Data Management & Sharing:

Making Progress to January 2023

October 2022 COGR Meeting

PRESENTERS

***Michelle Bulls*, NIH, Office of Policy for Extramural Research Administration (OPERA)**

***Michelle Christy,* COGR Partner**

***Jim Luther,* COGR Partner**

***David Kennedy,* COGR, Costing & Financial Compliance**

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Making Progress?

An Emphatic ***YES!!! …***
and by partnering with:

- *Association of Research Libraries (ARL)*
- *FDP & other associations*
- *COGR Membership & Workgroups*
- *U of Delaware & Duke U*
- *NIH*
- *DMS Resource Page*

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Data Mgt & Sharing Resource Page

Council on Governmental Relatio | Helpful Links | Council on Govern | NIH Data Management and Shar

cogr.edu/nih-data-management-and-sharing

NIH Data Management and Sharing Policy Resource Page

On October 29, 2020, NIH issued its Final Policy on Data Management and Sharing, effective for grant and contract applications submitted and other funding agreements executed on or after January 25, 2023. The Policy was issued to promote the management and sharing of scientific data generated from NIH-funded research, and established requirements for submission of Data Management and Sharing plans and compliance with ICO-approved plans. In addition to the Final Policy, NIH also released several supplemental notices and FAQs, and we have seen some ICOs release their own policies as well. COGR, working closely with colleagues from FDP, ARL, AAU, APLU, and others, has convened a workgroup of association and institutional representatives to assess and provide guidance on the Policies and their effect on the research community, analyzing the cost of compliance to research institutions and faculty, and advocating for harmonization where possible and articulating where clearer guidance is needed in a variety of areas. If you have any questions about this effort, please contact David Kennedy, Director of Costing and Financial Compliance at dkennedy@cogr.edu.

NIH Policies, Supplements, & FAQs

NEW NIH Data Sharing Info Website

COGR Readiness Guide

Latest Chapter

81°F Mostly sunny

2:59 PM 8/17/2022

COGR Council On Governmental Relations

Agenda

- ✓ NIH Policy, from a Research Institution Lens:

  Michelle Christy

- ✓ Getting Ready, Roles & Responsibilities:

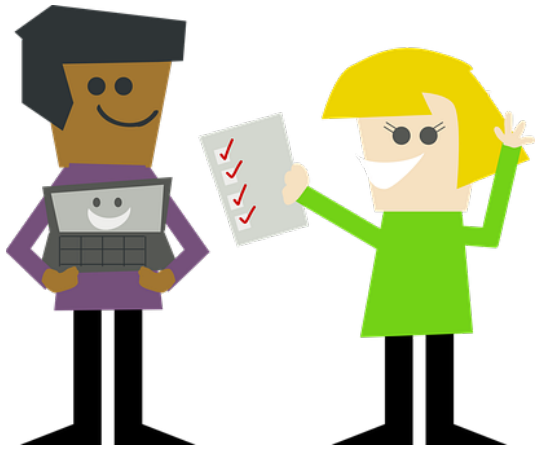
  Jim Luther

- ✓ Burden & Advocacy:

  David Kennedy

- ✓ The NIH Perspective:

  Michelle Bulls



Data Management and Sharing NIH Policy Summary

Level of Readiness for January 25th?

- **WHEN WE ASKED THIS AT THE JUNE COGR MEETING: What is your level of "readiness" for the NIH DMS implementation?**
  - We're just starting this work at my institution 50%
  - We're underway and making progress 34%
  - We've got this. We'll be ready 0%
  - I don't know, but I hope someone else is on this 16%

- **Update – What is your level of "readiness" now?**
  - Launch date minus ~3 months

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***POLL QUESTION:* What is your level of "readiness" for the NIH DMS implementation, TODAY?**

1) We're just starting this work at my institution
2) We're underway and making progress
3) We've got this
4) I don't know, but I hope someone else is on this

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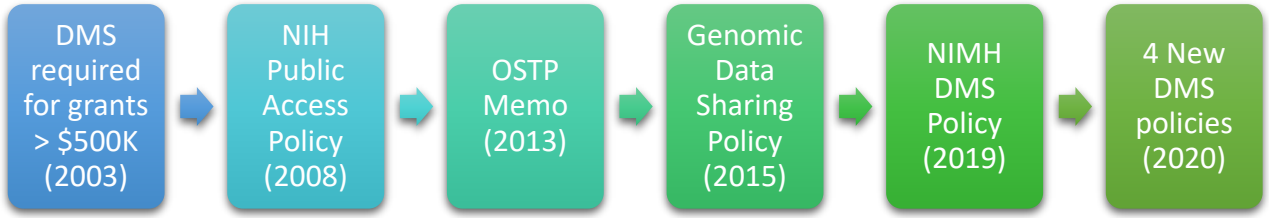
NIH Policy Matrix: Policies, Supplements, and FAQs (Excel Download)

