NIH Data Management & Sharing Policy Virtual Information Session January 12, 2023

Research Data Management & Sharing Working Group

Co-Chaired by representatives at BU from the University Libraries, Information Services & Technology (IS&T), and the Office of Research:

Ashley Jester, Associate University Librarian for Research & Learning, BU Libraries Wayne Gilmore, Director of Research Computing, BU IS&T Suzanne Rocha, Associate Director, BU Sponsored Programs



Agenda

- Overview of the new NIH Policy for Data Management & Sharing
- Data Management Plan Format and DMPTool
- Data Repositories and Other Resources
- Questions and Answers

Research Data Management & Sharing Working Group

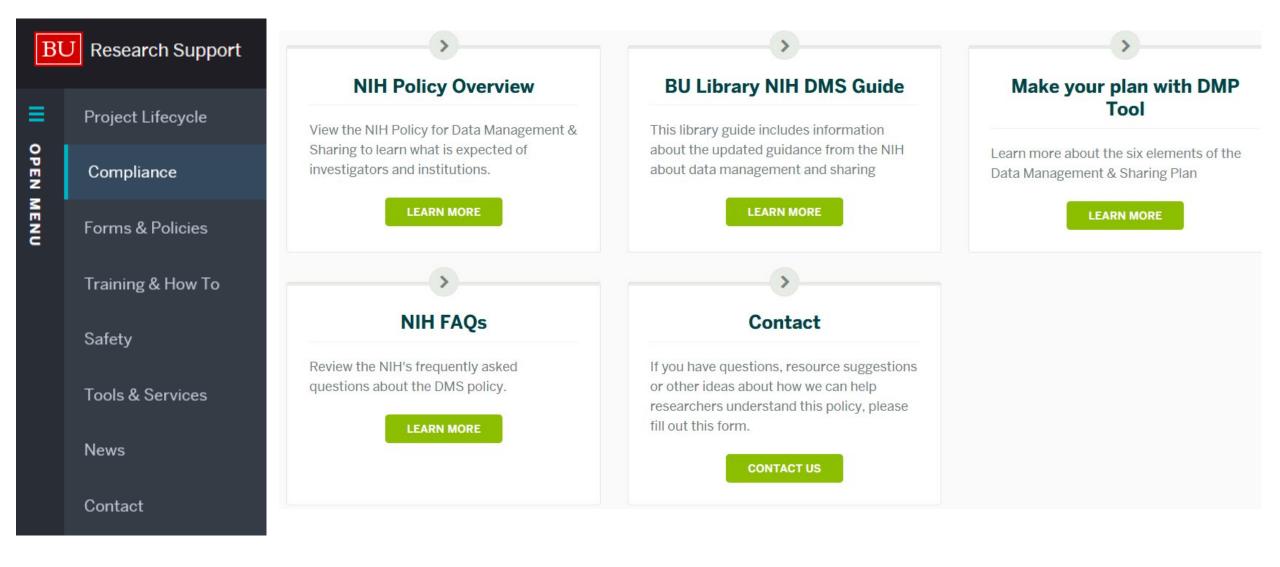
Daniel DiMatteo	BMC Research Technology Program
Caitlin Gaudreau	BMC Research Technology Program
Kate Flewelling	BUMC Alumni Medical Library
Helia Morris	BU Clinical & Translational Science Institute
Ernie Perez	BUMC IT
Jacqueline Presedo	BMC Research Compliance
Pamela Richmond	BU Research Compliance
Vanessa Rubin	BMC Sponsored Programs
LaTina Watson	BMC Research Compliance
Jami Wood	BMC Research Compliance

Overview of NIH Policy Changes for Data Management & Sharing



BU Resources for NIH Data Management & Sharing

https://www.bu.edu/researchsupport/compliance/bu-resources-for-nih-data-management-sharing/



NIH Policy for Data Management and Sharing (DMS Policy)

- Submission of Data Management & Sharing Plan with all applications for funding beginning January 25, 2023
 - Implementation Details for the NIH Data Management and Sharing Policy: <u>NOT-OD-22-189</u>
 Final NIH Policy for Data Management and Sharing: <u>NOT-OD-21-013</u>
- Incorporated into new FORMS-H application format
- **Compliance** with the Data Management and Sharing Plan approved by the funding NIH Institute, Center, or Office
- **DMS Policy:** Applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of "<u>scientific data</u>"

"Scientific data" is defined as: "The recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications."

Policy applies to proposals submitted before 1/24/2023	New Policy applies to proposals submitted on/after 1/24/2023	New Policy Notes
	Inclusion in Proposal	
applications that amount to	DMS Plan is required with every application for research projects regardless of amount. This includes all 'R' applications, some Career Development (K), SBIR/STTRs, Research Centers	Does not apply to Training (T), Fellowships (F), Certain non-research Career Awards (e.g., KM1), Construction (C06), Conference Grants (R13), Resources (Gs), Research Related Infrastructure Programs (S06)
	Length and Details	
	 Recommended to be two pages or less in length and 6 key elements must be included: Data Type Related tools, software, or code Standards Data preservation, access, and associated timelines Access, distribution, or reuse considerations Oversight of data management and sharing 	 template provided, not required 'to be determined' is not an acceptable response hypertext (e.g., hyperlinks and URLs) are not allowed

Policy applies to proposals submitted	New Policy applies to proposals submitted on/after	
before 1/24/2023	1/24/2023	New Policy Notes
	Budget	
 Applicants may request funds for data sharing in the budget and budget justification sections of their applications. Funds may be needed for: Preparing the dataset Preparing the associated documentation Providing support to data users Archival costs 	 Applicants may request funds toward data management and sharing in the budget and budget justification sections of their applications. Funds may be needed for: Curating data Developing supporting documentation Formatting data according to accepted community standards, or for transmission to and storage at a selected repository for long-term preservation and access De-identifying data Preparing metadata to foster discoverability, interpretation, and reuse Local data management considerations Preserving and sharing data through established repositories, such as data deposit fees 	 To request funds toward DMS costs, investigators should include: 1) A line item in the budget form 2) A brief summary of the DMS Plan and a description of the requested DMS costs in the budget justification 3) All allowable costs submitted in budget requests must be incurred during the performance period, even for scientific data and metadata preserved and shared beyond the award period.

Policy	New Policy	
applies to proposals submitted before 1/24/2023	•	New Policy Notes
	Assessment	
component for award issuance	aring plan is not a review Applications selected for funding will only be D	
	Compliance	
Data sharing plans not typically called out within official Notice of Award (NOA)	 The Plan will become a Term and Condition of the Notice of Award (NOA). Failure to provide updates in progress reports may result in enforcement actions, including the addition of special terms and conditions or award termination. Failure to deposit data after the end of the funding period may negatively influence future opportunities. 	

DMS Plan Submission

- A new "Other Plan(s)" field will be added to the PHS 398 form to collect a single PDF attachment.
- Data Sharing Plans and Genomic Data Sharing Plans (GDS) will no longer be submitted to the "Resource Sharing Plan(s)" field.

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

DMS Plan format page will be added to list of <u>Format Pages</u> and incorporated into FORMS-H application instructions

Submitting DMS Budgets

- Direct costs to support the activities proposed in the DMS Plan must be indicated as "Data Management and Sharing Costs"
 - **R&R Budget Form:** line item in section F. Other Direct Costs.
 - Brief summary of DMS Plan and description of DMS costs must be included within the budget justification attachment.

