What You Should Know About the NIH DMSP, Compliance, Monitoring, Prior Approvals, and Associated Costs

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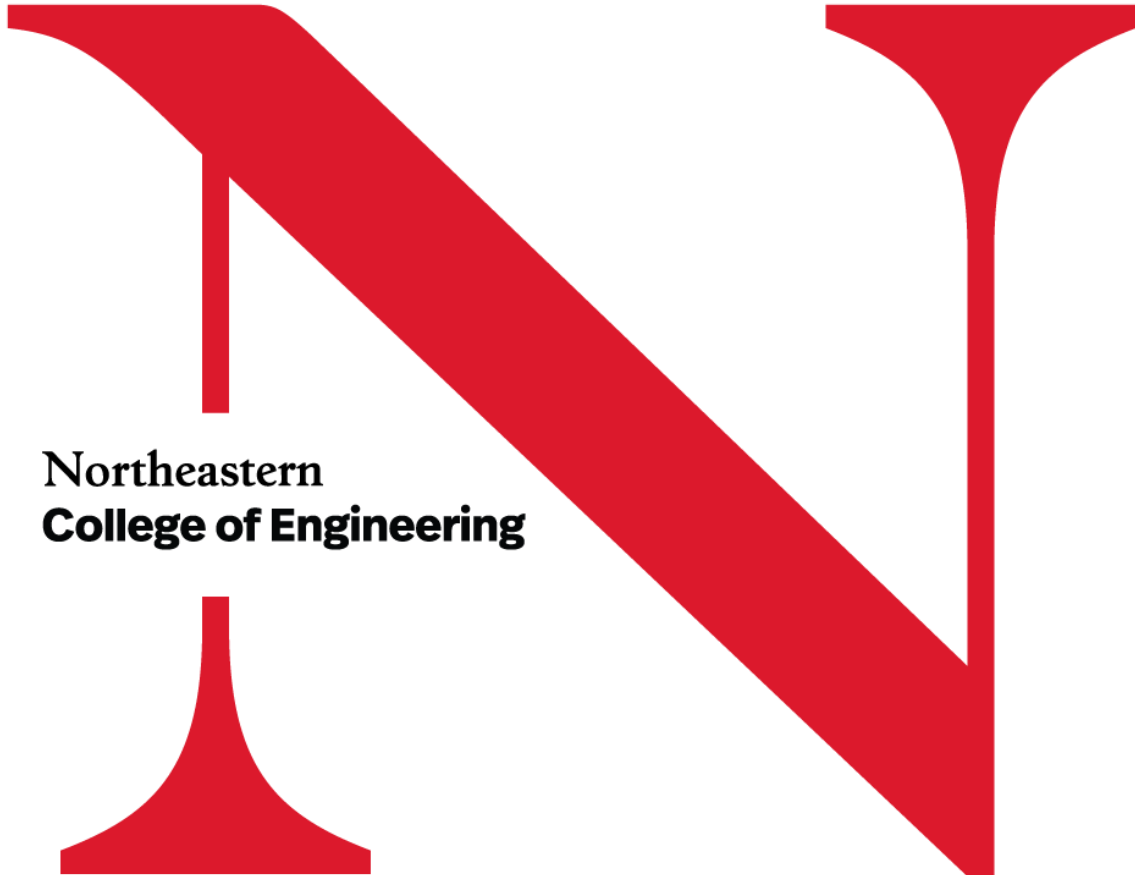
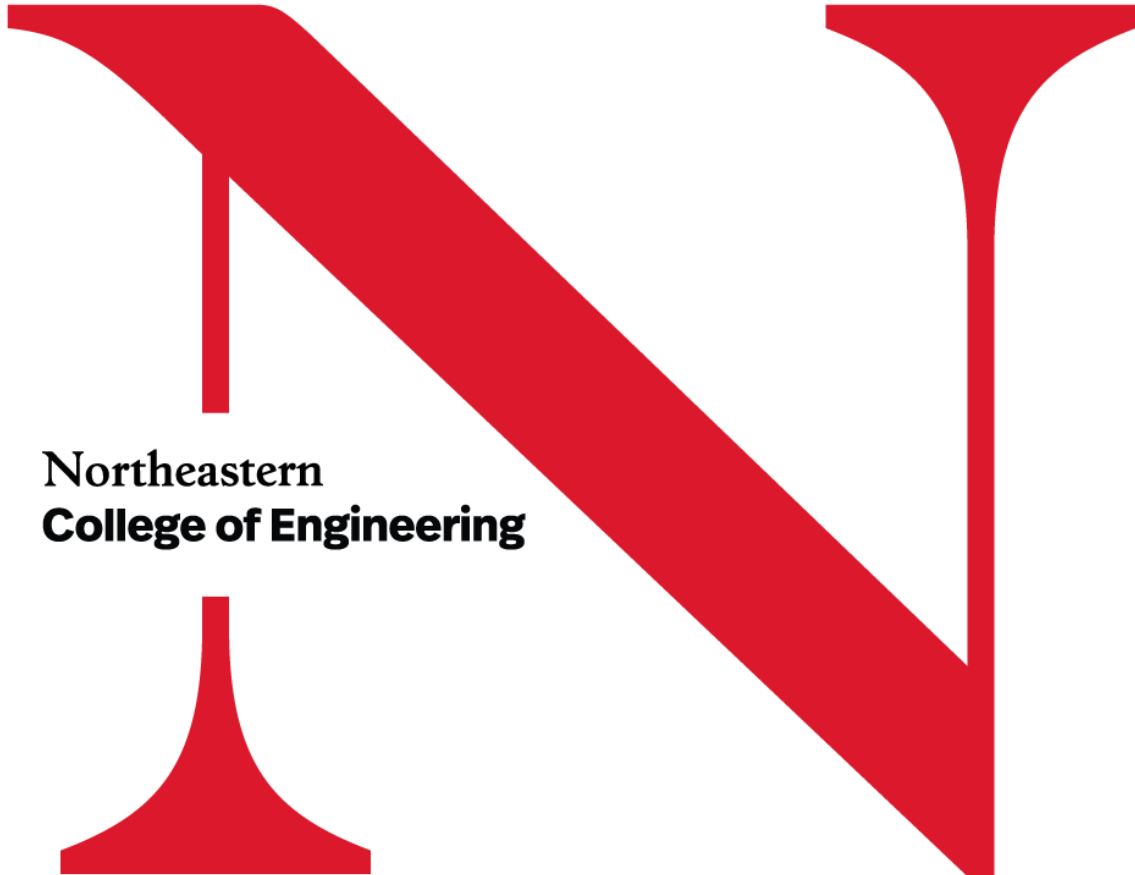


