NIH Data Management and Sharing Policy

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Talk Outline

- DMS Policy Details
- Budget, Justification, and Submission
- The DMS Plan Elements 1 to 6

Useful Overview Page:

https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing/writing-a-data-management-and-sharing-plan#after

Applications for Receipt Dates
BEFORE Jan 25 2023

Applications for Receipt Dates
ON/AFTER Jan 25 2023

Applications for Receipt Dates ON/AFTER Jan 25 2023

ON THIS PAGE:

- Submitting Data Management and Sharing Plans
- Data Management and Sharing Plan Format
- @ Elements to Include in a Data Management and Sharing Plan
- Sample Plans
- Assessment of Data Management and Sharing Plans
- Prevising Data Management and Sharing Plans
- Additional Considerations

From the NIH Grants Conference (Feb 1-2, 2023) — The NIH Policy for Data Management and Sharing (DMS) in Effect: Planning for Success

Goals of Data 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

From the NIH Grants Conference (Feb 1-2, 2023) — The NIH Policy for Data Management and Sharing (DMS) in Effect: Planning for Success

Policy Details

- 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 <u>scientific data</u>
 - What's in: "Recorded factual material... of <u>sufficient quality to validate and replicate</u>
 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 <u>publication</u> or <u>end of award</u> (for unpublished data), whichever comes first
 - How long to share data: Consider other relevant requirements and expectations (e.g., journal policies, repository policies)

Whatever is used to make tables or figures that can be validated and replicated





More on Submission and Compliance

- Submission: If a DMS Plan is <u>required</u> for that activity code and not included in the submission, 'it will likely be <u>returned</u> without review' (eRA validation)
- Compliance will be monitored by Program Officers during the annual progress report reviews (RPPR); noncompliance may result in (1) termination of award, (2) addition of special Terms and Conditions of Award and (3) factored into future funding decisions

Is your proposed research subject to new DMS policy?

✓ All NIH research that results in the generation of scientific data

Subject to DMS Policy (Examples)

- Research Projects (Rs)
- Some Career Development Awards (Ks)
- Small Business SBIR/STTR
- Research Centers (Ps)
- Cooperative Agreements (Us)

Not Subject to DMS Policy

- Training (Ts)
- Fellowships (Fs)
- Some conference grants (R13)
- Construction
- Resource Centers (Gs)
- Research-Related Infrastructure Programs (e.g., S06, S10)

NIH Activity Codes subject to DMS Policy

https://sharing.nih.gov/sites/default/files/flmngr/List-of-Activity-Codes-Applicable-to-DMS-Policy.pdf

This is a partial screenshot of page 1 of the List of
Activity Codes pdf

There are <u>19 pages</u> in this document, listing Program Codes from **D** to **U**

NIH Data Management and Sharing Policy: Applicable Activity Code:

Revised on December 16, 2022

A comprehensive listing of all NIH activity codes that generally require applicants to submit a Data Management and Sharing Plan.

rogram Code	Activity Code	Category	Title	Description	DMS Plan Requirement
D	DP1	Institutional Training and Director Program Projects	NIH Director's Pioneer Award (NDPA)	To support individuals who have the potential to make extraordinary contributions to medical research. The NIH Director's Pioneer Award is not renewable.	Υ
D	DP2	Institutional Training and Director Program Projects	NIH Director's New Innovator Awards	To support highly innovative research projects by new investigators in all areas of biomedical and behavioral research.	Υ
D	DP3	Institutional Training and Director Program Projects	Type 1 Diabetes Targeted Research Award	To support research tackling major challenges in type 1 diabetes and promoting new approaches to these challenges by scientific teams.	Υ
D	DP4	Institutional Training and Director Program Projects	NIH Director's Pathfinder Award - Multi-Yr Funding	To support multi-year funded research with unique, high impact ideas for addressing biomedical research including assuring a balanced and effective workforce. This research grant program will encourage exceptionally creative scientists to develop potentially transforming approaches for supported research. The proposed research must reflect ideas that are substantially different from those already being pursued or they must apply existing research designs in new and innovative ways. This is a multi-year, funded companion activity code to the existing Pioneer Award (DP1); thus ICs need OER prior approval to use the DP4.	Υ
D	DP5	Institutional Training and Director Program Projects	Early Independence Award	To support the independent research project of a recent doctoral degree recipient. This research grant program will encourage exceptionally creative scientists to bypass the typical post-doc research training period in order to move rapidly to research independence. It will encourage institutions to develop independent career tracks for recent graduates in order to demonstrate the benefits of early transition to independence both in terms of career productivity for the candidate and research capability for the institution.	Υ
E	E11	Health Professions Programs	Grants for Public Health Special Projects	To provide grants to public or nonprofit organizations for planning, development, demonstration, research, training, public information projects for preventive medicine, health promotion and disease prevention to improve the health of targeted populations.	Y
К	Коо	Research Career Programs	Post-doctoral Transition Award	To support the second phase of a Pre-Doctoral to Post-Doctoral Transition award program that provides 3-4 years of career support. Note: The K00 Post-doctoral Transition Award is anticipated to only be used in conjunction with the F99 Pre-Doctoral Award.	Y
К	K01	Research Career Programs		For support of a scientist, committed to research, in need of both advanced research training and additional experience.	Υ