	Policy	Effective date	Applicability	Management Plan Format/Where to Include in Application
Researching Policies/FAQ	NOT-OD-22-189 Implementation Details for the NIH Data Management and Sharing Policy	January 25, 2023	The DMS Policy applies to all NIH research, funded or conducted in whole or in part by NIH, that results in the generation of scientific data. Does not apply to non-research activities (e.g., training or construction awards). For more details see Research Covered https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policy/research-covered-under-the-data-management-sharing-policy#research-covered-by-the-2023-data-management-&-sharing-policy. Although the DMS Policy will apply also to Research and Development (R&D) contracts, NIH intramural research projects, and other funding agreements (e.g., Other Transactions), the forms changes and other implementation details provided in this Notice apply only to NIH extramural grant and cooperative agreement activities. Details applicable to R&D contracts will be incorporated into the appropriate Requests for Proposals, and details applicable to Other Transactions will be incorporated into the appropriate Research Opportunity Announcement.	A new "Other Plan(s)" field will be added to the following FORMS-H forms to collect a single PDF attachment containing the Elements of a DMS Plan (Form H coming Fall 2022)
	NOT-OD-22-198 - Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023 (August 31, 2022)	January 25, 2023	NIH intends to establish a single data sharing plan submission requirement for a research subject to both the NIH Genomics Data Sharing Policy (GDS policy) and the NIH policy for Data Management and Sharing (DMS policy). The implementation update will take affect for plan submission due dates on or after January 25, 2023.	Plans for sharing genomic data as expected by the GDS Policy are to be described in the DMS Plan submitted at the time of application, and not in a separate GDS Plan or at Just-in-Time.

NIH DMS Policy Timeline



Policy Summary

- Effective date – January 25, 2023, or earlier (NIMH, NIAAA now)
- Plan format – elements of a plan (template), 2 (or more?) pages; Form H
- Plan approval/update process – proposal stage, JIT, annual RPPR
- Costing institutions – allowable costs; cost calculator
- Human participant/privacy – genomics data sharing plans, consent process, AI/AN participant data
- Data storage – FAIR principles, NIH repositories, when to make the data available, for how long
- Monitoring and compliance – slow roll

Policy Differences Across ICs

- Generally, applies only research projects
- Repositories – IC-specific solutions - >100 NIH repositories; other options may be available if they meet *Selecting a Repository for Resulting Data* policy NOT-OD-21-016
- Plans & templates
  - NIMH Data Submission Agreement – to be completed by the PI and signed/submitted by the Signing Official in eRA Commons
  - NIAAA – model plan from March 2022 includes what PIs should expect to do for DMS, plus a minimal amount of information data to be collected/shared
  - FDP Demonstration will focus on this –

    (More from Michelle Bulls next)

Critical Considerations for Institutions

- Requirements from other ICs – plans, repositories, etc.

- Monitoring and Compliance – expected NIH approval process for plans; types of plan changes that trigger a prior approval; frequency of uploads

- How will the costing work - direct charges are allowable; quantifying costs for curation (day-to-day work); long-term storage; “takes away from the science”

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Roles & Responsibilities

Thanks to "Roles and Responsibilities" Team!

Suzanne Allard, Univ. Tenn. at Knoxville

Jennifer Ariansen, Duke

Raul Doyle, Duke

Walter Goldschmidts (Cold Spring Harbor)

Ted Hanss, Yale

Melissa Korf, Harvard

Jasna Markovac, Yale

Limor Peer, Yale

Alicia Reed, KU

Lindsey Spangler, Duke

Marissa Stroo, Duke

COGR Team: Toni Russo, David Kennedy, Michelle Christy, Krystal Toups, Jim Luther