Agenda

- Scope of the policy
- Applicability
- Timeline
- Basic requirements
- NIH PI DMSP expectations/format
- Getting started
- IRB considerations
- Budget information
- FDP DMS Pilot
- Northeastern Implementation
- Quick summary



Scope

- Scope
  - Applies to **ALL** research, funded or conducted in whole or in part by NIH, that results in generation of ***Scientific Data.***
  - *Not limited to awards greater than $500K*
  - Replaces 2003 policy

- Scientific Data
  - ”[T]he recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, *regardless of whether data are used to support scholarly publications.”*

Scope Continued

- Scientific Data **DO NOT** include
  - Data not necessary for or of sufficient quality to validate and replicate findings
  - Lab notebooks
  - Preliminary analyses
  - Completed case report forms
  - Plans for future research
  - Peer reviews
  - Communications with colleagues
  - Lab specimens

Applicability

- **All research generating scientific data including**
  - Research Projects
  - Certain Career Development Awards (K)
  - Small Business SBIR/STTR
  - Research Centers

- Policy **DOES NOT** apply to projects not generating scientific data or non-research projects
  - Training grants (T)
  - Fellowships (F)
  - Certain non-research Career Awards (e.g., KM1)
  - Construction grants (C06)
  - Conference Grants (R13)
  - Resources (Gs)
  - Research Related Infrastructure Programs (e.g., 506)

Effective Date

- **January 25, 2023**, and subsequent receipt dates for
  - All competing applications
  - Contract proposals
  - Other funding agreements – e.g., Other Transactions executed 1/25/23 or thereafter
  - Noncompeting awards not immediately included.

Basic Requirements

- Include two-page written Data Management/Sharing Plan (DMSP) with application/proposal in “Other Plans’ field on Form H

- Treat DMSP as a living document that should be updated throughout the award period and changes reviewed/approved by NIH

- Costs, associated with data curation and storage, **incurred during performance period** may be direct charged to grant if NOT included in IDC.