F. Other Direct Costs	Funds Requested (\$)
I. Materials and Supplies	
Publication Costs	
. Consultant Services	
ADP/Computer Services	
. Subawards/Consortium/Contractual Costs	
. Equipment or Facility Rental/User Fees	
. Alterations and Renovations	
Data Management and Sharing Costs	
).	

• PHS 398 Modular Budget Form: within Additional Narrative Justification

Budget Justifications				-
Personnel Justification		Add Attachment	Delete Attachment	View Attachment
Consortium Justification		Add Attachment	Delete Attachment	View Attachment
Additional Narrative Justification	1	Add Attachment	Delete Attachment	View Attachment

DMS Plan Format and DMPTool



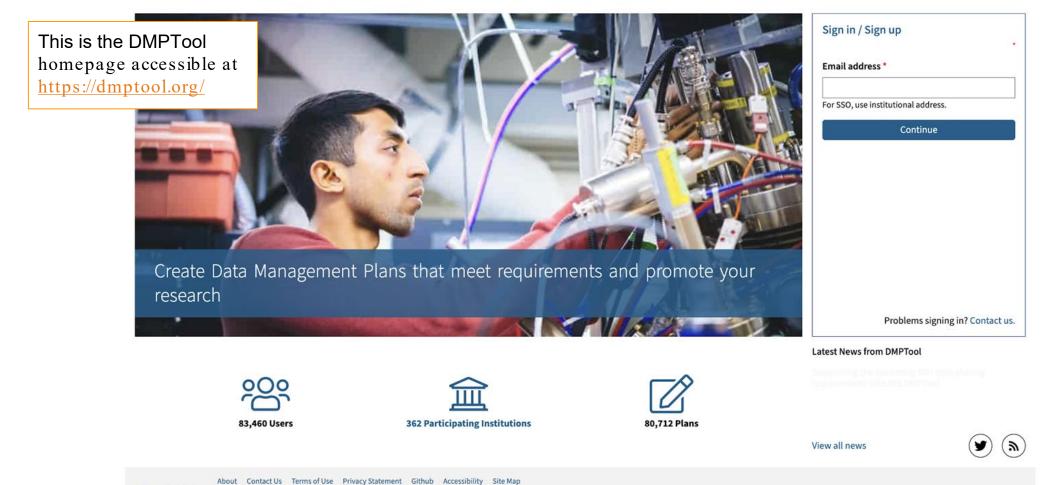
Format of a DMS Plan

- ✓ Plans should be no more than 2 pages in length
- ✓ Optional template is available now
- ✓ 6 key elements must be included:
 - 1) Data Type
 - 2) Related tools, software, or code
 - 3) Standards
 - 4) Data preservation, access, and associated timelines
 - 5) Access, distribution, or reuse considerations
 - 6) Oversight of data management and sharing

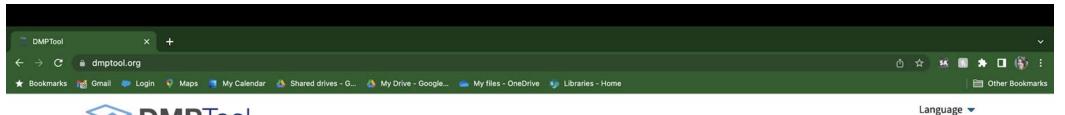




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Use your BU email address to prompt the institutional login.

Create Data Management Plans that meet requirements and promote your research

•
Email address •
ajester@bu.edu
For SSO, use institutional address.
Continue

Problems signing in? Contact us.

Latest News from DMPTool

Things to know about the updated DMPTool website







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Build your Data Management Plan Funder Requirements Public DMPs Help Sign in Email address ajester@bu.edu Your address is associated with: **Boston University** Sign in with Institution (SSO) Sign in with non SSO < Go back Create Data Management Plans that meet requirements and promote your research Problems signing in? Contact us. Latest News from DMPTool







You should see "Boston University" and an option to sign in with your institution (SSO).

Supporting the upcoming NIH data sharing

requirements with the DMPToo

View all news

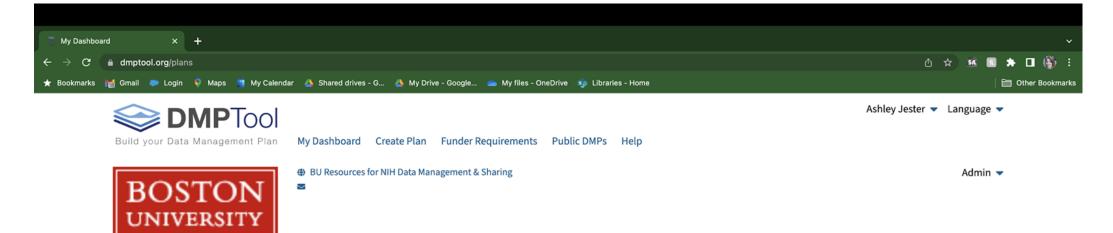


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★ Bookmarks 📷 Gmail 🧼 Login ♀ Maps 📑 My Calendar 📣 Shared drive:	s - G My Drive - Google 👝 My files - OneDrive 🥡 Libraries - Home	Cther Bookmarks
This is the familiar BU Login screen where you'll enter your BU credentials.	Jester Continue You have asked to login to DMPTool Production Instance	
Forgot Password		
Update Your Account		
Login Help		

Image: Boston University Login × + ← → C is shib.bu.edu/idp/profile/SAML2/Redirect/SSO?execution=e1s2 ★ Bookmarks Image: Gmail Image: Login Image: Maps My Calendar Ashared drives - G	📤 My Drive - Google 🥧 My files - OneDrive 🥵 Libraries - Home	℃ ☆ 🐱 🖪 ≽ 🗖 🚯 ÷ 📄 Other Bookmarks
You'll need to use Two- Step authentication for the DMPTool.	<image/>	



Successfully signed in

My Dashboard

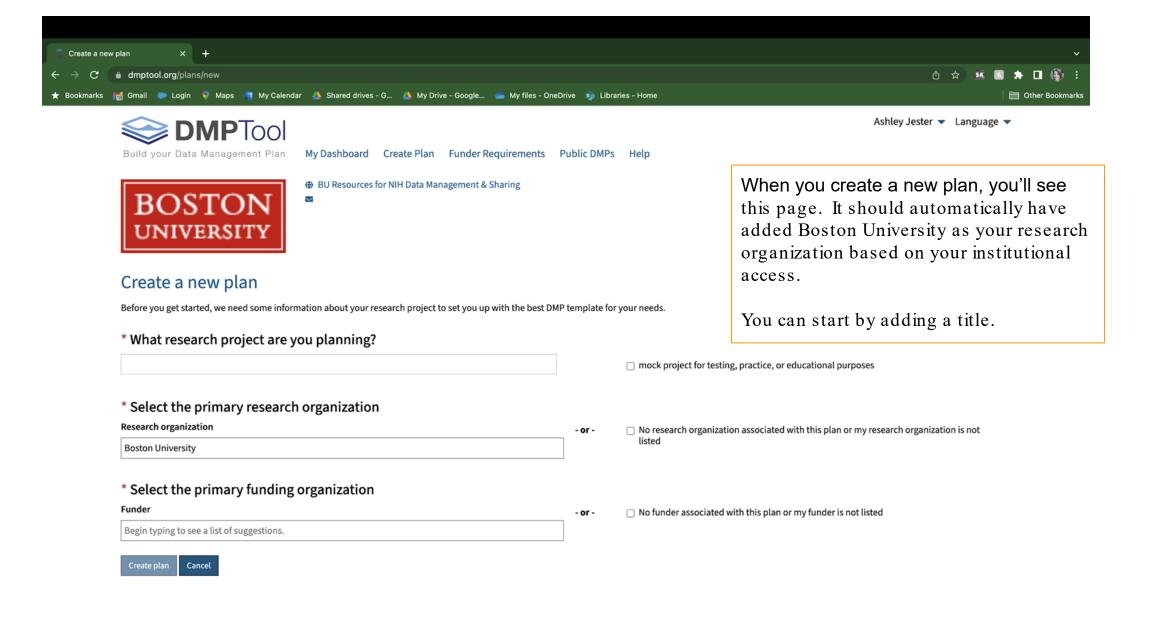
The table below lists the plans that you have created, and that have been shared with you by others. You can edit, share, download, make a copy, or remove these plans at any time.