Policy for No Cost Extensions & Competitive Renewals

- No cost extension: share scientific data no later than the time of an associated publication, or the end of the no cost extension, whichever comes first
- Competitive renewals: a DMS Plan should be submitted at the time of the renewal funding application for research generating scientific data; if the previous award included a Plan, an updated Plan consistent with the proposed competitive renewal application should be submitted

Policy for Genomic Data

- On or after January 25, 2023, NIH will no longer collect separate
 Genomic Data Sharing (GDS) Plans
- Submit a single Plan, addressing genomic data sharing considerations (e.g., where and when genomic data will be shared) within DMS Plan Elements

For example: describe genomic data such as sequencing reads and variant call files in Element 1 (Data Types) of the DMS Plan

When should scientific data should be shared?

As soon as possible, whichever is earlier of these 2 timepoints

- No later than the than the date on which an associated publication is first made available in print or electronic format, or
- End of the performance period at this time, all scientific data including null and negative findings, other unpublished findings documented in conference proceedings, book chapters, preprints*, etc.

^{*}note that some preprint servers and data repositories may require that data be shared upon preprint posting

DMS Plan Submission

New **FORM-H** Package (effective 01/25/2023)

 new form field #11 called 'Other Plans' on the PHS 398 Research Plan Form

PHS 398 Research Plan Form

View Burden Statement	PHS 398 Research Pla	an	OMB Number: 0925-0 Expiration Date: 09/30/2
Introduction			
Introduction to Application (for Resubmission and Revision applications)	Add A	Attachment	Delete Attachment View Attachmen
Research Plan Section			
2. Specific Alms	Add /	Attachment	Delete Attachment View Attachme
3. *Research Strategy	Add A	Attachment	Delete Attachment View Attachme
4. Progress Report Publication List	Add A	Attachment	Delete Attachment View Attachme
Vertebrate Animals Select Agent Research			Delete Attachment View Attachment
6. Select Agent Research	Add A	Attachment	Delete Attachment View Attachme
7. Multiple PD/PI Leadership Plan	Add /	Attachment	Delete Attachment View Attachme
8. Consortium/Contractual Arrangements [Add A	Attachment	Delete Attachment View Attachme
9. Letters of Support	Add A	Attachment	Delete Attachment View Attachme
10. Resource Sharing Plan(s)	Add /	Attachment	Delete Attachment View Attachme
11. Other Plan(s)	Add /	Attachment	Delete Attachment View Attachme
Authentication of Key Biological and/or Chemical Resources	Add /	Attachment	Delete Attachment View Attachme
Appendix			
13. Appendix Add Attachments D	elete Attachments View Attachments		

DMS Plan Submission

New **FORM-H** Package (effective 01/25/2023)