Sharing Parameters

- DMSP should maximize sharing
  - As soon as possible but not later than time of publication of findings in peer-reviewed journal **OR** end of award, whichever comes first

- NIH has identified reasons when acceptable to limit sharing
  - Not permitted by Informed consent, government or agreement restrictions
  - Participant privacy or safety would be compromised

- NIH has identified reasons **NOT** justifiable for limiting sharing
  - Data too small
  - Anticipate data will not be widely used
  - No suitable repository

Principal Investigator Expectations

- Budget for management and sharing of scientific data (as defined by NIH)
- All competing applications/contract proposals must include a DMSP
- If the project is also subject to the NIH Genomic Data Sharing Policy, PIs will consider these requirements when drafting DMSP
  - See **https://sharing.nih.gov/genomic-data-sharing-policy/about-genomic-data-sharing/gds-policy-overview**
- PIs will implement DMSP as written and approved by NIH Center/Institute making changes and securing approval as data needs evolve throughout the award.
- PIs are expected to maximize data sharing on a timely basis but no later than end of award
- **Compliance is the joint responsibility of PI and NU-RES**

Getting Started: What should be included in DMSP? NIH has identified 6 mandatory plan elements

Getting Started: Choosing a Repository

- https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/selecting-a-data-repository
  - Using established data repositories is highly promoted by NIH
  - For some programs and types of data, NIH will identify specific data repositories (or sets of repositories) for data preservation and sharing
  - For data generated from research for which no data repository is specified by NIH, researchers are encouraged to select an appropriate data repository. See the website listed below
    - https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/repositories-for-sharing-scientific-data
      - There are 70+ NIH-Supported Repositories that can be filtered through
      - Other repositories are available if you can't find one in the list above
  - **PI should Talk to NU-RES and library resources about suitable public repositories**

Data Sharing and Human Subjects Protections

- While the data should be made as widely and freely available as possible, the PI, IRB, and the Institution have **responsibility to protect the rights of research participants and the confidentiality of the data**.

- Researchers who are planning clinical trials and intend to share the resulting data should think carefully about the study design, **the informed consent documents, and the structure of the resulting dataset prior to the initiation of the study.**

- If research participants are promised that their de-identified data will not be shared with other researchers, the new protocol application should explain the reasons for such promises.
  - **For NIH funded research, those statements in ICFs should not be made routinely and without adequate justification**.

IRB Guidance: Informed Consent

- Informed consent must include a statement describing how the confidentiality of subject data will be maintained
  - **Should be written so it does not unduly limit an investigator's ability to share data with the research community**

  - Options provided include:
    - Future sharing of data for research purposes
    - Level of de-identification of the data being shared
    - Potential opportunities for withdrawal of consent

- When planning and selecting the ICF language, Investigators may decide whether to
  - **Completely anonymize the data**
  - **De-identify the data set by removing direct identifiers and/or code the data and maintain the confidential key code that will not be shared**, or
  - Not to share data with external researchers.
    - This will need to be justified primarily by sensitivity of the information or IRB decision for protection of privacy

- **PIs must work with the Northeastern IRB Office to develop a protocol that complies with these requirements.**

Data Collected Without Prior Consent for Future Use

- This refers to data previously collected from prior research studies, clinical data collected with a consent waiver, or de-identified clinical data that does not require informed consent.
- Sharing options include
  - Anonymized data (including the removal of indirect identifiers)
  - De-identified data with restricted access to the repository and/or a written data sharing agreement

Reasonable costs allowed in budget requests

- Curating Data and Documentation Costs
  - **Formatting** data according to accepted community standards
  - **De-identifying** data
  - **Preparing metadata** to foster discoverability, interpretation, and reuse
  - **Formatting data** for transmission to and storage at a selected repository for long-term preservation and access
- Local Data Management Costs
  - **Unique and specialized information infrastructure Necessary** to provide local management and preservation (e.g., before deposit into an established repository)
  - Not included in the indirect cost rate

Reasonable costs allowed in budget requests - continued

- Preserving and Sharing Data Costs
  - **Preserving and sharing data** through established repositories, such as **data deposit fees** necessary for making data available and accessible
  - **Important:** costs must be incurred and charged against the award during the performance period

Budget Tool: NIH NDA Data Submission Cost Estimation

- Tool to estimate how much staff time and effort will be required to deposit data
  - Allows users to replace sample answers to questions listed below with research project specifics
  - Cost estimate is for the entire project not per year.