NIH

– Michelle Bulls and Team

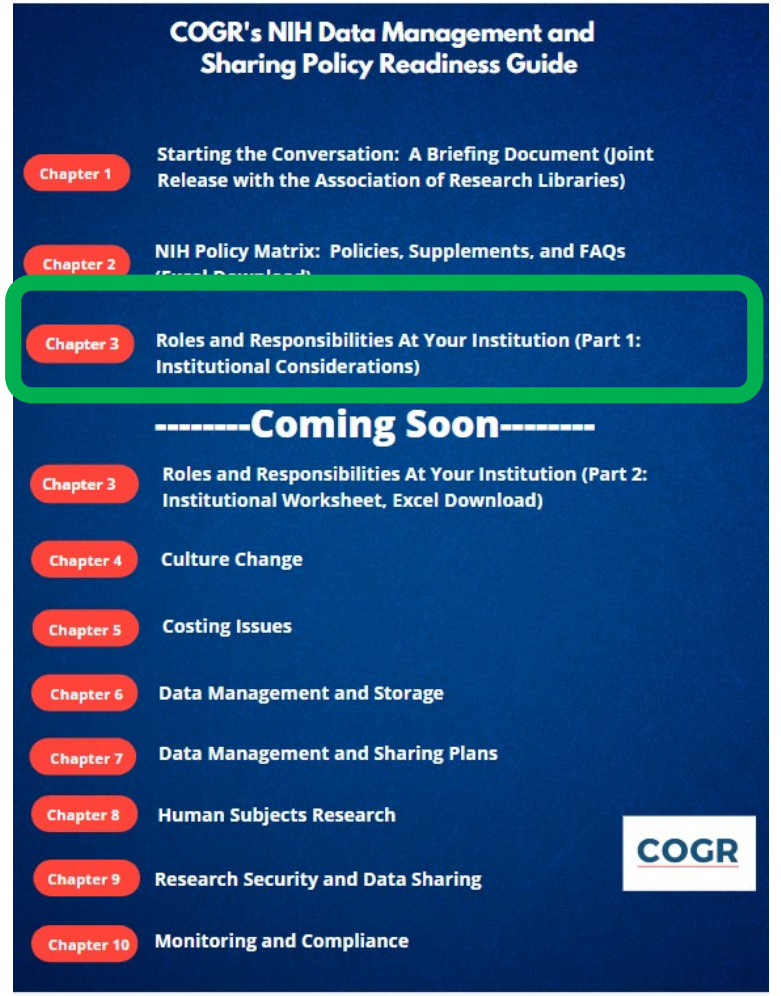
Association of Research Libraries (ARL)

- Cynthia Hudson-Vitale and Team

It's Not Over – Volunteers Still Welcome

Roles and Responsibilities At Your Institution (Part 1): Institutional Considerations

- "This considerations document is meant to be used as a starting point, and we encourage you to add to and customize the information for your own institution."
- Factors for Consideration (11)
  - 1) **"Roles" will differ significantly** by an institution's structure, size, and culture.
  - 2) Since many institutions have shared authority / accountability for technology, libraries, pre-award offices, etc., **consistent role assignments across the entire institution may be difficult**.
  - 3) The **level of institutional centralization / decentralization may impact implementation.**
  - 4) Institutions with large NIH portfolios that include grants of >$500k in annual direct costs, or large NSF portfolios, **may have developed solid structural competencies to support this expansion** as they may have been working with DMS for several years.
  - 7) **Many institutions may not currently have enough trained data management or other expertise** throughout this process lifecycle.
  - 10) **The number of researchers impacted by the change and their experience level may vary significantly**



Roles and Responsibilities At Your Institution (Part 2), Institutional Worksheet, Excel Download)

POLL QUESTION: How much are you involved in the implementation of the January 2023 requirement?

1) Not at all
2) A Little - I meet with the institutional implementation team to advise periodically (monthly)
3) A Lot - I meet with the institutional implementation team to advise regularly (weekly)
4) All the Time: I have significant responsibility to support the implementation but not I'm not responsible (semi-daily)
5) My Office is primarily responsible

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Responsibilities / "Primary" Activities

0) Institutional Readiness

- Confirmation/Development of Community Standards – Research teams work with colleagues internal and external to institution to identify and develop community data and sharing standards in general and specific to their discipline.
- Develop and provide training on the DMS Policy & Process
- Identify a single Point-of-Contact and Triage Process

1) Planning, Design and Start up of projects
2) Data Collection, Storage, and Management
3) Making Data Broadly Available
4) Data Retention, Including Preservation, Archive, and Long-Term Access
5) Project Closeout and Compliance

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Roles and Responsibilities At Your Institution (Part 2: Institutional Worksheet, Excel Download)

ion 10/1/22

Roles and Responsibilities: Lifecycle Data Management & Sharing

Preamble: the Introduction tab provides details for considerations as an institution uses this document. It is important for an institution to customize this spreadsheet based on its specific organizational hierarchy, level of decentralization, differing areas of expertise, etc. Institutions will likely add and delete rows (activities/responsibilities) and columns (roles) specific for their

