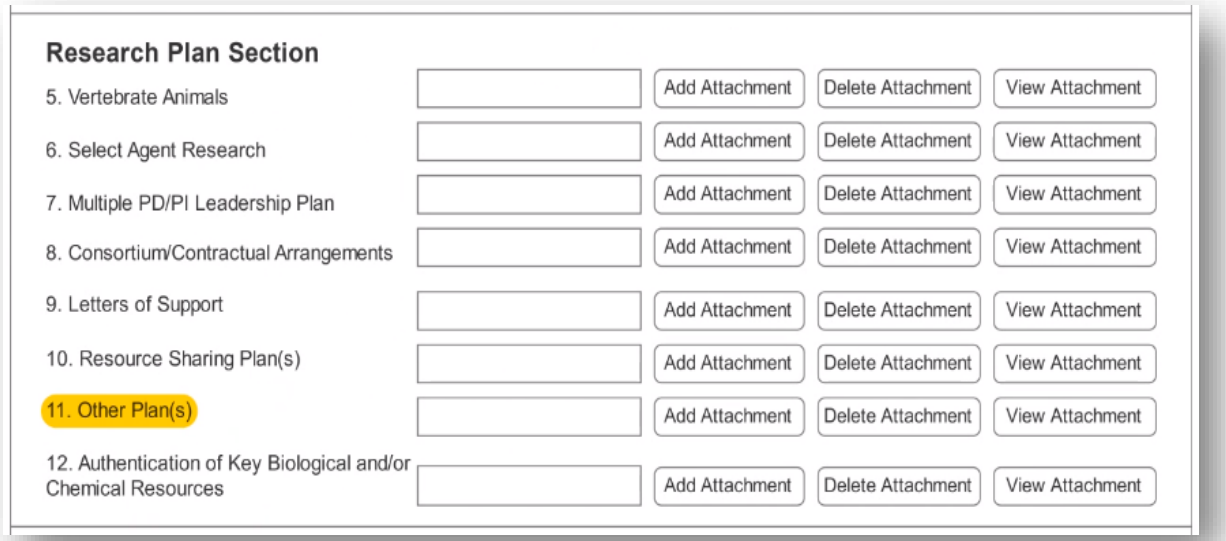
When will new application packages (Forms-H) be available?

- **New Funding Opportunity Announcements** posted beginning October 25, 2022 with initial due dates on or after January 25, 2023 will be posted with *FORMS-H* application packages, as appropriate

- **All active Parent and IC-issued FOAs** with due dates on or after January 25, 2023 will be updated to add *FORMS-H* application packages by November 25, 2022, but no later than 30 calendar days prior to receipt dates

Data Management & Sharing Plan Attachment

- A new “Other Plan(s)” field will allow attaching a DMS Plan in the following:
  - PHS 398 Research Plan
  - PHS 398 Career Development Award Supplemental Form
- **Genomic Data Sharing** will be addressed in the overall Data & Management Sharing Plan
- The DMS Plan must be attached as a single PDF attachment with a length of two pages or less
- An optional Data Management and Sharing Plan format page will be provided to assist applicants with the preparation of this attachment.



Budgeting for Data Management and Sharing Activities

The requested direct costs to support the activities proposed in the DMS Plan must be indicated as "Data Management and Sharing Costs" as follows:

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.	

R&R Budget Form: single line item in section *F. Other Direct Costs*

A description of the requested Data Management and Sharing Plan and Costs must be included within the budget justification attachment for *the R&R Budget Form*, or in the *Additional Narrative Justification* for *PHS Modular Budget Form*.

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

Allowable Costs in NIH Budget for DMS Plans

NOT-OD-21-015: Supplemental Information to the NIH Policy for Data Management and Sharing: Allowable Costs for Data Management and Sharing

Allowable Costs

- Curating data and developing supporting documentation
- Local data management considerations
- Preserving and sharing data through established repositories

NOTE: All costs must be incurred during the project performance period

Unallowable Costs

- Infrastructure costs that are part of F&A (costs may not be double charged or inconsistently charged as both direct and indirect costs.)
- Costs associated with routine conduct of research
- Costs associated with collecting or otherwise gaining access to research data (e.g., data access fees) are considered costs of doing research

Working with Digital Research Team to create inventory of existing resources to create guidance document to help with budgeting at proposal stage

How are DMS Plans Assessed?