Questions

1. # of subjects?
2. # of sites collecting patient data?
3. # times data from this project submitted?
4. # data structures will be submitted?
5. # unique experiments (e.g., omics, EEG, eye tracking, fMRI) will be conducted in the study?
6. # publications analyzing human subjects data are expected for this project?
7. $ hourly rate charged for the Principal Investigator?
8. $ hourly rate charged for the Data Manager?

Tool: https://nda.nih.gov/ndapublicweb/Documents/NDA_Data_Submission_Cost_Estimation_Tool.xlsx

Where to Include DMS Budget in Application

- Identify direct costs as "**Data Management and Sharing Costs**" on **R&R Budget Form:** line item in section F. Other Direct Costs

F. Other Direct Costs	Funds Requested ($)
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Data Management and Sharing Costs	
9.	
10.	

PHS 398 Modular Budget Form: <u>within</u> Additional Narrative Justification

2. Budget Justifications

Personnel Justification		Add Attachment	Delete Attachment	View Attachment
Consortium Justification		Add Attachment	Delete Attachment	View Attachment
Additional Narrative Justification		Add Attachment	Delete Attachment	View Attachment

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Where to Include Budget Justification in Application

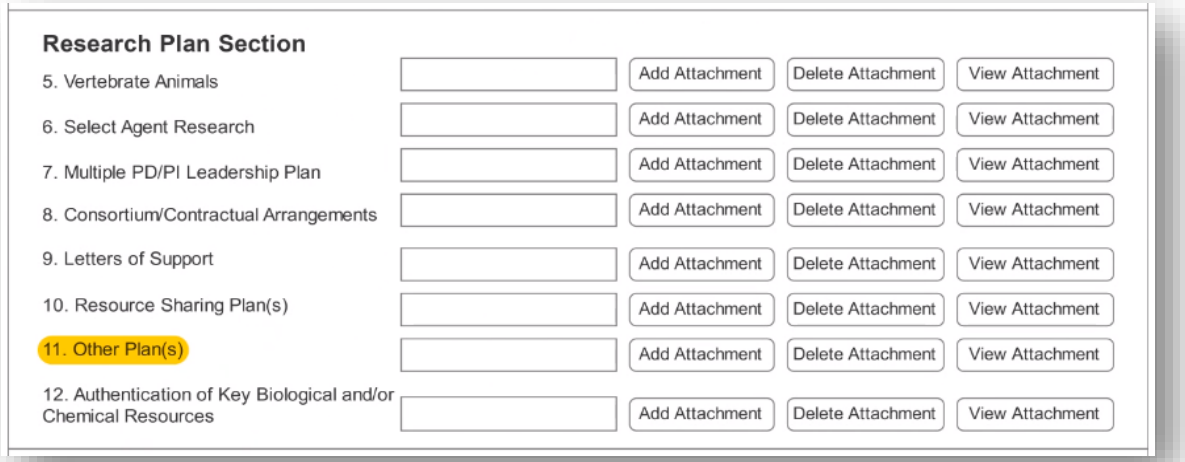
- Label "**Data Management and Sharing Justification**" within the overall budget justification
    - No more than half page (see Application Instructions for details)

- Include activities in the DMS Plan that will incur costs
    - **A brief summary** of type and amount of scientific data to be preserved and shared
    - Name of the established **repository(ies)** and
    - General cost categories

See Budgeting for Data Management & Sharing for details

Where to Submit DMS Plan in Application

- An "**Other Plan(s)**" field was added to the PHS 398 form to collect a single PDF attachment
- **Data Sharing Plans will no longer be submitted through the "Resource Sharing Plan(s)" field**



See Budgeting for Data Management & Sharing for details

Professional Association Efforts on DMS

- Federal Demonstration Partnership
  - Collaboration between federal funding agencies and research institutions
  - Focus on measuring administrative efforts and streamlining administrative burden and increase consistency
- Council on Government Relations
  - Association of Research Institutions
  - Focus on burden reduction and the cost of compliance