form field #17 'Other Plans' on the **Career Development Award forms**

PHS 398 Career Development Award Supplemental Form

OMB Number: 0925-0001

View Burden Statement Expiration Date: 09/30/2024 Introduction Introduction to Application (for Resubmission and Revision applications) Candidate Section 2. Candidate Information and Goals for Delete Attachme View Attachmer Career Development Research Plan Section Specific Aims Add Attachment 4. * Research Strategy Add Attachment View Attachme 5. Progress Report Publication List (for Renewal applications) 6. Training in the Responsible Conduct Add Attachment Delete Attachment View Attachme of Research Other Candidate Information Section 7. Candidate's Plan to Provide Mentoring Delete Attachmen Mentor, Co-Mentor, Consultant, Collaborators Section 8. Plans and Statements of Mentor and Co-Delete Attachm View Attachmer Mentor(s) 9. Letters of Support from Collaborators. Add Attachment Delete Attachment View Attachme Contributors, and Consultants Environment and Institutional Commitment to Candidate Section Add Attachment 10. Description of Institutional Environment 11. Institutional Commitment to Candidate's Research Career Development 12. Description of Candidate's Contribution to Add Attachment Delete Attachment View Attachme Program Goals Other Research Plan Sections 13. Vertebrate Animals Delete Attachmen View Attachmen 14. Select Agent Research Add Attachment Delete Attachmer View Attachme 15. Consortium/Contractual Arrangements Add Attachment Delete Attachmer View Attachmer 16. Resource Sharing Delete Attachmer View Attachmer 17. Other Plan(s) Delete Attachment Add Attachment View Attachmen 18. Authentication of Key Biological and/or Add Attachment Delete Attachment View Attachmer Chemical Resources

How will DMS Plans be reviewed?

- ✓ by Program staff at the proposed NIH Institute, Center, Office (ICO)
 - Program staff will assess whether the DMS Plan has adequately addressed 6 recommended elements
 - Peer reviewers will not be asked to comment on the DMS Plan
 - The Plan will **not** factor into the <u>Overall Impact score</u> (*unless* data sharing is *integral* to the project design and specified in the FOA; in this case, it may be factored into the score)
 - Applications selected for funding will only be funded if the DMS Plan is complete and acceptable

DMS Plan revisions at the Pre-Award Stage

proposals with <u>fundable scores but without an approved</u> DMS plan will be asked for *more information* or submit a *revised Plan*

- applicants will be notified through the Just-in-Time (JIT) process that the DMS Plan cannot be approved as submitted and more information is needed
- applicants should communicate with their NIH ICO Program Officer and/or Grants Management Specialist to resolve issues (a revised Plan may be required)

DMS Plan revisions at the Post-Award Stage

- the Plan should be updated or revised when changes occur during the support period that affect how data is managed or shared
- The NIH ICO-approved DMS Plan becomes part of the Terms and Conditions of Award
- Potential changes should be discussed with the NIH ICO Program
 Officer
- The updated Plan should be approved by the funding NIH ICO

DMS Plan - BUDGET

A budget is **not** required, unless DMS-related costs are requested

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)

From the NIH Grants Conference (Feb 1-2, 2023) – The NIH Policy for Data Management and Sharing (DMS) in Effect: Planning for Success

DMS Plan – BUDGET Requesting Costs - R&R Detailed Budget Form

Label costs as 'Data Management and Sharing Costs' line item, under F. Other Direct Costs (anywhere between line items 8-17, as applicable)

IMPORTANT: Type in **\$0** if **not** requesting costs (or ASSIST will return 'error' message

Justifying Costs

- Recommended to be ½ a page
- Include brief summary of type and amount of scientific data to be preserved, shared, name of repository(ies) to be used, and general cost categories.

F. Other Direct Costs	Funds Requested (\$)
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.	
9.	T
Up to 10 additional Other Direct Costs line items can be added. Examp 10. Technical Assistance, and Patient Care Costs.	oles of possible uses: Tuition Remission,
11.	
#FORMS-H: If a Data Management and Sharing (DMS) plan is included	
12. and Sharing Costs" line item covering DMS costs, including personnel data for the project). If no cost incurred, enter 0. Type the string as req	
not combine the line item with any "Other" costs.	decida (Maroat quotation marito) and de
15.	
16.	
17.	
G. Direct Costs	
Total Direct Costs (A thru F)	Funds Requested (\$)
H. Indirect Costs	
Indirect Cost Type Indirect Cost Rate (%) Indirect Cost Base (\$)	Funds Requested (\$)
Total Indirect Costs	
Cognizant Federal Agency (Agency Name, POC Name, and	
POC Phone Number)	
I. Total Direct and Indirect Costs	Funds Requested (\$)
Total Direct and Indirect Institutional Costs (G + H)	
J. Fee	Funds Requested (\$)
K. Total Costs and Fee	Funds Requested (\$)
Total Costs and Fee (I + J)
L. Budget Justification	
(Only attach one file.) Add Attachment Delete Attach	ment View Attachment
Budget Justification is required and must cover all budget periods.	
FORMS-H: If a Data Management and Sharing (DMS) plan is included, you must include a sectio	n titled "Data Management
and Sharing Justification" that provides a brief brief summary of DMS activities and justification fo	r their costs.
	,

DMS Plan – BUDGET

Requesting and Justifying Costs

PHS 398 Modular BudgetForm

Use the **Additional Narrative Justification** attachment of the PHS 398 Modular Budget Form

✓ This attachment should have information on the requested costs and justification

The PHS 398 Modular Budget form cannot be used if the application requests >\$250K in direct costs in any budget period, is submitted by foreign institution, or proposes the use of human fetal tissue from elective abortions.

