NIH DMS Policy Change Overview

TOPICS

- Effective 1/25/23
- Scope
- Impacts
- WVU Plan

SCOPE – ARE YOU IMPACTED?

*Applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of **scientific data**. This includes all NIH-supported research regardless of funding level, including: extramural grants, extramural contracts, intramural research projects, and other funding agreements.*

In Scope

Research generating scientific data:

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

Out of Scope

Research/activities that do not generate scientific data:

- Training (T)
- Fellowships (Fs)
- Construction (C06)
- Conference Grants (R13)
- Resource (Gs)
- Research-Related Infrastructure Programs (e.g., S06)

Applies to….

Applies regardless of funding amount:

- Competing Grant Applications
- Proposals for Contracts
- NIH Intramural Research Projects
- Other Funding Agreements (e.g., Other Transactions) unless otherwise stipulated by NIH.

The NIH defines Scientific Data as data 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.

What Changed?

- Plan Title: Data Sharing to Data Management & Sharing
- All submissions (was >$500K)
- Must provide more detailed information about the data and data management. (A two-page template provided by the NIH)
- Allowable costs are defined related to data management/sharing
- Allowable Costs must be incurred during the performance period
- The DMS Plan will become a T&C
- Data must be shared at the time of publication/end of the performance period (whichever comes first)
- Revisions are required throughout the life-cycle
- Must provide justification for data that cannot be shared
- Be aware of existing data agreement restrictions
- Informed Consent must be considered, robust language required
- Institutional oversight of plan compliance, roles, titles, must track repositories
- **Requires much more planning at the beginning of research**

IMAPACTS

RESOURCE IMPACTS

The new DMS policy will have a **significant** impact on the research life-cycle and resources, the chart below outlines the proposed roles and responsibilities. Roles with a higher level of impact are shown in green.

	Plan (Prep time will differ)	Proposal Submission	Conduct Research Close-Out	Ongoing
PI	Determine if assistance is needed ASAP Draft the DMS/Budget	Ensure DMS Plan and budget is reviewed & submit	Monitor DMS for changes, revise the plan before close-out, review cost estimates, prepare data, post research	Post research immediately & monitor
Dept Grant Admin Support	Review and assist with budget	Final Review of DMS Budget	Assist with revisions, track budget and spending	Project Closure
Dept Data Support WVU/HSC/CTSI/ InfoSec/RO	Consultation and assist with DMS Plan, cost estimates	Final review of DMS Plan	Assist with the revisions, review cost estimates	Test, transfer data, access provisioning, support tracking
The Library	General Data management consultation, training, guidance	General Data management consultation, training, guidance	Assist with revisions as needed	Institutional Tracking
The Research Office	Coordinate, provide assistance, guidance	Process the submission, ensure IRB approval, agreement compliance,	Process the revisions	Verify institutional tracking, auditing, ensure data is removed as planned

IMPACTS: New Requirements & Tasks

Planning

- ✓ Starting at least two months prior to submission will ensure a compliant DMS Plan.
- ✓ Review the notice for requirements related to repositories, etc.
- ✓ Estimate the amount and type of scientific data that will be shared (this is not always possible and can be modified later).
- ✓ Determine if Data Agreements exist or if data such as WVU Healthcare EMR has restrictions on use.
- ✓ Data Sharing – If data cannot be shared, verify with the RO and others, determine appropriate justification and discuss onsite WVU repositories.
- ✓ Tech Transfer/IP that may require planning for publications – *Consult with the WVU OTT.*
- ✓ Obtain an ORCID ID
- ✓ Attend DMPTool Training (WVU Libraries)
- ✓ Review any NIH institute or discipline-specific requirements
- ✓ Review the options for NIH repositories and other third-party repositories and fees/curation that should be included as allowable costs.