FDP DMS Pilot

- FDP partnered with NIH on a two-phase pilot to help assess and refine the data management and sharing plan quality and consistency both for grantees and NIH IC’s
- Two-phase pilot

FDP DMS Pilot Phase 1: Templates

- Testing effectiveness and usability of 2 templates:
  - **Alpha Template** is a prescriptive template designed to limit the need for free text entry
  - **Bravo Template** provides detailed prompts as well as more options for free text entry, as necessary
- Gathering researcher/faculty and NIH program feedback
- Tried one of the pilot templates?
  - Share your feedback here: https://nas.qualtrics.com/jfe/form/SV_b8lylBfDWnINcrA

FDP Phase 2: Costing & Budgeting

- NIH Feedback: plans are lacking budget requests, and lacking details in budget requests
- Cost requests need to account for specific costs such as:
  - Personnel support for preparing data submissions to repositories
  - Collaborations with institutional librarians or investigators on awards, such as data coordinating centers
  - Repository fees
- Pre-Planning – Phase 2
  - Improving budgeting of DMS costs
    - Create tools (Personnel Cost Estimator)
    - Guidance on allowability (direct, indirect, and service center costs)
    - Addressing post-closing related costs
    - Modular budgets
  - Understanding the total cost to the institution
    - If not a direct charge, where are the institutional costs being incurred (& possibly recovered)

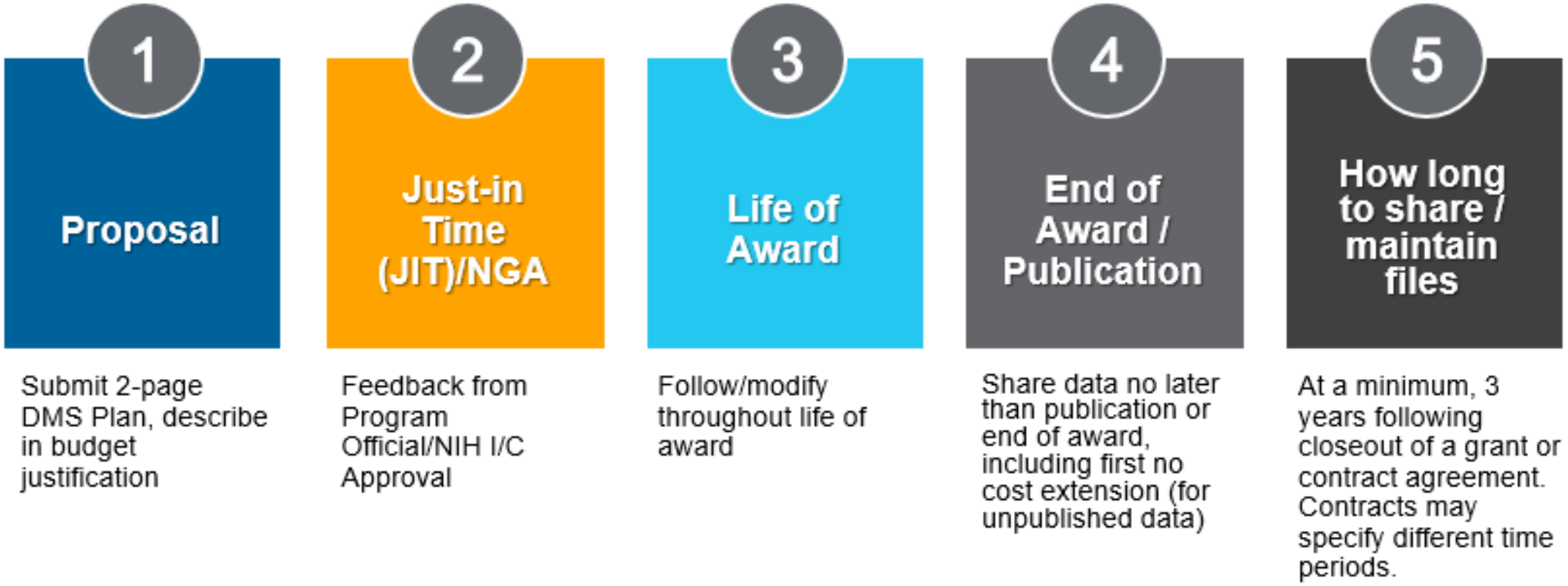
Subawards

- NU-RES has a process to incorporate this into subawards
- This is different to the data access requirements for foreign subawards, which are also addressed in the subaward template