PHS 398 Modular Budget

OMB Number: 0925-0001 Expiration Date: TBD

	Budget Period: 1	Form allows for	or up to 5 Budget Per	riods.	
Start Date:	End Date:			,	
A. Direct Costs				Funds Requested (\$)	
Direct costs requested must be \$250K or less per p	period to		ortium Indirect (F&A)	0.00	
use Modular Budget form. Request in "modules" of			ortium Indirect (F&A) Total Direct Costs	0.00	
Some grant programs have limits on Total Direct C	osts. Check announcem	ent.	Total Direct Good	0.00	
B. Indirect (F&A) Costs Indirect (F&A) Type		Indirect (F&A) Rate (%)	Indirect (F&A) Base (\$)	Funds Requested (\$)	
Form allows for up to for four F&A entries.					
Cognizant Agency (Agency Name, POC Name and Phone !	Number)				
Indirect (F&A) Rate Agreement Date		Total	Indirect (F&A) Costs		
C. Total Direct and Indirect (F&A) Costs (A + E	3)	ı	Funds Requested (\$)	0.00	
Cur	mulative Budget Info	mation Sys	stem calculated.		
1. Total Costs, Entire Project Period					
Section A, Total Direct Cost less Consortium Indi	rect (F&A) for Entire Project	Period \$	0.00		
Section A, Total Consortium Indirect (F&A) for Entire Project Period \$					
Section A, Total Direct Costs for Entire Project Period \$ 0.00					
Section B, Total Indirect (F&A) Costs for Entire Project Period \$					
Section C, Total Direct and Indirect (F&A) Costs (A+B) for Entire Project Period \$ 0.00					
2. Budget Justifications	provide this attachme	nt and include a	a section titled "Data	an is included, you must Management and Sharing	
Personnel Justification	for their costs.	rides a brief brie	er summary of DMS a	activities and justification	
Consortium Justification		Add Attachment	Delete Attachment	View Attachment	
Additional Narrative Justification		Add Attachment	Delete Attachment	View Attachment	

Preparing the DMS Plan

- Structure: length and content
- DMS Plan Template https://grants.nih.gov/grants/forms/all-forms-and-formats/data-management-and-sharing-plan-format-page
- Sample DMS Plans https://sharing.nih.gov/datamanagement-and-sharing-policy/planning-and-budgeting-fordata-management-and-sharing/writing-a-data-managementand-sharing-plan#sample-plans

Showing Again: Overview Page has the relevant links

https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing/writing-a-data-management-and-sharing-plan#after

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- Data Management and Sharing Plan Format
- @ Elements to Include in a Data Management and Sharing Plan
- Sample Plans
- Assessment of Data Management and Sharing Plans
- Revising Data Management and Sharing Plans
- Additional Considerations

Preparing the DMS Plan - Structure

- Length: recommended to be 2 pages or less (except for large projects or those that generate many data types)
- Content: address 6 elements
 - 1) Data Type
 - 2) Related Tools, Software and/or Code
 - 3) Standards
 - 4) Data Preservation, Access, and Associated Timelines
 - 5) Access, Distribution, or Reuse Considerations
 - 6) Oversight of Data Management and Sharing
 - No hyperlinks (no URLs): use name of the data repository, dataset identifier, or relevant resource or NIH may withdraw your application from consideration

From the NIH Grants Conference (Feb 1-2, 2023) – The NIH Policy for Data Management and Sharing (DMS) in Effect: Planning for Success

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

The NIH Sharing Plan Format (Template)

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.qov. 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 Time-

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.

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.

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).)

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).