Project Title 🗘	Template 🗘	Edited 👻	Role	Test	Visibility	Shared	
Bilateral trade balances	NSF-SBE: Social, Behavioral, Economic Sciences	11-04-2022	Owner		Private	No	Actions -
RDS Test Project	NIH-GEN DMSP (Forthcoming 2023)	10-11-2022	Owner	<	N/A	No	Actions ~



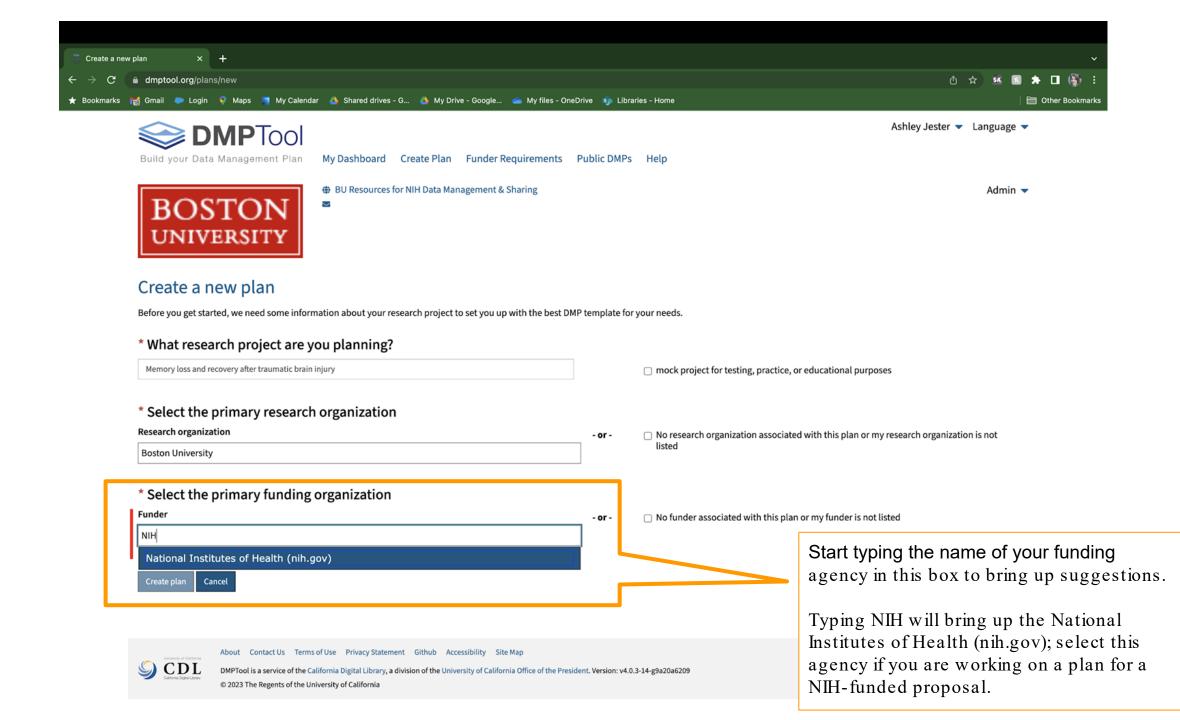
Once you've signed in successfully, you'll land on your dashboard page inside of DMPTool. Any existing plans will be displayed here.

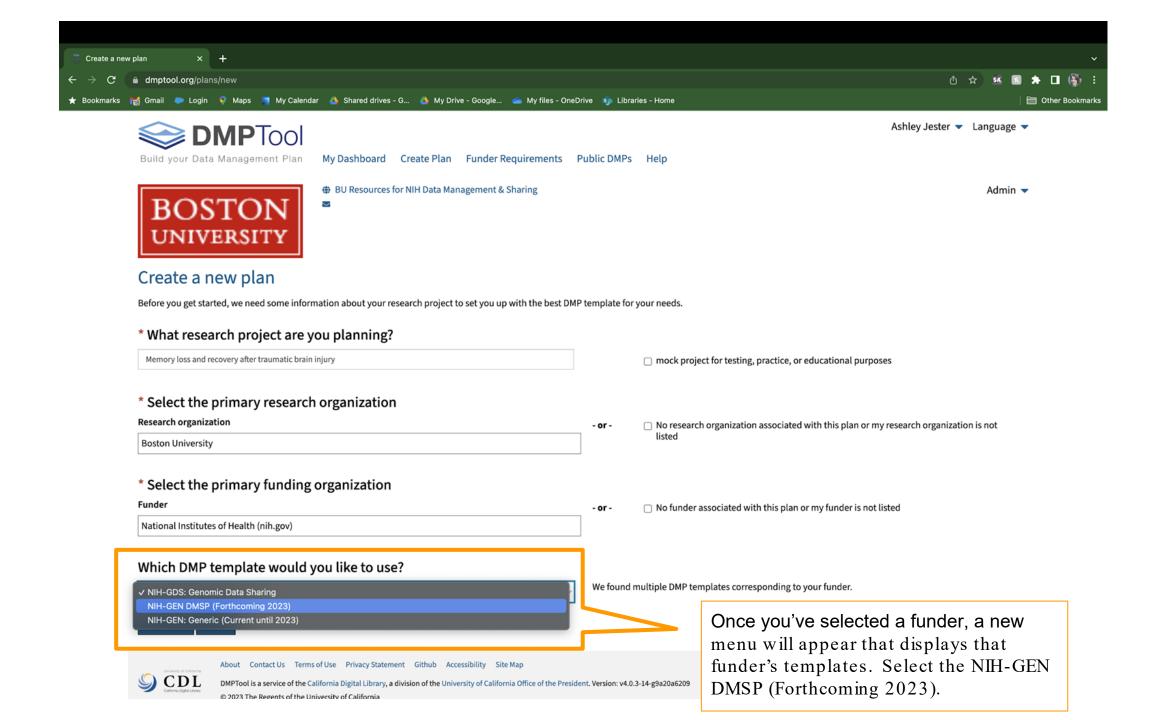
Click "Create plan" get started with a new plan.

