

NIH Data Management and Sharing

Implementation of Roles & Responsibilities: Considerations for Institutions

This document discusses what institutions should consider when developing their implementation plans for the January 2023 Final NIH Policy for Data Management and Sharing (DMS) (NOT-OD-21-013) and considerations related to institutional culture, resources & infrastructure, and organizational structure. NIH has stated that a primary goal for the new policy is cultural change, aimed at challenging researchers to develop their projects with the goal of data sharing in mind. Researchers are expected to share the results of their NIH-funded studies throughout the life of the project to maximize research outcomes (taxpayer dollars) while supporting research rigor & reproducibility. These changes may impact a significant number of researchers and institutional resources. Consider the factors below when implementing your institution's approach to complying with these new regulations¹.

Start early, think broadly, assess the current environment, make connections.

Critical first steps include:

- Discuss the <u>COGR Briefing Sheet</u>² with senior leadership (Operations, Library, IT, Faculty, etc.); consider customizing the briefing sheet for use in institutional outreach efforts.
- Estimate how many Data Management & Sharing Plans (DMSPs) will be needed annually based on prior year's proposal data; inventory where your organization may already have some organizational competencies in developing and implementing DMSPs based on NIH awards over \$500k in annual direct costs, as well as experience with existing NIH institute specific DMSP requirements.
- Determine how many PIs would be new to developing DMSPs and identify where they are in the organization. Can you leverage areas of experience?

¹ For more information on NIH's Final Policy for Data Management and Sharing, including COGR advocacy letters, updates to the membership, meeting materials, and COGR's Readiness Guide, visit our DMS resource page here: https://www.cogr.edu/nih-data-management-and-sharing

² Institutions may find it helpful to customize this Briefing Document. An editable version can be found here (log in required): https://cogr.member365.org/sharingnetwork/workspace/view/20



- Create a committee with research leadership, IT, library staff, research administration support, faculty, a member of the IRB, etc., as applicable, to review institutional resources and policy/process requirements. Communicate with the research community and institutional leadership early and often.
- Encourage researchers to discuss these new requirements with colleagues in their field in order to help shape expectations within their particular scientific community around data management and sharing.
- Identify a single collection point for feedback from PIs about DMS; share with other researchers.

Factors for Consideration

- 1) "Roles" will differ significantly by an institution's structure, size, and culture. However, "Responsibilities" include the specific tasks or activities for implementing the Policy and apply to all grantee institutions. For example, faculty or postdocs may be asked to develop their DMSPs independently at some institutions. In contrast, at other institutions, the office of the vice president/provost for research or the library may provide researchers with resources and services. Further, this may vary significantly for large, complex institutions, academic medical centers, and scientific disciplines.
 - a. Approach:
 - i. Share the responsibilities with the various stakeholders, understanding that, for example, microbiology, chemistry, cardiology, and the genomics institute, may all have different support mechanisms, levels of experience with data sharing, and resources.
 - ii. Discuss whether centralizing some aspects of the responsibilities may be beneficial to researchers and might provide economies of scale.
- 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. For example, many universities have separate IT functions for their school of medicine and main campus schools; this may also be the case for the libraries. Large centers and institutes have significant autonomy and internal support mechanisms at some institutions and may not rely as much on central resources. This shared and distributed support may mean different models for roles and responsibilities and implementing the policy/processes.
 - a. Approach:
 - i. Identify and inventory the breadth and level of expertise of potential support units at the institution level, school level, departmental level, and center/institute level (e.g., cancer center); identify existing gaps.



- ii. Task the committee or subgroups with developing guidance and policy for each high-level area (e.g., planning, design & start-up of the project, data collection, storage & management, open access, etc.).
- iii. Evaluate where shared services support exists that could be beneficial.
- iv. As some researchers may have appointments in multiple departments/schools, ensure clear guidance for faculty who may be part of one department but submit a grant in another department as the support structure may differ across units.
- 3) The level of institutional centralization/decentralization may impact implementation. Institutions vary significantly on how resources, authority, and accountability are managed. In some cases, central offices (e.g., library, IT, and research administration) provided a high level of support and oversight. Support may be provided at the department/school level at other institutions. Institutions should avoid situations where different stakeholders are working on the same problem without knowing it. Note that it may be challenging to identify all the stakeholders that need to be involved in planning.
- 4) Institutions with large NIH portfolios that include grants of >\$500k in annual direct costs, or large NSF portfolios, may have developed solid structural competency to support this expansion as they may have been working with DMS for several years. This may provide these researchers or departments with expertise that could be shared across the institution.
 - a. Approach:
 - i. Evaluate the prior year's proposal data to understand which faculty and departments currently have NIH awards greater than \$500k or NIMH funding where the policies have been in place for some time, and where there may be skills, resources, and team to support this. Work with these groups to identify lessons learned.
 - ii. Many NIH-funded large, collaborative programs include an administrative core with an ability to charge DMS administrative effort as a direct cost. Those programs may also be operating under different NIH expectations. Nevertheless, they may have expertise that can be leveraged in your team development, communication, and training.
- 5) Significant institutional effort has gone into managing numerous institution-wide issues over the last several years, including COVID-19, undue foreign influence, research security, and other local initiatives, absorbing resources, leadership focus, and operational attention. These factors may make it very challenging to prepare for the significant change related to this data management policy implementation.
 - a. Approach:
 - i. Engage change management experts to assist with communication planning.