Sample Plans

9 DMS Plans are currently available at NIH, for *educational purposes only*. NIH notes that these documents are not intended to be used as templates; their use does **not guarantee** NIH approval

- Sample Plan A: Clinical and/or MRI data from human research participants
- Sample Plan B: Genomic data from human research participants
- Sample Plan C: Genomic data from a non-human source
- Sample Plan D: Secondary data analysis
- Sample Plan E: Human genomic data
- Sample Plan F: **Technology** development
- Sample Plan G: Human clinical and genomics data
- Sample Plan H: Gene expression analysis data from non-human model organism (zebrafish)
- Sample Plan I: Human survey data

DMS Plan – Element 1: Data Type

- A. Type and amount of scientific data expected to be generated in the project: In general terms, address the *type and amount/size* of scientific data expected to be collected and used in the project; indicate the *data modality* (e.g., imaging, genomic, mobile, survey), *level of aggregation* (e.g., individual, aggregated, summarized), and/or the *degree of data processing* (i.e., how raw or processed the data will be)
- B. Scientific data that will be preserved and shared, and the rationale NIH does not anticipate that all data will be preserved and shared. Decide which to preserve and share based on *ethical*, *legal*, *and technical* factors that may affect the extent to which data are preserved and shared. Provide the rationale for the decision
- C. Metadata and 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

DMS Plan – Element 2: Related Tools, Software and/or Code

• Indicate 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.

For example (1) data will be processed and analyzed with STATA and shared in many widely accessible formats, including SAS, STATA, SPSS, dBase, Excel, and ASCII

- (2) All newly developed software and code for processing and analyzing data will be distributed as version controlled, open-source code written in R or Python via GitHub, with detailed user documentation
- If applicable, specify how **needed tools** can be **accessed** (e.g., *open source* and *freely available* or 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.

DMS Plan – Element 3: Standards

 Many scientific fields have developed and adopted common data standards - indicate what standards will be applied (i.e., data formats, data dictionaries, data identifiers, definitions, unique identifiers, and other data documentation)

Example: RNA-Seq data: Data will be QC'd and analyzed according to ENCODE Bulk RNA-seq Data Standards. FASTQs, BAM alignment files, and TSV transcript quantifications will be shared.

In fields were there are no common standards, indicate that no consensus data standards exist for the scientific data and metadata to be generated, preserved, and shared.

DMS Plan – Element 4: Data Preservation, Access, and Associated Timelines

- A. Repository where scientific data and metadata will be archived: Will discuss in next few slides
- B. How scientific data will be findable and identifiable

 For example: 'The dataset will be registered in dbGaP and assigned an ID. Data will be findable and identifiable using standard data indexing tools. We will reference the accession number(s) for our dataset(s) in all relevant future publications
- C. When and how long the scientific data will be made available

 For example: 'We will meet the data submission and release timeframes specified by the DMS Policy as described on NIH's data sharing website';

 The data will be available for as long as the repository preserves the dataset

Data Repositories - Element 4 of DMS Plan

NIH Guidelines on Repositories

- Use <u>FOA</u>- or <u>ICO-designated</u> data repositories
- If no specific data repository is noted, select one that is <u>appropriate for</u> the data generated from the research project, as long as repository meets list of *desirable characteristics*
- Preference given to data repositories that are <u>discipline</u> or <u>data-type</u>
 <u>specific</u> to support effective data discovery and reuse

Selecting a data repository

https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/selecting-a-data-repository

Home > Data Management and Sharing Policy > Sharing Scientific Data > Selecting a Data Repository

Selecting a Data Repository

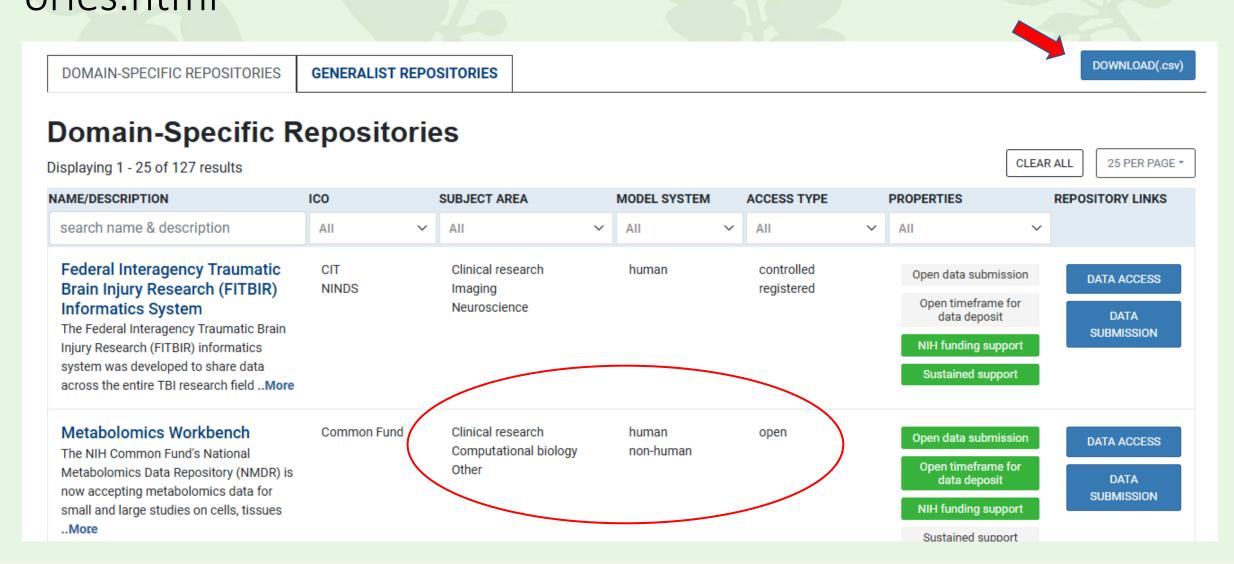
Learn how to evaluate and select appropriate data repositories.