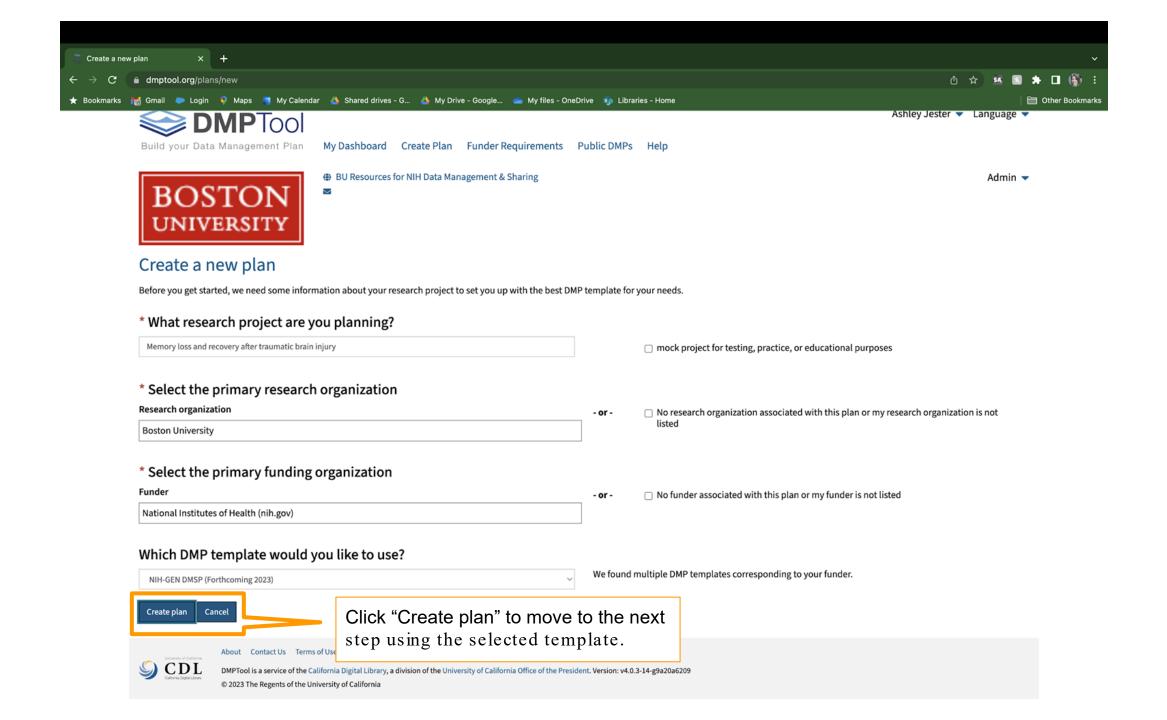


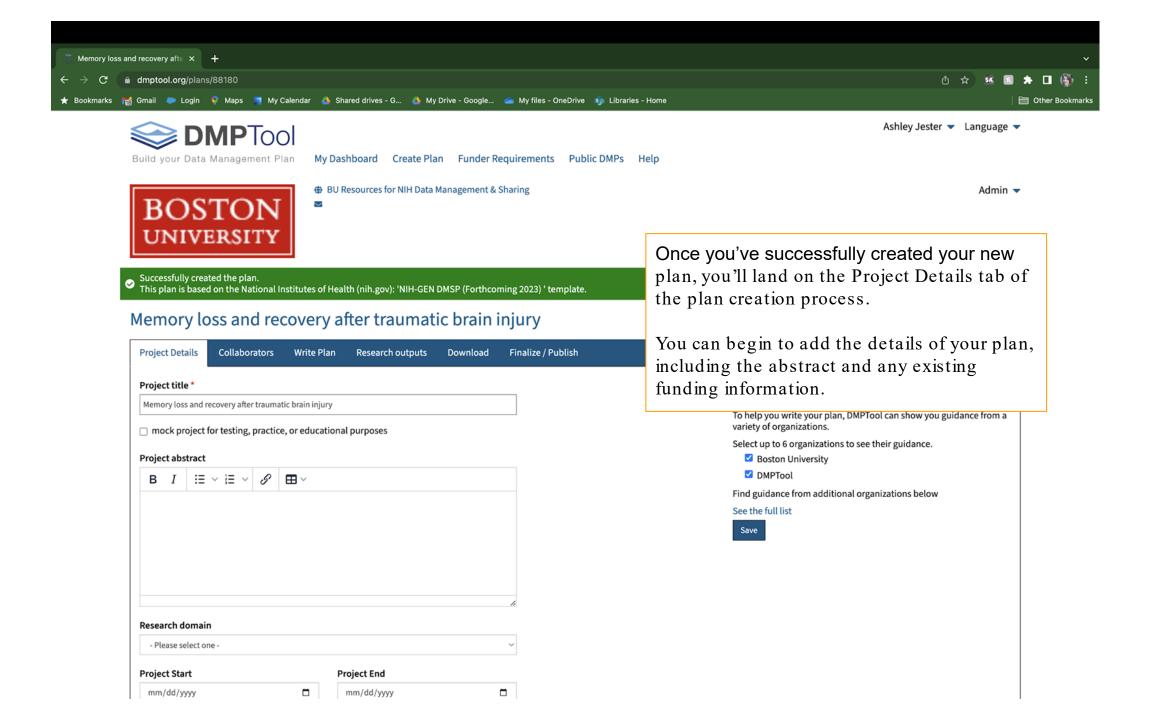


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Memory loss and recovery after x +			~
← → C ≜ dmptool.org/plans/88180			ol ☆ 📧 🖬 🏚 🖬 🚯 E
★ Bookmarks 🃷 Gmail 🐡 Login Maps 🧃 My Calendar 🔮	🕨 Shared drives - G 🔥 My Drive - Google 🥌 My file	s - OneDrive 🦚 Libraries - Home	🛅 Other Bookmarks
Research domain - Please select one - Project Start mm/dd/yyyy Research outputs may have ethical concerns Funder National Institutes of Health (nih.gov) I cannot find my funder in the list Funding status - Please select one - Funding opportunity number Grant number/url Brelated works + Add a related work	Project End mm/dd/yyyy s	If this is building on existing work, you can add information about those projects here.	

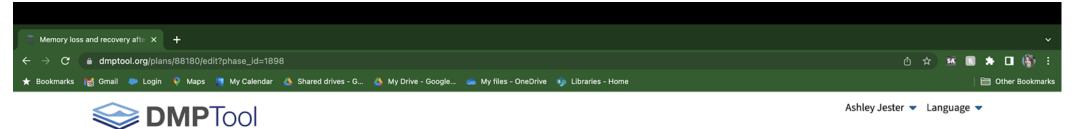
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Memory loss and recovery after traumatic brain injury

Project Details Collaborators Write Plan Research outputs Download Finalize / Publish	1	
Project Contributors Please list the project's Principal Investigator(s) and those responsible for data management. No contributors have been defined. Add a contributor		The Collaborators tab is where you can add project contributors, including co-investigators using the "Add a contributor" button.
DMP Collaborators Invite specific people to read, edit, or administer your plan. Invitees will receive an email notification that the Email address ajester@bu.edu	y have access to this plan. Permissions Owner	This tab also allows you to add DMP Collaborators who will be given access to the plan within DMPTool so that they can make
Invite collaborators	direct contributions and edits.	
Email * Permissions * Co-owner Editor Read only Submit		You will see yourself as the owner; anyone you invite as a collaborator will appear in this list with the associated permissions.