IMPACTS: New Requirements & Tasks

Data Management Tasks

- ✓ **Curation** – Understand repository requirements, estimate the time needed for these activities and associated cost for resources as appropriate.
- ✓ **Supporting Documentation** - Understand repository requirements, estimate the time needed for these activities and associated cost for resources as appropriate.
- ✓ **Meta Data** - Understand repository requirements, estimate the time needed for these activities and associated cost for resources as appropriate.
- ✓ **Use the NIST FAIR Data Principles** (Findable, Accessible, Interoperable, Reusable).
- ✓ **De-identification** – Engage WV CTSI early to obtain approval that data has been certified to be shared in an external repository – *Service exists, and the process is in progress.*
- ✓ **Quality Assurance** - Verify that all materials needed to access the data and replicate results are functioning.

IMPACTS: New Requirements & Tasks

Research Process Tasks

- ✓ Ensure that a Scientific Data Agreement has been completed for the transfer and sharing of the data.
- ✓ Develop a budget for the DMS Plan addressing allowable costs.
- ✓ Ensure that Informed Consent Forms include the standard approved text by WVU ORHP.
- ✓ Ensure that the DMS Plan and budget are updated as needed throughout the performance period.

IMPACTS: BUDGET CONSIDERATIONS

Allowable Costs

Must be incurred during the performance period

- Data Curation
- Developing Supporting Documentation
- Formatting
- Transmission
- De-identifying Data
- Preparing Metadata
- Local Data Management Considerations (during active research)
- Fees related to preserving and sharing data through established repositories (multiple repositories are allowable)

Budget/Costing Considerations:

- Data Management & Sharing Costs are currently represented as a single line item

  NIH NOT-OD-22-189:

  - R&R Budget Form: Single Line Item in Section F Other Direct Costs
  - PHS 398 Modular Budget Form: As text embedded with the Additional Narrative Justification
- There are known issues related to the single line item – Contact your pre-award staff or the Research Office (OSP) for guidance.
- During the initial year be prepared to address modifications/revisions during Just-In-Time. Consider if changes to the plan impact the budget.
- DMS information is included in progress reports/RPPR.
- The Council on Government Relations (COGR) has provided information and recommendations for budgeting and costing while the NIH refines the requirements. (next slide)

COGR Recommendations:

Approaches to budgeting (be sure to maintain internal documentation for approaches used for budgeting)

1. Use the NIMH Data Archive (NDA) Data Submission Cost Estimation Tool (does not capture non-labor costs such as repository fees. 2 CFR)
2. Calculate high-level cost items using estimates only. (For PIs with experience budgeting for DMS costs)
3. Calculate labor costs as a percentage of the direct costs. (Use when specific details are unavailable or unknown at the time of the proposal)

To review the full guidance document from COGR visit the Budget Toolkit section of the resource web page.

IMPACTS: DATA SHARING COSIDERATIONS

Data Sharing Guidance:

Data Type

- Human Research Data – Discuss sharing and de-identification with WV CTSI
- Research Data with IP Considerations – Discuss sharing with the Office of Technology Transfer/Review NIH IP Policy
- Other Research Data Types– Discuss sharing with RO HPC Services, ECAS, CEMR local IT support, InfoSec
- Reusing existing shared data - Scientific data can result from secondary research, but researchers are not expected to share the existing, shared primary data used to conduct the secondary research

Existing Restrictions

- Existing data agreements that may restrict sharing (Note WVU Medicine data must be reviewed before sharing)
- Explicit federal, state, local, or Tribal law, regulation, or policy that prohibits disclosure

Repositories

- Repository Options – **The NIH encourages PIs to use an established repository**
- Repository Options – WVU Libraries, WV CTSI, Local IT/Pre-Award Support, Research Office
- Access controls may be needed (some NIH repositories have access controls)
- How long will the data be shared? (allowable cost - must be incurred during the performance period)

NIH Considerations

- Check the NIH definition of SCIENTIFIC DATA to determine data that is required to be shared
- Check the NIH policy and notices related to data sharing (on the NIH and WVU websites)
- Check individual NIH Institutes, Centers, or Offices for additional policies and expectations

NIH Data Sharing Policy:

NIH Definition of 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 functions.*

Potential Examples of Scientific Data

- Single-cell RNA sequencing (scRNA-seq) of T lymphocytes or other immune cells in a study of HIV/AIDS.
- Electrophysiological recordings and fMRI images in a study of a rodent model or PTSD.
- Step activity from a wearable device in a study of cardiovascular health.