- ii. Reach out to individual stakeholder groups, including faculty, research admin support, and IT/library; share the <u>Briefing Sheet</u> and <u>COGR DMS website</u> as resources.
- iii. Create audience-specific communication and training, including the relevant roles and responsibilities for each group
- iv. Create an institutional committee to provide oversight, coordination, and consistent communication.
- 6) Institutions can influence, change, and drive culture. Since this implementation is mainly about culture change and the role that data plays in the research mission, implementation challenges may vary significantly.
 - a. Approach:
 - i. Identify ways to help researchers update their practices to align with the federal requirements while maintaining practices that meet their needs. See Chapter 4 of the COGR Readiness Guide "Culture Change³"
 - ii. Recognize barriers to sharing, including lack of access to data management experts or ethical considerations that would preclude the data from being widely shared.
 - iii. Devise institutional policies that support data sharing, incentivize researchers, and communicate the benefits of data sharing at the same time (e.g., cost savings and rigor & reproducibility).
 - iv. Develop communication, training, and implementation strategies that are broad regarding roles/functional areas involved; effective implementation takes the entire village, at least until the new culture takes hold.
 - v. Check the <u>COGR DMS Website</u> frequently, as additional documents will be added regularly.
- 7) Many institutions may not currently have enough trained data management or other expertise throughout this process lifecycle.
 - a. Approach:
 - i. Review the <u>NIST Research Data Framework</u> as it may be relevant and helpful. Specifically, the "ENVISION" stage focuses on Workforce/Career paths and references to other concepts like the valuation of data workers.
 - ii. Evaluate the use of **DMPTool**.
 - iii. Evaluate areas in the university that may already have these competencies to develop staffing models or job description templates that can be leveraged to scale a broader institutional solution.
 - iv. Consider development of role-based training to ease onboarding of data professionals and strategies to retain talent once developed.

³ As of the publication of this document, Chapter 4 is expected to be released in early fall 2022.



- 8) The 24 NIH Institutes, Centers, & Offices (ICOs) have the discretion to develop policy and guidance to fit their mission. Therefore, institutions may need to customize training, technology, and resources to support varied ICO-specific requirements. Implementation could be more complex where ICO policies are not harmonized. ICOs have been asked to issue guidance before the January 2023 deadline.
 - a. Approach:
 - i. Monitor COGR's "NIH Data Management and Sharing Policy Matrix" for a summary of the ICO documents and communications.
 - ii. Review your institution's NIH funding portfolio to determine the most significant ICOs.
 - iii. Consider developing a process/system for PIs to notify key offices of their intent to submit a proposal to help ensure that all have adequate time to provide the necessary support.
 - iv. Identify a single collection point for feedback from PIs about DMS; share with other researchers; notify COGR where there are conflicts between the policy and the ICO implementation.
- 9) Institutions may struggle with monitoring DMSP compliance and concurrence in the current vacuum of guidance related to monitoring expectations. This area will mature as the NIH ICOs become more familiar with their policies and refine their practices. Note: As needed, COGR will work with NIH to determine what is required to report on adherence to the plan or what types of changes might trigger a need to obtain NIH prior approval.
 - a. Approach
 - i. Identify a single collection point for feedback from PIs about DMS; share with other researchers; notify COGR where there are conflicts between the policy and the ICO implementation.
 - ii. Consider system solutions to enable the institution to maintain records on DMSP obligations
- 10) The number of researchers impacted by the change and their experience level may vary significantly. This will be determined by the population of faculty with DMS experience (e.g., with awards >\$500k annual direct costs, existing NIH Institute specific requirements or other federal funding with DMS requirements). Knowing your institution's ratio of newly impacted PIs or the level of data intensity for their projects is critical information to have to ensure that resources are directed appropriately (See p. 5 of COGR Briefing Sheet).



11) Large spikes in proposal submissions around the major deadlines (June 5th/July 5th, Oct 5th/Nov 5th, Feb 5th/March 5th) may be especially challenging. DMS support needs will not be evenly distributed throughout the year, and institutions will need to be prepared to support spikes. Award receipt volume steadily increases from November until the end of the government fiscal year at the end of the following September. Needs for support in negotiating DMSPs at the Just In Time stage and project onboarding will likely follow the same pattern.

a. Approach:

- i. Evaluate your institution's pattern of proposals and awards throughout the year and design resourcing plans to be able to accommodate identified spikes in volume.
- ii. Develop and share resources with researchers ahead of significant deadlines

12) Stay closely connected with COGR!

a. Approach:

- i. Watch for chapter releases of COGR's <u>Readiness Guide</u>, available on our <u>NIH DMS Resource Page</u>.
- ii. Ensure you're signed up for COGR's Listserv⁴.
- iii. Read our updates to the membership⁵, released 6-8 times per year.
- iv. Participate in COGR meetings/webinars relevant to NIH DMS and reference previous COGR meeting materials⁶ as needed.
- v. <u>Contact COGR</u> with questions, issues, and challenges with implementing the Policy.
- vi. Connect with colleagues at fellow COGR member institutions. A directory of institutional members and individuals is available through the COGR Member Portal and searchable by demographics and area(s) of expertise.

If you have any questions about this document, or would like more information on COGR's response to the NIH Final Policy for Data Management and Sharing, please contact David Kennedy at dkennedy@cogr.edu and Krystal Toups at ktoups@cogr.edu

⁴ If you have requested access to the COGR Member Portal, you are signed up for the Listserv. To request access to the Portal, click here: https://www.cogr.edu/cogr-portal-log-and-account-creation

⁵ Available on COGR's website under "Latest News": <u>https://www.cogr.edu/News-Stories</u>

⁶ Slides are available here: https://www.cogr.edu/cogr-meeting-materials-re-nih-dsmp, and recordings of our virtual sessions are available here (log in required): https://cogr.member365.org/sharingnetwork/education/videolibrary