

Preparing for Implementation of the new NIH Policy for Data Management and Sharing

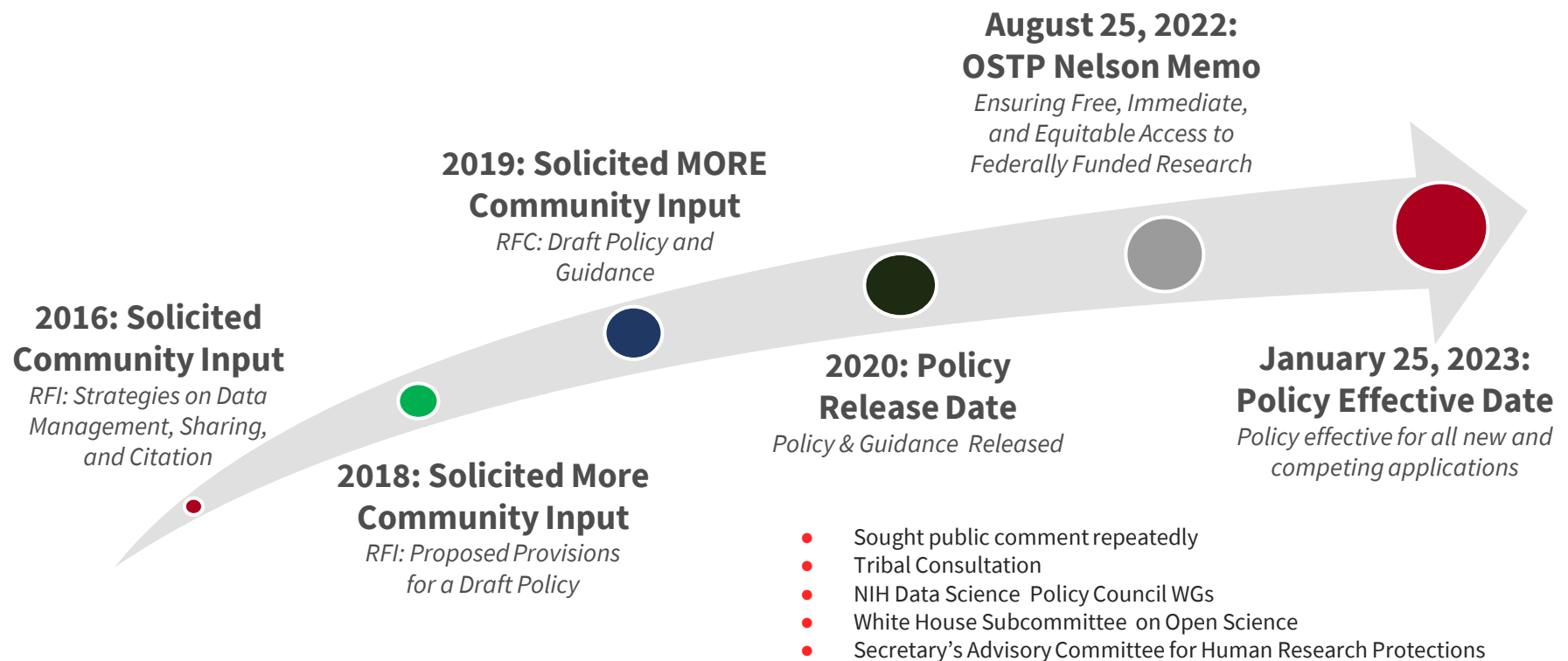
Amy Camilleri
Melissa Korf
Caitlin McCarty
Caroline Wood

HMS/HSDM Open Forum
December 1, 2022

Agenda

- NIH Data Management and Sharing (DMS) Policy overview
- Federal Demonstration Partnership (FDP) Pilot
- GMAS Updates
- DMS Application Instructions
- Budgeting Considerations
- Roles & Responsibilities
- Working Group Updates and Next Steps
- Discussion