During Review	NIH IC Staff	• Ensure Elements of the DMS Plan have been adequately addressed • Assess the reasonableness of the responses • Applications selected for funding will only be funded if the DMS plan is complete and acceptable
	Peer Review	• DMS Plans will **not** be evaluated by peer reviewers and will not be factored into the Overall Impact score • DMS Plan attachment is not sent to peer reviewers, *unless sharing data is integral to the project design and specified in the FOA.*** • Peer Reviewers will see the proposed budget and the Budget Justification for DMS Plan and may evaluate the reasonableness of the budget request ***Where data sharing is integral to the project design and tied to a scored review criterion, peer reviewers will be able to view the DMS Plan attachment and may factor that information into the score as outlined in the evaluation criteria.*

What Happens After Funding Decision?

JIT	Program Officer or Grants Management Specialist	• NIH will notify applicant if additional information is required • May require submission of a revised DMS Plan • Award will not be made until DMS Plan is approved
Post-Award	PI/Institution	• Approved DMS Plan becomes Term and Condition of Award • Progress reported in RPPR • May revise DMS Plan at RPPR or other times with approval by the funding NIH Institute/Center (IC)

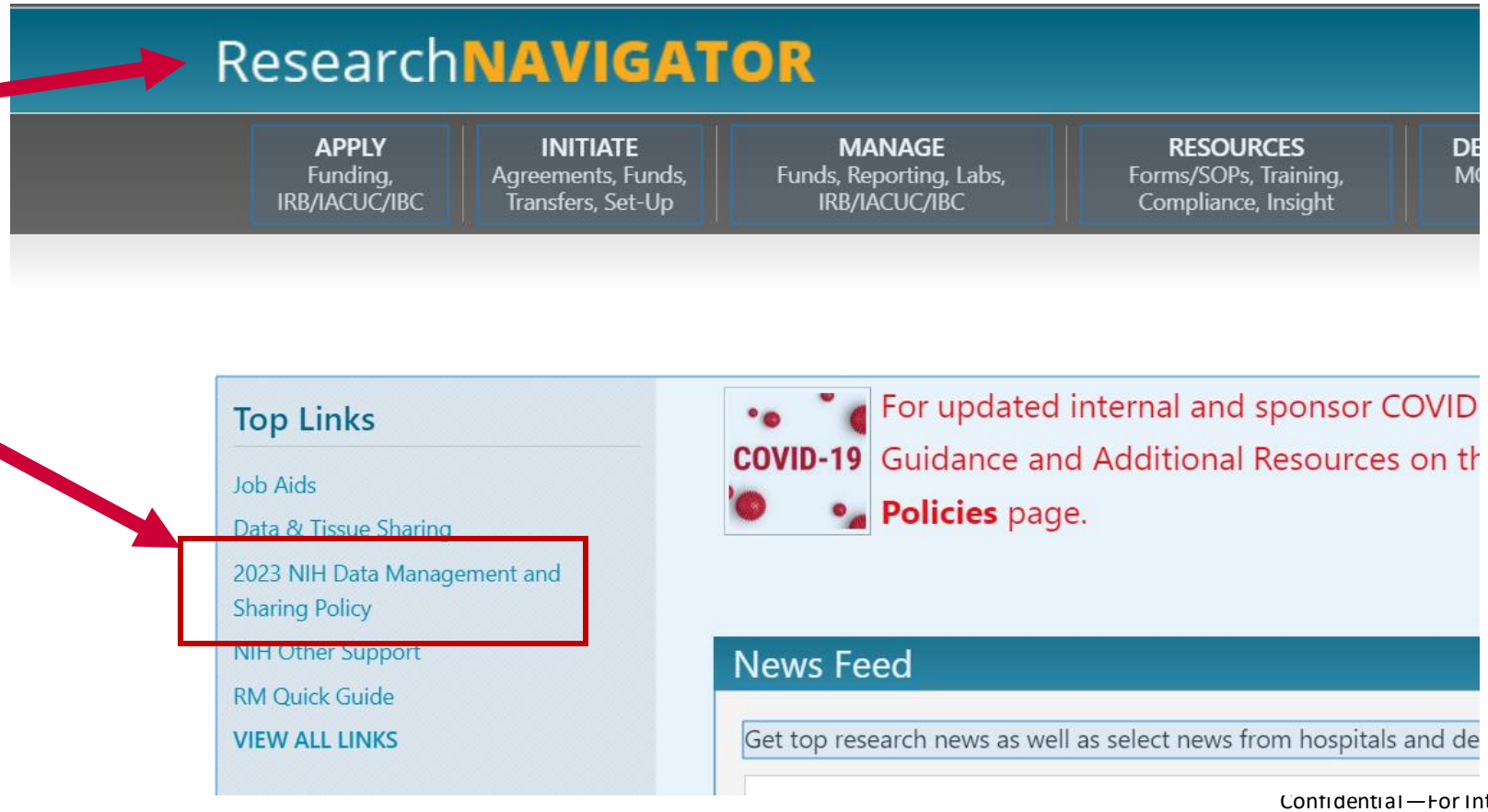
	NIH IC Staff	• Review annually for compliance
		• Noncompliance:
		  • Enforcement Action
		  • Additional special terms and conditions
		  • Termination of award
		  • Impact future funding decisions