Quick Summary

When	The effective date of the DMS Policy is January 25, 2023.
What	Plan for managing and sharing scientific data that addresses 6 recommended elements. Applications subject to Genomic Data Sharing requirements should include GDS.
Who	All NIH funded projects that to generate scientific data. Complete list of NIH activity codes subject to the DMS Policy application.
Where	NIH strongly encourages investigators to use an established repository to maximize the sharing of scientific data. Note that some funding opportunities or programs may require the use of a specific repository.

PI Quick Guide: Applicability and Timing



NIH Implementation Details:

2023 NIH Data Management and Sharing Policy | NIH Office of Intramural Research

NOT-OD-22-189: Implementation Details for the NIH Data Management and Sharing Policy

NU Implementation: Roles and Responsibilities

- PI responsibilities:
  - Draft the DMSP
  - Ensure personnel (including sub PI) are aware and agree to the plan
  - Report on the plan to the funding agency
  - Ensure the plan is executed

- NU-RES responsibilities:
  - Review DMSP for compliance with agency expectations
  - Review progress report for compliance with agency expectations
  - Ensure DMSP requirements are in subawards

NU Implementation: Resources and Help

- FAQs:
  - https://nu-res.compliance.northeastern.edu/data-management-sharing-plans-dmsp/
- Roles & Responsibilities:
  - https://nu-res.research.northeastern.edu/lifecycle-management/develop-proposal/roles-and-responsibilities/
- Agency Specific Tools:
  - https://nu-res.research.northeastern.edu/lifecycle-management/develop-proposal/agency-specific-tools/

Questions/Suggestions

Thank you!

Q&A

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What about costs associated with data storage or related activities after the end of the award? How should these be handled?

- Include in the budget for the last year of the award.
- Funds must be expended BEFORE the end of the performance period.
- NEU will need to develop a process to manage pre-payment to cover cost in out years to the term when storage costs will be incurred.

Does uploading data in a repository alleviate a PI's need to retain data?

- PIs are still required to retain and maintain NEU data, including original data, with all identifiers where applicable, collected under a NEU research project or its auspices or collected using NEU resources.

- These data are owned by NEU and must be retained by the PI in a location that meets NEU Information Security requirements and in accordance with the Institute's research data retention policy.

Is the new DMS Plan separate or in addition to the existing Resource Sharing plan? Are both required? Where should they be uploaded in grant application?

- The DMS Plan is separate from Resource Sharing.

- The DMS Plan, including Genomic Data Sharing where applicable, is now submitted as an attachment under “Other Plans.”

The DMP Tool format does not create a document in the NIH format (e.g., wrong size font, headers, footers.) How can we modify the document to meet NIH formatting?

- The DMP Tool defaults to PDF but includes an option to use DOCX which allows the DMP to be reformatted to meet NIH requirements.

In addition to the DMP Tool, are there DMS Plan templates for PI use?

- NIH posted resources to assist PIs in drafting their DMS Plan. These range from identification of the six required elements with detailed information on each element to six sample plans in the areas listed below
    - Clinical and/or MRI data from human research participants
    - Genomic data from human research participants
    - Genomic data from non-human source
    - Secondary data analysis
    - Human genomic data
    - Technology development
- NIH sample plans may include specific I/C expectations. PIs should consult the FOA to determine the expectations of the I/C that will fund their project.
- Link: Writing a Data Management & Sharing Plan | Data Sharing (nih.gov)

How does the new NIH Data Management and Sharing Policy apply to applications where NEU is not the Prime?

- Prime is responsible for DMS Plan development, application submission, and implementation throughout the award
- Generally, the subaward PI is not required to include DMS Plan in Statement of Work
- Subaward PI is responsible for familiarizing themselves with and implementing the Prime's DMS Plan at NEU once an award is made.

What about when NEU is the Prime?

- NEU PI is responsible for
  - Developing the DMS Plan to meet NEU needs and those of collaborators
  - Including costs in budget
  - Submitting Plan and budget with application
  - When award is made
    - Implementing locally
    - Educating subaward collaborators on Plan requirements
    - Monitoring subaward data sharing activities