NIH Data Management and Sharing Policy Timeline



New NIH Policy for Data Management and Sharing--Overview

- Replaces the 2003 NIH Data Sharing Policy, which only required a DMSP for projects over \$500K in annual direct costs
- Applies to new and competing applications submitted for due dates on or after January 25, 2023; does **not** apply retroactively to currently active awards or awards issued in response to proposals submitted prior to the effective date
- Costs associated with data management and sharing are allowable in budgets
- Unless data sharing is integral to the program and specified in the FOA, peer reviewers will not be asked to comment on the DMSP or provided with a copy of the separate DMSP Attachment
- Reviewers **will** comment on the reasonableness of the budgeted costs, but these comments will not impact the overall score
- Program staff will assess the DMSP and request any changes that may be needed at JIT.
- DMSPs may be updated during the annual RPPR process
 - However, changes must be approved prior to implementation

DMSP Submission and Review Overview

Plan Submission

With application
Brief Plan description in
Budget Justification
Full Plan as separate
attachment

Plan Assessment

Peer reviewers comment
on (not score) budget

NIH program staff assess
Plans

Plans revisions may be
requested at JIT

Plan Compliance

Incorporated into Terms
and Conditions

Monitored at regular
reporting intervals and
updates included in
annual RPPR

Compliance may factor
into future funding
decisions

NIH Data Management and Sharing Plan Elements

1) Data Types --describe the types and estimated amounts of scientific data expected to be generated in the project; describe which data will be preserved and shared, and the rationale

2) Related Tools, Software and/or Code

3) Standards

4) Data Preservation, Access, and Associated Timelines

[Selecting a Repository for Data Resulting from NIH-Supported Research](#)

5) Access, Distribution, or Reuse Considerations

[Protecting Privacy When Sharing Human Research Participant Data](#)

6) Oversight of Data Management and Sharing

Data Management Plan Templates



1. Go to <https://dmptool.org>
2. Login using your Harvard Key
3. Create plan
4. Select NIH Funding
5. Select the NIH-GEN DMSP (Forthcoming 2023)
6. Write plan
7. Schedule a consultation for review/to discuss your DMSP

Create a new plan

Before you get started, we need some information about your research project to set you up with the best

* What research project are you planning?

Draft NIH Grant

* Select the primary research organization

Research organization

Harvard University (harvard.edu)

* Select the primary funding organization

Funder

National Institutes of Health (nih.gov)

Which DMP template would you like to use?

NIH-GEN DMSP (Forthcoming 2023)

DMPTool NIH-GEN DMSP (Forthcoming 2023) Template

+ Data Type (0 / 3)

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

A general summary of the types and estimated amount of scientific data to be generated and/or used in the research. Describe data in general terms that address the type and amount/size of scientific data expected to be collected and used in the project (e.g., 256-channel EEG data and fMRI images from ~50 research participants). Descriptions may 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 that has occurred (i.e., how raw or processed the data will be)

B I [List Icon] [List Icon] [Link Icon] [Table Icon]

Save

NIH example answer

This project will produce _____ [Data type, e.g., imaging, sequencing, experimental measurements] data generated/obtained from _____ [e.g., instrument, method, survey, experiment, data repository]. Data will be collected from _____ [number] of research participants/specimens/experiments, generating _____ [number] datasets totaling approximately _____ [amount of data] in size. The following data files will be used or produced in the course of the project: _____ [list input data files, intermediate files, and final, post-processed files]. Raw data will be transformed by _____ [analysis, method] and the subsequent processed dataset used for statistical analysis. To protect research participant identities, _____ [e.g., individual, aggregated, summarized] data will be made available for sharing.

Comments & Guidance

Guidance

Comments

NIH

Harvard

DMPTool

NIH Guidance

The final DMS Policy defines Scientific Data 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."

Even those scientific data not used to support a publication are considered scientific data and within the final DMS Policy's scope. We understand that a lack of publication does not necessarily mean that the findings are null or negative; however, indicating that scientific data are defined independent of publication is sufficient to cover data underlying null or negative findings.