Scientific Data Do NOT Include:

- Data not necessary for or of sufficient quality to validate and replicate research findings
- Laboratory notebooks
- Preliminary analyses
- Completed case report forms
- Drafts of scientific papers
- Plans for future research
- Peer Reviews
- Communication with colleagues
- Physical objects (e.g., laboratory specimens)

NIH Data Sharing Policy- Continued:

When should SCIENTIFIC DATA be shared?

Scientific data should be made accessible **as soon as possible**, and no later than the time of an associated publication or the end of the performance period of the extramural award that generated the data. Specifically, the DMS Policy expects scientific data to be shared **by the earlier** of two timepoints:

The time of an associated publication:

Scientific data underlying peer-reviewed journal articles should be made accessible no later than the date on which the article is first made available in print or electronic format.

OR

The end of the performance period:

Scientific data underlying findings not disseminated through peer-reviewed journal articles should be shared by the end of the performance period unless the grant enters into a no-cost extension.

If a no-cost extension is permitted, then the recipient should share the data by the end of the extended performance period. These scientific data may underlie unpublished key findings, developments, and conclusions; or findings documented within preprints, conference proceedings, or book chapters.

For example, scientific data underlying null and negative findings are important to share even though these key findings are not always published. Researchers should be aware that some preprint servers may require the sharing of data upon preprint posting, and repositories storing data may similarly require public release of data upon preprint posting.

NIH Policy Data Sharing Policy – Continued:

Potential examples of justifiable factors include:

1. Informed consent will not permit or will limit the scope or extent of sharing and future research use
2. Existing consent (e.g., for previously collected biospecimens) prohibits sharing or limits the scope or extent of sharing and future research use
3. Privacy or safety of research participants would be compromised or place them at greater risk of re-identification or suffering harm, and protective measures such as de-identification and Certificates of Confidentiality would be insufficient
4. Explicit federal, state, local, or Tribal law, regulation, or policy prohibits disclosure
5. Datasets cannot practically be digitized with reasonable efforts

Examples of reasons that would generally not be justifiable factors limiting scientific data sharing include:

1. Data are considered to be too small
2. Data that researchers anticipate will not be widely used
3. Data are not thought to have a suitable repository

IMPACTS: NIH REVIEW PROCESS FOR DMS PLANS

NIH Review Process for the DMS Plan

- DMS Plans are NOT part of scored peer review criteria unless specifically noted in the Funding Opportunity Announcement**.**
- Peer Review will NOT see or review DMS Plans but will consider any budget-related items.
- DMS Plans will be stored in the eRA Commons with limited access.
- NIH program staff will review the DMS Plan for acceptability and may request modifications prior to award as appropriate.
- DMS Plans must be approved by the funding institute prior to award.
- NIH PEER REVIEW – Review of the budget supporting the DMS Plan will be reviewed (Not the DMS Plan).
- The DMS Plan is assessed by NIH Program Staff.
- DMS Plan becomes a part of the Terms and Conditions for the Award.

NIH FAQ to Note:

How will an offeror's history or experience of data sharing or lack thereof be considered for future contracts?

The DMS Policy, NOT-OD-21-013 states, "after the end of the funding period, non-compliance with the NIH ICO-approved Plan may be taken into account by NIH for future funding decisions for the recipient institution." Within contracts, enforceability of the DMS Plan does not extend beyond the period of performance of the contract. COs are encouraged to use alternative means of evaluating an offeror's history of data management and sharing outside the performance period of a contract. For example, CO's could provide the DMS questionnaire (data management and sharing history) to offerors in solicitations and use Contractor Performance Assessment Reporting System (CPARS) to capture DMS during contract performance.