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BU Resources for NIH Data Management & Sharing

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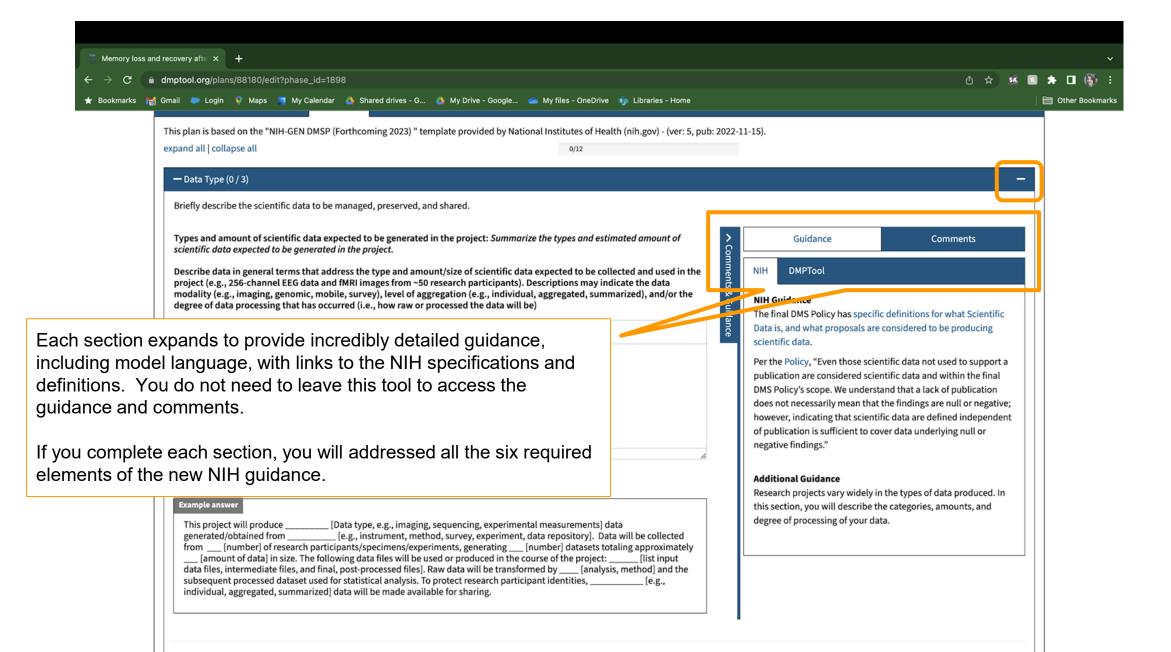
Memory loss and recovery after traumatic brain injury

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Project Details Collaborators Write Plan Resea	arch outputs Download	Finalize / Publish
This plan is based on the "NIH-GEN DMSP (Forthcoming 202 expand all collapse all	23) " template provided by Nat	ional Institutes of Health (nih.gov) - (ver: 5, pub: 2022-11-15).
+ Data Type (0 / 3)		+
+ Related Tools, Software and/or Code (0 / 1)		This is the most important tab in +
+ Standards (0 / 1)		this section. Here you will find +
+ Data Preservation, Access, and Associated Timelines (0) / 3)	the six elements of the new NIH data management and sharing +
+ Access, Distribution, or Reuse Considerations (0 / 3)		guidance. Each section expands +
+ Oversight of Data Management and Sharing (0 / 1)		to provide detailed guidance and +
		walks you through the process
		step-by-step.

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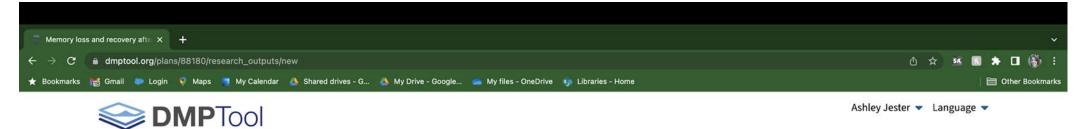




Scientific data that will be preserved and shared, and the rationale for doing so: Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.









Build your Data Management Plan My Dashboard Create Plan Funder Requirements Public DMPs Help

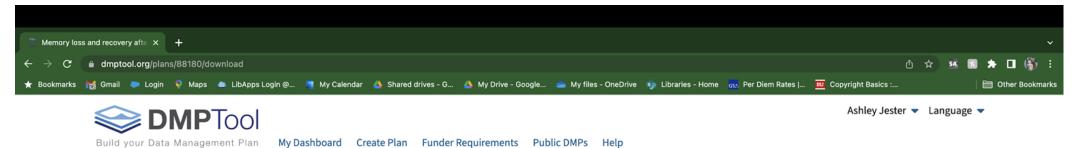
BU Resources for NIH Data Management & Sharing

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Memory loss and recovery after traumatic brain injury

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Project Details Collaborators	Write Plan	Research outputs	Download	Finalize / Publish		
New research output						View all research outputs
Type * ✓ - Please select one - Audiovisual Collection Data paper Dataset Event Image Interactive resource]		Abbreviati	on	The Research outputs and Finalize/Publish tabs are optional as they are not part of the NIH requirements.
Model representation Physical object Service Software Sound Text Workflow Other May contain sensitive data? Intended repositories			🗆 May contain	personally identifiable informa	# ation?	If you want to use the Research Outputs section, you can add information about all the outputs you expect to generate, including datasets.



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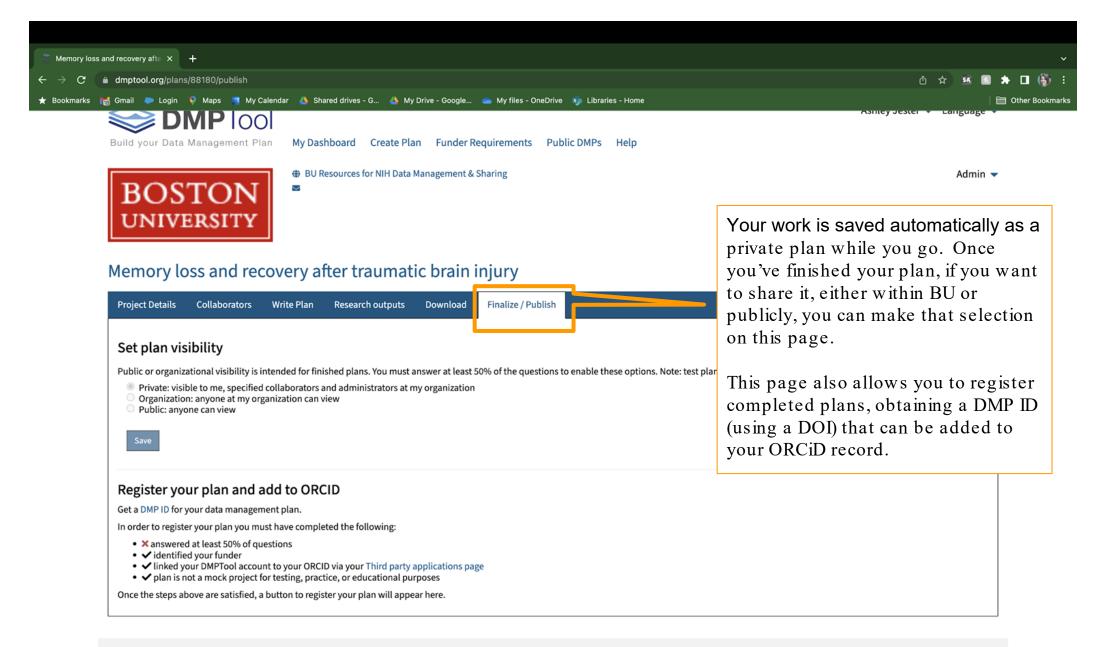
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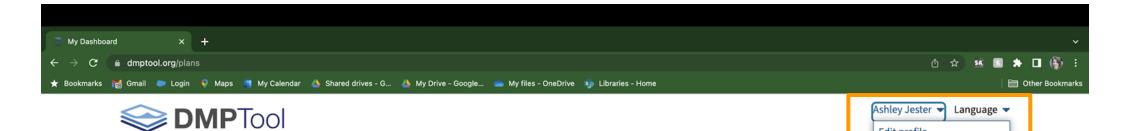
Project Details Collaborators Write Plan Research outputs	Download	Finalize / Publish
html pdf text docx json Download settings Optional plan components project details coversheet section headings guestion text (will only display your answers)		From the Download tab, you can export a copy of your data management and sharing plan in a range of file formats. Depending on the format you choose, different export options will appear.
unanswered questions Download Plan		We strongly recommend choosing the .docx/W ord version since you will have the ability to easily edit the file after download as needed before submission.