ON THIS PAGE:

- Overview
- Selecting a Data Repository
- Desirable Characteristics for All Data Repositories
- Additional Considerations for Human Data
- Repositories for Scientific Data

NIH-Supported Repositories:

https://www.nlm.nih.gov/NIHbmic/domain_specific_reposit ories.html



Domain-Specific Repository Spreadsheet (from previous slide)

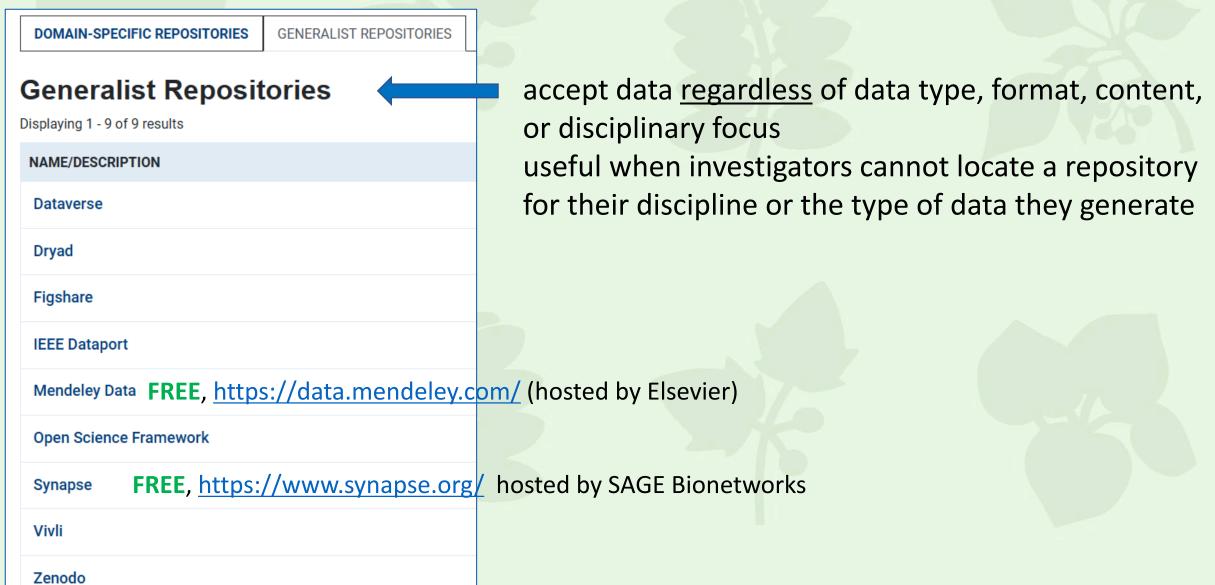
Has information on: URL, Subject Area, Access Type (open, registration required, controlled), Model System, and Open Data Submission

Open data submission: accepts data from a broad set of investigators; any investigator funded by a particular NIH ICO. There are **75** repositories that allow open data submission in this list