Federal Demonstration Partnership (FDP) Pilot

- Currently in planning phase; pilot kick-off planned for January 2023
 - Working with NIH OER, OPERA, and ICO contacts to develop template(s) to be tested in the pilot
 - Determining data collection/evaluation methods
- For more information see:
 - [Slides](#) and [video](#) from September 2022 FDP session
 - [Slides](#) from October 2022 COGR session
- In large part thanks to this pilot, NIH has stated that, “***First year of implementation will be a learning period for NIH, applicants and recipients. We will use the pilot to gather data that will inform future compliance efforts and to assist folks with neutralizing the process.***”

GMAS Updates

- GMAS is the system of record for the final submitted/accepted DMSP
- New document tag to identify the final version of the DMSP
 - Will develop a report/QA process within ORA to ensure the document is uploaded and tagged properly
- Two new questions added to GMAS:

Edit school specific information

HMS^Harv Med School

 Info

Does this project include work related to SARS-CoV-2/COVID-19?

☐ Yes ☐ No

Does this award/proposal require a data management and/or sharing plan?

☐ Yes ☐ No

Does this request include a new/updated data management and/or sharing plan?

☐ Yes ☐ No

Per [HMS Sponsored Awards Budgeting \("low IDC"\) Policy](#) and SOP, will this award meet the HMS minimum effective IDC rate by including IDC as direct costs and/or making up the difference from PI/dept funds? (NOTE: FEDERAL AWARDS SHOULD BE NO)

☐ Yes ☐ No

New GMAS questions

- Appear in initial, competing, supplement, and continuation requests
- As of Monday, November 14th, have been added to all such pending requests (not in “submitted” status) and will need to be answered prior to finalizing the request
- To be completed by the PI/dept but verified by PAO during proposal/RPPR review
- We are considering the next month to be a pilot phase and will collect feedback to help us:
 - Refine the language of the questions
 - Develop tool tip language that can be added to GMAS
 - Refine our accompanying review process

Application Instructions

- Forms-H application package must be used for submissions on or after January 25th
- New “Other Plan(s)” section added to enable the DMSP to be attached as a single pdf
- [DMSP Format Page](#) preview available now; fillable form version available by Fall 2022
- Approach section of the Research Strategy should reference the DMSP as appropriate

Budget Pages

- R&R Detailed Budget
 - Requests for direct costs to support the DMS activities must be reflected as a single line item under Other Costs titled “Data Management and Sharing Costs”
 - NIH instructs that personnel costs related to DMS activities should be included in this Other Costs line item rather than the Personnel section
 - However, Harvard’s guidance is that ALL effort for the PI(s) and Senior/Key Personnel must remain in the Personnel section
- Modular Budget
 - Costs associated with DMS activities referenced in the Additional Narrative Justification
- Allowable costs must be incurred during the period of performance and should not include costs associated with the routine conduct of research, such as data acquisition costs

R&R Budget Justification/ Additional Narrative Justification

- A summary of the DMSP and a description of the associated requested costs should be included in the budget/additional narrative justification section – ***this is the language that reviewers will review and comment on***
- Provide a brief summary of type and amount of scientific data to be preserved and shared and the name of the established repository(ies) where they will be preserved and shared.
- Indicate general cost categories such as curating data and developing supporting documentation, local data management activities, preserving and sharing data through established repositories, etc., including an amount for each category and a brief explanation.
- The recommended length of this section of the justification is no more than half a page.

Looking ahead – RPPR questions

- A new section (C.6 Data Management and Sharing) will be added to the Products section of the RPPR with questions as follows:
 - C.6. a. Has scientific data been generated and shared during this reporting period? Describe activities related to the approved Data Management and Sharing Plan. Enter response below.
 - C.6.b. Are there changes to the Data Management and Sharing Plan?
 - ☐ No Change
 - ☐ Enter description of change and upload revised Data Management and Sharing Plan
- For awards not subject to the new policy (competing application was submitted prior to the January 25, 2023 policy effective date), we will indicate that these questions are not applicable.