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Build your Data Management Plan

My Dashboard

The table below lists the plans that you have created, and that have been shared with you by others. You can edit, share, download, make a copy, or remove these plans at any time.

My Dashboard Create Plan Funder Requirements Public DMPs Help

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Project Title 🗢	Template 🗢	Edited 🚽	Role	Test	Visibility	Sh	red	
Memory loss and recovery after traumatic brain injury	NIH-GEN DMSP (Forthcoming 2023)	01-04-2023	Owner		Private	N		Actions ~
Bilateral trade balances	NSF-SBE: Social, Behavioral, Economic Sciences	11-04-2022	Owner		Private	٥١		Actions -

Create plan

Once you've completed your plan, you can return to your dashboard, where you'll see your plan listed.

Edit profile

Sign out

3rd party applications

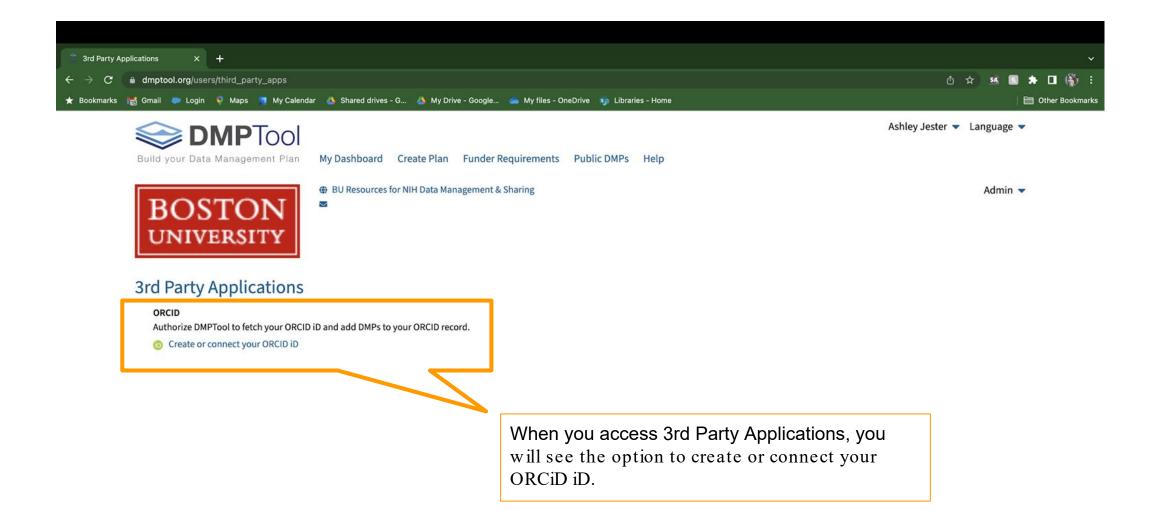
Developer tools

The dashboard is also where you can access the 3rd party applications menu that allows you to connect your ORCiD iD to DMPTool.



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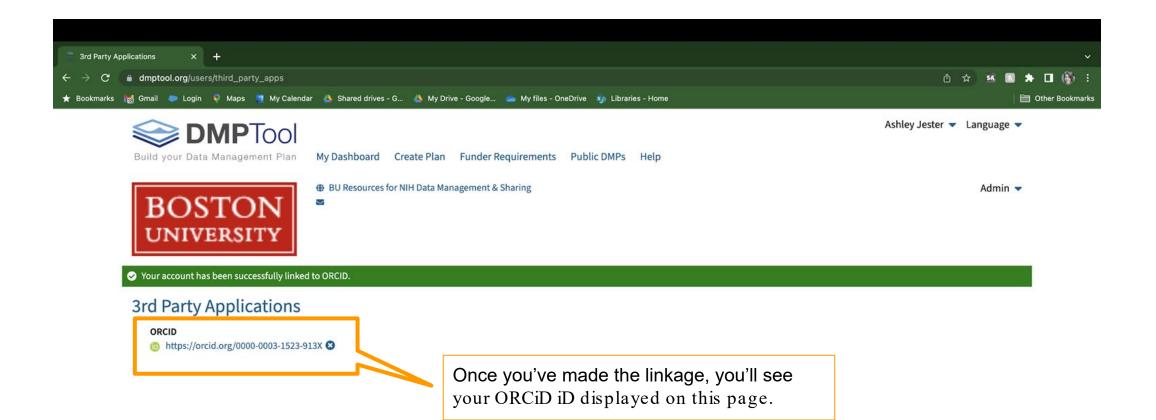
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This is the ORCiD sign in screen; you can sign into your existing account or create an ORCiD iD if you don't have one.

			Sign in			
		Email or 16-di	git ORCID iD			
n; you car	1	Password				
or create one.			SIGN IN ssword or ORCID ID? RCID iD yet? Register now			
			or			
		血 G	Access through your inst			
		•	Sign in with Faceboo	k		
(0)]20031	COMMIN The text of this		Under a CCO license. Images an		copyright and tradema	's protection
About ORCID	Privacy Policy	Terms of Use	Accessibility Statement		Dispute procedures	Brand Guidelines





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Funder Requirements

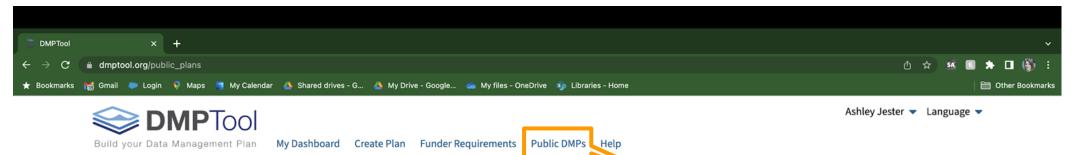
Search

Q

Templates for data management plans are based on the specific requirements listed in funder policy documents. The DMPTool maintains these templates, however, and policy documents directly for authoritative guidance. Sample plans are provided by a funder or another trusted party.

You can access current guidance directly from the Funder Requirements page.