Additional Resources and Information

Research Navigator Website

Pages - 2023 NIH Data Management & Sharing Policy (sharepoint.com)

Click on Research Navigator from any page and then use Top Links




Mass General Brigham

Resources

NIH Final Policy on Data Management and Sharing Supplemental Information • Elements of an NIH Data Management and Sharing Plan • Allowable Costs for Data Management and Sharing • Selecting a Repository for Data Resulting from NIH-Supported Research	**NOT-OD-21-013** **NOT-OD-21-014** **NOT-OD-21-015** **NOT-OD-21-016**
Implementation Details for the NIH Data Management and Sharing Policy New NIH "FORMS-H" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2023	NOT-OD-22-189 NOT-OD-22-195
NIH Home Page on Data Sharing	Home Page | Data Sharing (nih.gov)
NIH FAQ on Data Management & Sharing Policy	Frequently Asked Questions (FAQs) | Data Sharing (nih.gov)
NIH email for questions	Sharing@nih.gov
Council on Government Relations (COGR) Home Page for NIH DMS Policy	NIH Data Management and Sharing | Council on Governmental Relations (cogr.edu)
COGR Policy Matrix of Funding Requirements on Sharing	NIH DMS Policy Matrix 070522_V1.0.xlsx (live.com)

Resources

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NIH Home Page on Data Sharing	Home Page | Data Sharing (nih.gov)
NIH FAQ on Data Management & Sharing Policy	Frequently Asked Questions (FAQs) | Data Sharing (nih.gov)
NIH email for questions	Sharing@nih.gov
Council on Government Relations (COGR) Home Page for NIH DMS Policy	NIH Data Management and Sharing | Council on Governmental Relations (cogr.edu)
COGR Policy Matrix of Funding Requirements on Sharing	NIH DMS Policy Matrix 070522_V1.0.xlsx (live.com)

NOTES FOR US – Other Development

Review of Limitations in depth
Informed Consent Changes

Not Available yet:

Requests for comment on Changing NIH Genomic Data Sharing Policy

NOT-OD-22-029: Request for Information on Proposed Updates and Long-Term Considerations for the NIH Genomic Data Sharing Policy

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

NOT-OD-22-104: Notice of Extension of the Public Comment Period for NOT-OD-22-064 DRAFT Supplemental Information to the NIH Policy for Data Management and Sharing: Responsible Management and Sharing of American Indian/ Alaska Native Participant Data (April 28, 2022)

NOT-OD-22-064: Request for Public Comments on DRAFT Supplemental Information to the NIH Policy for Data Management and Sharing: Responsible Management and Sharing of American Indian/ Alaska Native Participant Data

Request for Comment on Supplemental Information on Protecting Privacy

NOT-OD-22-131: Request for Public Comments on DRAFT Supplemental Information to the NIH Policy for Data Management and Sharing: Protecting Privacy When Sharing Human Research Participant Data (May 12, 2022 due June 27, 2022)