						1			
ICO	Repository_Name	Repository_Url	Description	Data_Subi Data_Access_Url	Subject_Area	Access_Type	Model_System	NIH_Fun	d Open_Data 🗐
Common I	Metabolomics Workbench	https://www.metabolomic	The NIH Common Fund's National Metabolomics Data Repos	https://whttps://www.metabolor	Clinical research, Compu	open	human, non-huma	TRUE	TRUE
Common I	Stimulating Peripheral Activity to	https://sparc.science	The SPARC Portal provides interactive access to a growing co	https://dc https://docs.sparc.scien	Clinical research, Compu	open	human, non-huma	TRUE	TRUE
Common I	Open Data Commons for Spinal Co	https://odc-sci.org/	The Open Data Commons for Spinal Cord Injury (ODC-SCI.org	https://ochttps://odc-sci.org/	Computational biology, N	controlled, regist	non-human	TRUE	TRUE
Common I	SenNet Consortium	https://data.sennetconsort	The goal of the Cellular Senescence Network (SenNet) is to i	undefinec undefined	Computational biology, I	controlled, regist	human, non-huma	TRUE	TRUE
Common I	4D Nucleome Data Portal	https://data.4dnucleome.o	The 4D Nucleome Data Portal is an open repository for genor	r https://da https://data.4dnucleom	Imaging, Sequence biolo	registered, open	human, non-huma	TRUE	TRUE
DPCPSI	Monarch Initiative	https://monarchinitiative.o	The Monarch Initiative is an integrative data and analytic pla	t undefinec https://archive.monarch	Clinical research, Imaging	open	human, non-huma	TRUE	TRUE
DPCPSI, N	The Universal Protein Resource (U	https://www.uniprot.org/	The Universal Protein Resource (UniProt) is a comprehensive	http://ww.https://www.uniprot.org	Sequence biology	open	human, non-huma	TRUE	TRUE
FIC, NCAT	INCLUDE Data Hub	https://portal.includedcc.or	The INCLUDE (INvestigation of Co-occurring conditions across	https://whttps://portal.includedc	Behavioral and social scie	controlled, regist	human, non-huma	TRUE	TRUE
NCATS	BioSystics Analytics Platform (BioS	https://mps.csb.pitt.edu/	The BioSystics Analytics Platform accesses, manages, analyze	https://m https://mps.csb.pitt.edu	Clinical research, Compu	registered, open	human, non-huma	TRUE	TRUE
NCATS, NI	National COVID Cohort Collaborat	https://covid.cd2h.org/	The N3C Data Enclave is a secure platform through which the	https://nchttps://covid.cd2h.org/a	Clinical research	controlled, regist	human	TRUE	TRUE
NCCIH	Natural Products Magnetic Resona	https://np-mrd.org/	The Natural Products Magnetic Resonance Database is a free	https://nr.https://np-mrd.org/dow	Other	open	non-human	TRUE	TRUE
NCCIH, NE	OpenNeuro	https://openneuro.org/	A free and open platform for validating and sharing BIDS-con	rundefinechttps://openneuro.org/s	Imaging	open	human, non-huma	TRUE	TRUE
NCCIH, NE	The DANDI Archive	https://dandiarchive.org/	The BRAIN Initiative archive for publishing and sharing neuro	undefined https://dandiarchive.org	Neuroscience	open	human, non-huma	TRUE	TRUE
NCCIH, NE	The Neuroscience Multi-omic Arch	https://nemoarchive.org/	The Neuroscience Multi-omic Archive (NeMO Archive) is a da	undefined https://nemoarchive.org	Sequence biology	controlled, open	human, non-huma	TRUE	TRUE
NCCIH, NE	Brain Image Library (BIL)	https://www.brainimagelib	The Brain Image Library (BIL) is a national public resource en	https://whttps://submit.brainima	Imaging, Neuroscience	open	human, non-huma	TRUE	TRUE
NCCIH, NE	Brain Observatory Storage Service	https://bossdb.org/	BossDB is a volumetric database for 3D and 4D neuroscience	undefinechttps://bossdb.org/proj	Imaging, Neuroscience	open	human, non-huma	TRUE	TRUE
NCI	Cancer Nanotechnology Laborator	https://cananolab.cancer.go	caNanoLab is a data sharing portal designed to facilitate info	https://wihttps://wiki.nci.nih.gov/	Other	registered, open	human	TRUE	TRUE
NCI	The Cancer Imaging Archive (TCIA)	https://www.cancerimaging	TCIA is a service which de-identifies and publishes medical i	https://whttps://www.cancerimag	Imaging	controlled, regist	human, non-huma	TRUE	TRUE
NCI	The Network Data Exchange (NDE)	https://www.ndexbio.org	NDEx is an online commons where scientists can upload, sha	https://hchttps://home.ndexbio.c	Computational biology, (open	human, non-huma	FALSE	TRUE
NCI, NIAIE	Protein Data Bank	https://www.rcsb.org/	The mission of the RCSB Protein Data Bank (PDB) is to sustain	https://w https://www.rcsb.org/	Computational biology, I	open	human, non-huma	TRUE	TRUE
NHGRI	The NHGRI Genomic Data Science	https://anvil.terra.bio	The NHGRI Genomic Data Science Analysis, Visualization, and	https://anhttps://anvilproject.org/	Clinical research, Compu	controlled, regist	human	TRUE	TRUE
NHGRI	Zebrafish Information Network (Z	https://zfin.org/	The Zebrafish Information Network (ZFIN) is the database of	https://zf https://zfin.org/	Sequence biology	open	non-human	TRUE	TRUE
NHGRI	WormBase	https://wormbase.org/#012	WormBase is an international consortium of biologists and co	https://whttp://www.informatics.	Rehavioral and social scie	open	non-human	TRUE	TRUE