Template Name	Download	Organization name	Last Updated	Funder Links	Create a new plan	Sample Plans (if available)
Alfred P. Sloan Foundation	w L	Alfred P. Sloan Foundation (sloan.org)	10-25-2021	Sloan Grant Proposal Guidelines	Đê	
Arctic Data Center: NSF Polar Programs	w Ż	National Science Foundation (nsf.gov)	10-25-2021	NSF Arctic Data Center DMP Resources NSF Proposal & Award Policies & Procedures Guide (PAPPG)		
BCO-DMO NSF OCE: Biological and Chemical Oceanography	w K	National Science Foundation (nsf.gov)	10-25-2021	NSF OCE Sample and Data Policy NSF GEO Directorate Guidance	Ð î	
DataWorks! Data Management and Sharing Plan Challenge		Federation of American Societies for Experimental Biology (faseb.org)	12-09-2021	Call for Submissions to the DataWorks! Data Management and Sharing Plan Challenge Final NIH Policy for Data Management and Sharing Elements of an NIH Data Management and Sharing Plan Selecting a Repository for Data Resulting from NIH- Supported Research Allowable Costs for Data Management and Sharing		
Department of Defense (DOD)	ŵ K	United States Department of Defense (DOD) (defense.gov)	10-25-2021	DOD Public Access Plan Data Archiving Plans for NIJ Funding Applicants	Ð	
Department of Energy (DOE): Generic	۳ ۳	United States Department of Energy (DOE) (energy.gov)	10-25-2021	DOE Policy for Digital Research Data Management DOE Suggested Elements for a Data Management Plan DOE Office of Science Statement on Digital Management	t î	



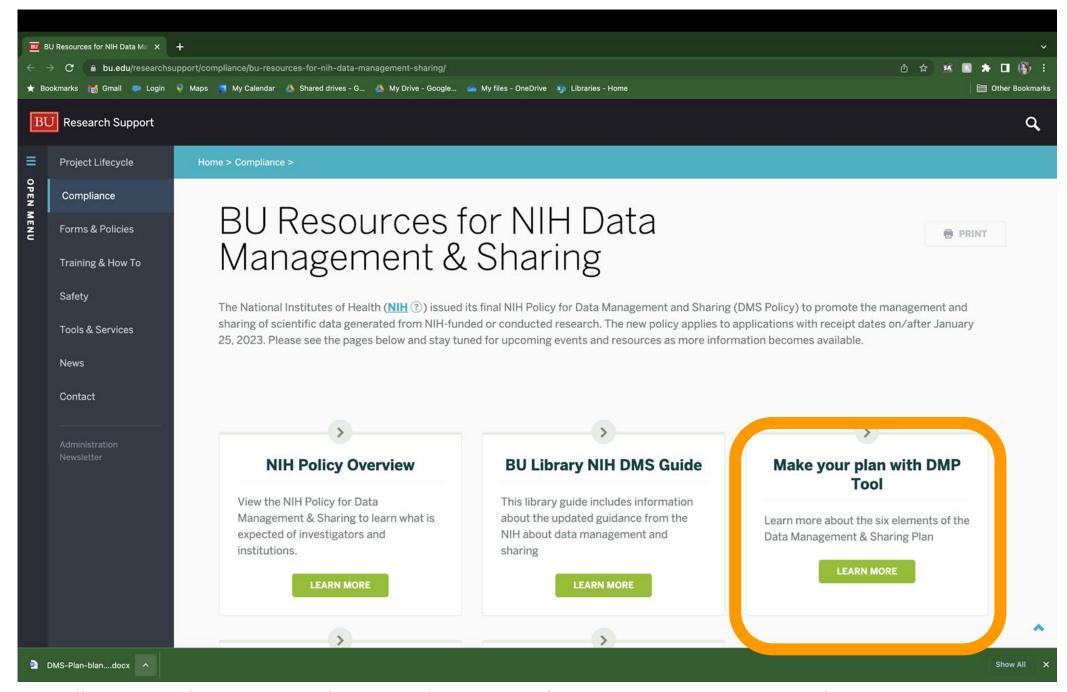
BOSTON UNIVERSITY	 ⊕ BU Resources for NIH Data Management & Sharing ≤ 	You can access shared plans from this link.	Admin 👻
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Public Plans

Public DMPs are plans created using the DMPTool service and shared publicly by their owners. They are not vetted for quality, completeness, or adherence to funder guidelines.

Find a plan	Plans (810)	Sort by: Featured -
Search	S FEATURED	
Q	DataWorks! Data Management and Sharing Plan Challenge DMP ID:	10.48321/D1J31B
Clear Search	FAIR annotated dataset of stroke MRIs, CTs, and metadata Creation date:	10-14-2022
Funder (62) +	Andreia Faria, Johns Hopkins University (jhu.edu) Language:	English (US)
Institution (207)	S FEATURED	
Language (2)	Arctic Data Center: NSF Polar Programs DMP ID:	10.48321/D1R316
Subject (40) +	Coastal Ocean Processes of North Greenland Creation date:	
No filters applied	Andreas Muenchow, University of Delaware (udel.edu) Language:	English (US)
Clear Filters	S FEATURED	
	Digital Curation Centre (português) DMP ID:	10.48321/D10601
	Compatibilização entre aços/concretos inovadores: Uma abordagem interdisciplinar e multiescala Creation date:	03-15-2022
	Guilherme Koga, Universidade Federal de São Carlos (ufscar.br) Language:	English (US)

FEATURED



https://www.bu.edu/researchsupport/compliance/bu-resources-for-nih-data-management-sharing/

Data Repositories and Other Resources



Detailed information on Where, When, and How to share data can be found in the BU NIH Data Management & Sharing Policy Research Guide:

https://library.bu.edu/NIH_DMS#slg-box-29797601



BU Libraries

Search research guides

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Research Guides

Boston University Libraries / Research / Guides / NIH 2023 Data Management and Sharing Policy / NIH 2023 DMS Policy

NIH 2023 Data Management and Sharing Policy

Information about the updated guidance from the NIH about data management and sharing

NIH 2023 DMS Policy
The 2023 NIH Data Management and Sharing Policy
What do I need to do?
Data sharing
Where do I share my data?
When do I need to share my data?
How do I prepare my data for sharing?
How can I estimate the
budget for managing and
sharing my data?
How will compliance be monitored?

BU Computing and Data Support Services

NIH Guidance

Data Management Plan Examples

Exampleo

Acknowledgment

Webinars and Other Resources

The 2023 NIH Data Management and Sharing Policy

Previously, the NIH only required grants with \$500,000 per year or more in direct costs to provide a brief explanation of how and when data resulting from the grant would be shared.

The 2023 NIH policy is entirely new. Beginning January 25, 2023, ALL grant applications or renewals that generate Scientific Data must include a robust and detailed plan for managing and sharing data during the entire funded period. This includes information on data storage, access policies/procedures, preservation, metadata standards, distribution approaches, and more. You must provide this information in a data management and sharing plan (DMSP). The DMSP is similar to what other funders call a data management plan (DMP).

The **DMSP** will be assessed by NIH Program Staff (though peer reviewers will be able to comment on the proposed data management budget). The Institute, Center, or Office (ICO)-approved plan becomes a Term and Condition of the Notice of Award.

What do I need to do?

A Data Management & Sharing Plan (DMSP) must be submitted as part of the funding application for all new and competing proposals/renewals that generate Scientific Data for January 25, 2023, and subsequent receipt dates. The term Scientific Data is defined in the policy as "The recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data do not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens."