A

Activity			
Lifecycle Public Data Access Activities	**Sub-Activities** B	C **Lifecycle / Timing**	**Reference**
Confirmation/Development of Community Standards - Research teams work with colleagues internal and external to institution to identify and develop community data and sharing standards in general and specific to		Infrastructure / Pre-Proposal	
	Develop and work with discipline-specific data managers and support staff; engage with research societies who have a critical role in developing standards.	Infrastructure / Pre-Proposal	
	Work with CORES and institutional service providers to evaluate storage and data management options to support your institutions and scientific discipline.	At Proposal	
	Develop and provide training on the DMS Policy & Process for faculty, grants office, support teams, post-docs; determine level of department grant management	Infrastructure / Pre-Proposal	
	Identify a single Point-of-Contact and Triage Process for required clarifications and issues that require escalation internally and to NIH; critical at deadline for	Infrastructure / Pre-Proposal	
	Based on risk, burden management, and level of decentralization: evaluate effectiveness of internal control environment related to Data Lifecycle (policy,	Infrastructure / Life-cycle	
	Develop training for full life cycle of this orocess (DMS Plan development, data management/curation, storage options, monitoring, clsoeut, etc.0	Infrastructure / Life-cycle	
Planning, Design and Start up of projects			NIH Notice and IC specific guidance
Determine if your proposed research is subject to the DMS policy.	Review Funding opportunity announcement for requirements and specific guidance related to the awarding IC.		Determine if your proposed research is subject to the DMS
Identify appropriate methods/approaches and repositories for managing and sharing scientific data	Review institutional tools/guidance/resources related to your specific discipline		
	Review COGR readiness guide		
	Evaluate institutional roles & responsibilities for critical steps in the DMS Plan support		
Identify a data resource manager			
Preparing a data management plan	* Note that applications subject to both the DMS Policy and the GDS Policy will submit a single Plan.		Develop a Plan for managing and sharing
	Review IC specific data sharing expectations (e.g., scientific data to share, relevant	At Proposal	

Roles and Responsibilities At Your Institution (Part 2: Institutional Worksheet, Excel Download)

NIH / Peer Review / Program Staff	Legal / Regulatory / Etc.	Single POC to Triage Issues	Tech Transfer	Repository	VPR	PI	Library	Postdoc / Grad Student	Dept. Grant Support Staff	Pre-award (Central	(

Role										
Post-award (Central	Central Compliance Oversight	Research Program Development	Human Research Support (as	Institutional Data Management	Proc. / Other	IT	Costing / Accounting	Training	etc.

Roles and Responsibilities: Issues for Consideration

- Specific “Responsibilities/Activities” and “Roles” may differ significantly
  - By institution (see Part 1 (Considerations))
  - Depending on whether the grant is using a repository (internal or external)

- There is ongoing discussions about the role of the institution in monitoring and accountability; this includes:
  - Completeness/accuracy of DMS Plan
    - Budget, Data storage commitments, Compliance with DUA, Security, IRB, etc.
  - Monitoring for compliance throughout life - Compliance with NOA and Terms & Conditions – Prior approval requirements and process
  - Post closing compliance, etc.

- Timing and level of enforcement of all requirements

- THIS DOCUMENT → Part 2: Roles and Responsibilities
  - “Version 1” is released but will iterate and change
  - Customize to your institution – add and delete columns and rows → Excel Sheet

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COGR & FDP Support for NIH Readiness

- COGR
  - Fully engaged with COGR DMS Team
  - Assisting with Roles and Responsibilities development from NIH perspective (TBD → Peer review, Program Office, RPPR guidance, etc.)
- FDP – Two Phase Pilot Demonstration
  - Co-Chair of FDP Pilot on NIH Data Sharing and Management; other NIH participants include Julia Slutsman and Cindy Danielson
  - Institutional Participants: Christi Keene, Melissa Korf, Jim Luther
  - Objectives
    - Phase 1: Develop templates with OPERA and the participating ICs and test their effectiveness to meet ICs requirements while reducing burden for institutions
    - Phase 2: Costing policies - Focus on ways to establish common cost principles, types of costs required, and determine how to identify additional/unforeseen costs that may be required to meet the spirit of the data sharing policy

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Burden & Advocacy

Burden & Advocacy

- Administrative Burden, it's real
  - New processes across admin units, IT, the library, etc.
  - Expectations of PIs when their data plans are questioned
- Cost Burden , it's real … too
  - How to Budget? Direct Charging?
  - How to Pay? F&A? Infrastructure supplements?
  - Cost of data storage/maintenance beyond the period of performance?
- And then there's that little matter of "Enforcement"
  - What would one-year of grace look like?
  - Intersection with the FDP Pilot?