Planning questions to discuss with PI(s)

- Is there a deposit fee for any of the repositories you are planning to use?
- Will you need dedicated staff time or the services of a core or vendor to support any of the following data management and sharing activities to meet repository requirements?
 - Data curation?
 - Developing supporting documentation?
 - Formatting data according to accepted community standards or for transmission and storage at selected repository?
 - Preparing metadata?
 - De-identifying data?

Planning questions to discuss with PI(s) cont.

- Where are you planning to store the data while the project is active? Is there an associated fee?
- Is there a fee associated with any tools or software you are planning to use to collect or analyze the data?
- Do you have subrecipients?
 - If yes, will they be responsible and need to budget for data management and sharing activities?
 - If yes, who will be responsible for depositing into each selected repository and/or be responsible for covering the associated fees?

HMS Roles & Responsibilities

- R&R matrix draft identifies a wide variety of offices/roles that play an advisory role in Data Management & Sharing Plan (DMSP) development
- The matrix identifies the PI as having primary responsibility for most of the activities
- Version 1.0 of the R&R matrix was shared with relevant stakeholders for feedback, is being finalized, and will be posted in the RAD and on the ORA website when complete

Highlighted Contacts

- **Library:** available to connect members of the Harvard community to services and resources that span the research data lifecycle, identify relevant repositories and appropriate data preservation standards
- **HMS Research Cores:** will provide information about data types generated in their cores, recommended public repositories for those data types, and, in some cases, assistance uploading data into public repositories
- **Research Computing:** can advise on appropriate tools, software, storage, and code and budgeting relevant costs. Support data management, data access, and IT services throughout the lifecycle
- **ORA:** available to consult on sponsor requirements and provide support in responding to program feedback on submitted DMSPs
- **ORA Research Data Compliance:** available to consult on DMSP development and management related to use of acquired data or other forms of sensitive data
- **IRB:** available to consult on ethical considerations when using, managing, and/or sharing human subjects data
- **Information Security:** available to consult on access management and data safety plan components

Pre-Award Officer

- Advise on ICO- or RFA-specific data sharing expectations
- May advise on when Research Computing, IT, or School Security Officer (SSO) review is recommended
- Review and approve DMSP and budget/budget justification at Proposal to ensure all required elements are addressed
- Review and submit updated DMSP at JIT
- Review report on DMS activities in annual RPPR

Grants & Contracts Officer

- Advise on reuse limitations/considerations and when school security officer (SSO) review is recommended
- Advise on negotiation of DMSP updates at JIT
- Assist with planning timing and review/execution of data sharing/access agreements
- Advise on subaward negotiations related to DMSP requirements as necessary

Award Management

- AMS
 - Confirm the correct version of the DMSP has been incorporated into the NoA when received
 - Confirm which DMSP components need to be flowed down to subrecipients
 - Assist with mid-year requests for prior approval of changes to the DMSP and provide guidance on when such a request may be required
 - Assist with final report on DMS activities within the final RPPR
- Contracts Coordinator
 - Flow down applicable DMSP requirements in subaward agreements

Research Data Compliance

- Available to advise on various components of the DMSP, particularly as when acquired data is being used
- Advise on when IRB/HMS IT/SSO guidance/approval should be sought
- Assist with planning timing and review/execution of data sharing/access agreements
- Advise on when formal approval may be needed for updates to the DMSP

Next Steps

- University-wide updates provided at Research Management Meetings (next RMM scheduled for December 7th at 2:30 pm)
- University-wide and HMS working groups continuing to develop and publish resources – notifications to be included in RAD
- ** Please create the GMAS shell for any NIH proposals for deadlines on or closely following the January 25th effective date (February 5th, March 5th, etc.) as soon as possible – this will enable targeted outreach to these investigators to provide support

Discussion