Associate University Librarian for Research & Learning









Kate Flewelling she/her



Contact:

Choosing a Data Repository

Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository

for Data Resulting from NIH-Supported Research

Notice Number:

NOT-OD-21-016

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-016.html



Open Domain-Specific Data Sharing Repositories

This table lists NIH-supported domain-specific data repositories that make data accessible for reuse and are open for both submitting and accessing data. Submission is typically limited to data of a certain type or related to a certain discipline. The table provides links to information about submitting data to and accessing data from the listed repositories. Repositories in this list have current NIH funding, sustained support, open data submission and access, and open time frame for data deposit, based on information provided by the repository about funding and data availability. This non-exhaustive list is also available in a downloadable Excel version.

re we missing a domain-specific data sharing repository that should be included in this list? Do you have comments or feedback on this list or the website? Conta

ICO	Repository Name	Repository Description	Data Submission Policy	Access to Data
Common Fund	Metabolomics Workbench (MetWB)	The Metabolomics Program's Data Repository and Coordinating Center (DRCC), housed at the San Diego Supercomputer Center (SDSC), University of California, San Diego, has developed the Metabolomics Workbench. MetWB will serve as a national and international repository for metabolomics data and metadata and will provide analysis tools and access to metabolite standards, protocols, tutorials, training, and more.	How to submit data to MetWB	How to access MetWB data
Common Fund	Stimulating Peripheral Activity to Relieve Conditions Portal (SPARC)	The SPARC Portal provides interactive access to a growing collection of data, maps, and computational studies that focus on the role of the autonomic nervous system in controlling organ function. These resources are made available to the public with the intent of advancing bloelectronic medicine towards more precise treatment of	How to submit data to SPARC	How to access SPARC data

For some programs and types of data, NIH ICO's and Funding Opportunity Announcements *identify particular data repositories* to be used to preserve and share data.

Primary consideration should be given to data repositories that are discipline or data-type specific. A list of NIH recommended data repositories can be found here: <u>https://www.nlm.nih.gov/NIHbmic/domain_specific_reposit</u> ories.html

Choosing a Data Repository

There are many *generalist repositories* available to researchers. <u>https://www.nlm.nih.gov/NIHbmic/generalist_repositories.html</u>



Smaller datasets (up to 2GB in size) many be included as supplementary material submitted to PubMed Central

Very small data sets (<100MB) can be shared through OpenBU managed by BU Libraries.

Many of the above repositories providing pricing guides for researchers for inclusion in their budgets.

The Data Management & Sharing Working Group will be surveying the landscape of data sharing solutions and provide recommendations on possible future service offerings in this area.

BU Computing and Data Support Services

Many resources are available to researchers for analyzing their data, managing study data and reporting, and development of software products for their research. A partial list includes:

Research Computing Services (RCS)

Housed within Information Services & Technology, RCS provides researchers with large-scale computing and storage services, such as the Shared Computing cluster (SCC), coupled with consulting, programming assistance, and training to support a wide range of scientific disciplines across BU.

https://www.bu.edu/tech/services/research/

Software Application & Innovation Lab (SAIL)

Housed within the Hariri Institute of Computing, SAIL is a professional research, software engineering, and consulting lab that acts as both a driver and collaborative partner for computational and data-oriented research efforts across BU.

https://sail.bu.edu/

Biostatistics and Epidemiology Data Analytics Center (BEDAC)

Housed within the School of Public Health, BEDAC provides research services to BU investigators and government, foundation and industry partners. Core areas include project and data management, study monitoring and reporting, biostatistics and epidemiology, data sciences, and geospatial technologies.

https://www.bu.edu/sph/research/biostatistics-and-epidemiology-data-analytics-center-bedac/

Clinical & Translational Science Institute (CTSI)

The CTSI provides clinical investigators with tools, services, and resources to maximize the impact of discoveries and speed the translation of research into improved patient care through collaborative approaches. <u>https://www.bu.edu/ctsi/</u>

Who do I contact?

Any questions should be directed to your <u>Sponsored Programs</u> <u>Research Administrator</u> (SP RA)

Find your SP RA:

https://www.bu.edu/researchsupport/contact/departmental-contacts/

Additional Frequently Asked Questions can be found on the following Research Support site:

https://www.bu.edu/researchsupport/compliance/bu-resources-fornih-data-management-sharing/

Questions and Answers



Q: If informed consent was obtained decades ago and data sharing wasn't explicitly addressed, is this a valid reason for not sharing?

Several points to consider (since the question doesn't contain a lot of details):

- It is possible that sharing is not permitted given the scope/terms of consent. Any limitations of data sharing should be included in the DSMP.
- If this is a funding proposal to generate new scientific data using previously collected data, the requirements will likely apply. For secondary use, sharing the primary data source is not required (and those primary data, if decades old, hopefully no longer contain identifiers, meaning the data may no longer be considered to include 'human subjects').
- If this question pertains to a decades-old project that has since been closed, the new policy does not apply (unless it falls within the 2003 Policy).
- Review the NIH Policy FAQs there is guidance on when not sharing, or limiting sharing, may be justified.
- Investigators are required to maintain all applicable confidentiality and privacy standards and should indicate in their Plans how they will address this issue.
- NIH has a tool to help assess whether a data sharing policy applies to certain research: <u>https://sharing.nih.gov/other-sharing-policies/which-policies-apply-to-my-research</u>.
- When in doubt, ask your NIH program officer.

Q: I'm curious about data sharing policies regarding inherently sensitive data such as digital voice recordings. If there are (or can be) transcripts created from the voice recordings, or the use of voice altering technology, these may be acceptable alternatives to the original recordings?

Accommodations may be requested in the budget to meet the requirements. Investigators are required to maintain all applicable confidentiality and privacy standards and should indicate in their Plans how they will address this issue. Researchers should follow the guidance provided by the IRB for their specific project.

Q: How does the policy apply to qualitative data, like transcripts, ethnographic fieldnotes, or oral/video histories?

The research institute to which you are applying may have more specific guidance in this area, however presumably the Policy would apply if you are generating scientific data: 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.

Q: Helpful to know whether BU will expand Y-drive and other shared storage for data retention purposes?

Q: Is BU planning to offer the infrastructure necessary to data sharing? (please!)

BU currently has limited options for sharing data broadly to the community. The Research Data Management & Sharing working group plans to survey the landscape of data sharing solutions and provide recommendations on possible future service offerings in this area.

When possible we encourage researchers to utilize existing NIH Data Repositories for sharing their data. Further details can be found in the BU NIH 2-23 Data Management & Sharing Policy libguide located here: <u>https://library.bu.edu/NIH_DMS#s-lg-box-29797602</u>

For small datasets (under 100MB) Researchers can utilize the Open BU service managed by BU Libraries. Please see <u>https://open.bu.edu/</u> for more information.

Q: Does this refer only to making the data available to researchers outside of the project? What about sharing between subs?

The new NIH policy (effective January 2023) is specifically about sharing data publicly, with researchers and others who are not on the project. Sharing data with sub-awardees and other collaborators is a separate question and not part of compliance with this policy.

Q: Can the working group create a template for the data sharing plan document we have to include in R01 applications?

NIH has created a sample template, available for use, although not required. The sample template can be found here: <u>https://grants.nih.gov/sites/default/files/DMS-Plan-blank-format-page.pdf</u>

Additional sample plans are located on NIH's web page on Writing a Data Management & Sharing Plan which is located here: <u>https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing-plan#sample-plans</u>