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And the Survey Says …

- COGR "Burden" Survey completed in early October
- 34 responses across diverse institutions
  - < $50M thru > $500 M
  - Some NIH-centric, others not
- Measurement of Specific Activities:
  - Data plan design, data integrity, data storage, monitoring
- And burden within:
  - Pre-award, Library, IT, Dean, PIs, Post-award, etc.
- Using a scale of:
  - "1" Low, "2" Low/Mod, "3" Mod/High, "4" High

Preliminary Results

Do you expect this activity will create new administrative burden at your institution?

- Planning/Design/Start-up: YES = 33/34 = 97%
- Data Collection/Secure Storage: YES = 32/34 = 94%
- Data Integrity/Retention/Sharing: YES = 33/34 = 97%
- Monitoring/Oversight/Audit: YES = 34/34 = 100%
- Closeout/Cost Recovery: YES = 32/34 = 94%

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Q & A (Institutional Considerations) ???

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NIH Implementation of the New Data Management and Sharing Policy

NIH OFFICE OF POLICY FOR EXTRAMURAL RESEARCH ADMINISTRATION (OPERA)

OCTOBER 20, 2022

National Institutes of Health
Office of Extramural Research

New Data Management and Sharing (DMS) Policy (NOT-OD-21-013)

- Effective January 25, 2023, the DMS Policy will require researchers to prospectively plan for how scientific data will be preserved and shared through submission of a DMS Plan (*replaces 2003 Data Sharing Policy*).
- Applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of scientific data.
- The DMS Policy requires:
  - Submission of a DMS Plan outlining how scientific data and any accompanying metadata will be managed and shared, taking into account any potential restrictions or limitations.
  - Compliance with the awardee's plan as approved by the NIH Institute and Center (IC).

Potential Impact on Recipients

- Flexibility of NIH ICs to develop IC-specific requirements may require recipients to prepare more than one version of a DMS plan which will place an added administrative burden on applicants.
- Potential for additional DMS plan implementation costs incurred during project period not included in original application.
- Planning for DMS implementation cost for programs that provide budget caps for funding.
- Some data may carry explicit limitations on sharing.
- May require planning for long-term storage and archiving of data beyond the period of performance.

NIH Implementation Considerations

- NIH is prepared to work with our extramural community to address any challenges.
- 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.
- OPERA has asked ICs to put individual IC data sharing policies on hold during the transition.
- NIH will collaborate with applicants to ensure data sharing plans are acceptable prior to issuing awards (at JIT). Our goal is not to reject applications simply due to inadequate data sharing plans.

NIH Efforts to Reduce Administrative Burden: The DMS Demonstration Pilot Project

- Federal Demonstration Partnership collaboration with NIH OPERA, Office of Extramural Research SMEs and NIH ICs.
- Goals of the DMS Demonstration Pilot:
  - Generate greater consistency in DMS Plan requirements across NIH ICs and programs.
  - Mitigate the administrative burden for researchers associated with DMS Plan development and implementation.

DMS Demonstration Pilot: Implementation

Phase 1: Test Standardized DMS Plan Templates

- Pilot participants will test the effectiveness of new web-based (DMPTool) templates to support the generation of a DMS Plan that is compliant with the new NIH policy and meets the varying needs of ICs.

Phase 2: Focus on Cost Policies

- Establish common cost principles.
- Identify types of costs required.
- Determining how to identify additional/unforeseen costs that may be required to meet the spirit of the data sharing policy.

Timeline for Implementation (tentative):

- Initial Planning: September 1, 2022 - November 30, 2022
- December 1, 2022 – January 25, 2023: sharing templates, evaluation criteria, pilot guidelines with relevant participants
- January 26, 2023 – December 31, 2023: data collection

Data Management and Sharing Policy Resources

- Data Management and Sharing Policy Website
- NOT-OD-21-013 – Final NIH Policy for Data Management and Sharing
- NOT-OD-21-014 – Supplemental Information to the NIH Policy for Data Management and Sharing: Elements of an NIH Data Management and Sharing Plan
- NOT-OD-21-015 – Supplemental Information to the NIH Policy for Data Management and Sharing: Allowable Costs for Data Management and Sharing
- NOT-OD-21-016 – Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research
- NOT-OD-22-189- Implementation Details for the NIH Data Management and Sharing Policy
- NOT-OD-22-198 – Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023