NIH-Supported Repositories:

https://www.nlm.nih.gov/NIHbmic/domain_specific_repositories.html



Other good resources for finding suitable data repositories

https://www.nature.com/sdata/policies/repositories#general

View data repositories

- Biological sciences: Nucleic acid sequence; Protein sequence; Molecular & supramolecular structure; Neuroscience; Omics; Taxonomy & species diversity; Mathematical & modelling resources; Cytometry and Immunology; Imaging; Organism-focused resources
- Health sciences
- https://journals.plos.org/plosone/s/recommended-repositories

Repositories by type						
<u>Biochemistry</u>	<u>Neuroscience</u>	Social Sciences				
Biomedical Sciences	<u>Omics</u>	Structural Databases				
Marine Sciences	Physical Sciences	Taxonomic & Species Diversity				
Model Organisms	Sequencing	Unstructured and/or Large Data				

- https://data-repository-finder.ll.mit.edu/
- https://github.com there is a free option (basic service)

Data Repositories - More Options

- Small datasets (up to 2 GB in size): included as supplementary material to accompany articles submitted to PubMed Central
- University of Hawaii Cyberinfrastructure and the <u>UH Library</u> <u>System</u>: we are exploring these options (*should meet the* accessibility requirement of the NIH DMS Policy)

DMS Plan – Element 5: Access, Distribution, or Reuse Considerations (largely applicable to human subject research)

Discuss and justify applicable *factors* or *data use limitations* affecting subsequent access, distribution, or reuse of scientific data related to *informed consent*, *privacy*, *proprietary issues*, *confidentiality protections*, and any other considerations that may *limit* the extent of data sharing

- Informed Consent: discuss disease-specific limitations, particular communities' concerns
- <u>Protections</u> for privacy, rights, and confidentiality of human research participants (i.e., de-identification, Certificates of Confidentiality, and other protective measures)

For example: 'only genomic data will be shared; we are not obtaining demographic or phenotypic information from BIOBANK X'; OR 'upon receipt of an NIH Award, the data for this study will be protected by a Certificate of Confidentiality'

DMS Plan – Element 5 continued

- Discuss whether access to scientific data derived from humans will be controlled (i.e., made available by a data repository only after approval).
- Discuss any restrictions imposed by federal, Tribal, or state laws, regulations, or policies, or existing or anticipated agreements (e.g., with 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).

Please see sample DMS Plans with human subjects and clinical data

DMS Plan – Element 6: Oversight of Data Management and Sharing

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

For example:

The *study PI* will oversee the execution of this Data Management and Sharing Plan.

Progress on data sharing will be reported in the Research Performance Progress Report. If changes occur during the project that might affect the proposed data management and sharing plans, we will provide an update and/or revision.

A Few More Notes -

- Some NIH ICOs have ICO-specific DMS Plan requirements NIMH, for example requires use of their data repository, the NIMH Data Archive (or NDA). They also require a Validation Schedule in the Plan and submission of a Data Use Agreement signed by the PI and Institutional Official
- Some FOAs also have specific requirements
- If you need assistance, please go to the Pre-Award website and submit a ticket: https://jabsom.hawaii.edu/admin/dir-rge/support-for-research/

We request those who will receive NIH feedback on their submitted DMS Plans (sometime in June-July) to please share the feedback with us so that we can develop templates and examples for future submissions from JABSOM faculty