WVU PROCESS AND GUIDANCE

WVU RESEARCH PLAN

The Research Office (RO) chairs a cross-departmental committee to ensure WVU researchers are prepared to comply with the new policy. As a result of the White House OSTP's recent memo requiring all agencies to implement policies related to data management and sharing by 12/31/22, we expect more change soon.

Short Term Plan – Meet the NIH Requirements for Q1/Q2

- Survey to determine NIH submission plans for 2023 by quarter.
- Survey PIs with active grants to determine planned submissions in 2023.
- Develop a consultation form and meet with the PIs to begin education and planning.
- Assist the PI with determining repositories and associated costs.
- Assist with the development & review of the DMS Plan.

Long-Term Plan – Institutionalize DMS processes

- Implement planning processes for PIs to communicate technology needs for research VERY early in the process.
- Develop comprehensive guidance, and processes to assist PIs with technology and data-related requirements throughout the research life cycle.
- Develop an institutional knowledge base of research technology experience (staff and training).
- Ensure WVU is prepared for new requirements and policy changes.
- Create a culture of sharing and collaboration to assist PIs with the complex requirements

Research DMS Committee:

Rosemary Casteel – RO Chair
Katie Schneller – RO OSP
Nate Garver-Daniels – RO HPC
Kasandra Lambert – RO OHRP
Jonah McAllister-Erikson – Library
Beau Smith – Library
Faythe Thurman – HSC Library
Susan Crayne – WV CTSI
Wes Kimble – WV CTSI
Emily Morgan – WV CTSI
Erica Bentley – ECAS
Mike Starling – ECAS
Stan Hileman – ORGE
Lana Yoho – ORGE
Kathleen Cullen – CEMR
Rick Pritt – CEMR
ITS, SRA, InfoSec – As Needed

Committee Work Status:

- Complete - Survey Research Community to determine 2023 Submission Plans
- Complete - Proactive Consultations - Target Q1 and Q2 Submissions
- Complete - Resource Web Page
- Complete - Initial Education and Information
- Complete - Roles and Responsibilities
- Complete – Guidance for ORCID and persistent identifiers
- Complete – Institutional implementation of DMPTool with approved institutional text options
- Complete – How to get help with Data Formatting and Curation

- In Progress – Budget Guidance (long and short term)
- In Progress – WVU On Site repository services
- In Progress – Institutionalizing Process: IRB, OSP Intake/Close-out, De-identification, OSP Agreements.
- In Progress – Roles and process for managing plans at the institutional level
- In Progress – FAQs and improved guidance for data sharing, budgets, curation

NIH DMS Link: https://sharing.nih.gov/data-management-and-sharing-policy

Notes:

- The NIH is currently piloting the new policy with the Federal Demonstration Partnership (FDP) to refine policy requirements.
- 2023 will be challenging – We are all learning.
- NIH guidance on budgeting is limited and may seem counterintuitive at times, according to sources such as COGR (seek help early and often).
- **The DMPTool is now integrated with WVU Single Sign-On (Institutional Benefits) – Sign-up for Training (WVU Libraries)**
- **Use of the DMPTool is not yet required but is expected to be as the DMS Pans require institutional accountability.**
- WVU Libraries and other departments offer training and education, check the resource page.
- We can and will adjust as new guidance is released.
- The goal is to develop DSM Plans that are as compliant as possible with the new policy based on current information.
- While full staffing is not in place, **expertise and guidance is available**. However, it will take time to support all PIs – Please be as proactive as possible!

Resources

- Research Office Web Page – Link to all information and resources

  https://researchportal.wvu.edu/nih-dms-policy-change

- Departmental & College IT and Pre-Award Staff
- WVU Research Office
- WV CTSI
- WVU/HSC Libraries

Questions?

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