

FDP NIH Data Management & Sharing Pilot:

Supporting NIH Goals While Mitigating Administrative Burden

By Christi Keene, Melissa Korf, Jim Luther, and Michelle Bulls

Hot
Topic



In October 2020, NIH released its Final Policy for Data Management and Sharing, which became effective for all new and competing proposals submitted to NIH on or after January 25, 2023 (US HHS, n.d.). The 2023 policy requires a data management and sharing plan for all NIH-funded projects generating scientific data, an expansion from the 2003 policy requirement for a data sharing plan for all projects over \$500K in annual direct costs. The policy seeks to maximize research outcomes (and the benefits resulting from the investment of taxpayer dollars) while supporting rigor and reproducibility by leading a “cultural shift that makes data sharing the norm” (Jorgenson, 2022). It also emphasizes the importance of good data management practices while establishing an expectation for maximizing the appropriate sharing of scientific data generated from NIH-funded or conducted research.

The policy often references adherence to best practices in the scientific community or a particular field and affords a lot of flexibility to NIH Institutes, Centers, and Offices (ICOs) to provide additional guidance on expectations related to the particular field(s) funded by that ICO. However, significant variations in ICO-specific requirements could place substantial administrative burden on researchers to first navigate the varying requirements before they can even begin developing their Data Management and Sharing Plan (DMS Plan). Recognizing this potential challenge, NIH has been working together with its Federal Demonstration Partnership (FDP) colleagues to plan and implement the FDP NIH Data Management and Sharing Pilot, which seeks to ensure the goals of the 2023 policy are realized while also mitigating the associated administrative burden on researchers (FDP, n.d.).

With the NIH DMS Policy and the FDP NIH DMS Pilot both several months into implementation, the FDP Pilot co-chairs, Christi Keene (University of Chicago), Melissa Korf (Harvard Medical School), Jim Luther (Yale University), and Michelle Bulls, Director, NIH Office of Policy for Extramural Research Administration (OPERA), share their thoughts on the importance of the new policy as well as the pilot, progress towards implementation, and vision for the future of both.

FDP Pilot Co-Chairs: Why is the new DMS Policy so important to NIH?

NIH OPERA: NIH has a longstanding commitment to making the results of NIH-funded research publicly available. Responsible data management and sharing has many benefits, including accelerating the pace of biomedical research, enabling validation of research results, providing accessibility to high-value datasets, and promoting data reuse for future research studies. This policy formalizes what NIH has always believed is part of doing good research.

FDP Pilot Co-Chairs: How does this fit into broader guidance from OSTP relating to public access?

NIH OPERA: In August 2022, the White House Office of Science and Technology Policy (OSTP) issued updated guidance on “Ensuring Free, Immediate, and Equitable Access to Federally Funded Research” (USG, 2022). The implementation of the NIH DMS Policy will allow NIH to meet all aspects of the scientific data expectations of this August 2022 OSTP Memorandum.

FDP Pilot Co-Chairs: What benefits does NIH hope to receive from the FDP Pilot?

NIH OPERA: Our long-standing participation in FDP is important to us. We value the partnership and our ability to roll up our sleeves and tackle initiatives that impact NIH, NIH-funded researchers, and administrators. This unique relationship allows us to road-test initiatives and create solutions that work for everyone. Specifically, the pilot aims to generate greater consistency in DMS Plan requirements across our ICOs and programs and mitigate the administrative burden for researchers associated with DMS Plan development and implementation.

FDP Pilot Co-Chairs: What led ICOs and program officials to develop the more standardized templates for DMS Plans being used in the pilot rather than promote use of the more narrative format sample published by NIH initially?

NIH OPERA: During the Just-in-Time (JIT) phase, ICOs and program officials will need to be able to quickly review submitted DMS Plans for key information and compliance with the policy requirements. A more standardized template will help ensure researchers have a clear understanding of the specific information needed to facilitate this review and hopefully minimize the need to seek additional information at JIT. In the future, ICOs and program officials hope to be able to track and report on key data elements from DMS Plans, and a standardized template format is a first step towards being able to accomplish this.

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FDP Pilot Co-Chairs: Phase 2 of the pilot will focus on budgeting and costing policies. What do you think are the top priorities for this next phase?

NIH OPERA: NIH needs to be able to forecast the cost associated with implementation of the new policy but in a way that maintains compliance with uniform guidance cost principles. We look forward to working with our FDP colleagues and others at recipient institutions to refine our strategies for meeting these needs. We also understand concerns from our recipient community regarding how they can cover the costs of data management and sharing activities that persist after the end of the period of performance as well as being able to accurately estimate costs that may increase (or decrease) quite a bit over the life of the award.

Hot Topic

By, Carpentato (Tanta) Myles and Lisa Nichols, Senior Administrator Contributing Editors

The U.S. Government has demonstrated continued commitment to an open research environment embodied in two recent White House Office of Science and Technology Policy (OSTP) initiatives. On August 25, 2022, OSTP published the memorandum Ensuring Free, Immediate, and Equitable Access to Federally Funded Research. It requires manuscripts from federally funded research and the data that support them to be made accessible to the public immediately upon publication. On January 11, 2023, OSTP launched the Year of Open Science to advance national open science policies and showcase open science's benefits. As a part of the initiative, OSTP and the National Science and Technology Council released an official definition of open science for use across federal agencies:

“The principle and practice of making research products and processes available to all, while respecting diverse cultures, maintaining security and privacy, and fostering collaborations, reproducibility, and equity.” The establishment of an official definition is vital to ensuring congruency across agencies to minimize burden to institutions, researchers and the general public.

This issue includes a discussion of the National Institute of Health's (NIH) efforts to meet the OSTP requirements via the agency's Data Management and Sharing (DMS) Policy and NIH's partnership with the Federal Demonstration Partnership (FDP) to pilot a DMS plan as a means to “generate greater consistency in DMS Plan requirements across [NIH Institutes, Centers, and Offices] and programs, and mitigate

the administrative burden for researchers.” In addition, the FDP Pilot Co-chairs share their thoughts on the importance of the policy and pilot, progress towards implementation, and the vision for these efforts.

Also in this issue is an article on the Council on Governmental Relations' Readiness Guide which assesses the NIH policy and its impact on the research community. The Readiness Guide includes a policy matrix as well as “institutional considerations when identifying, budgeting, [and] reviewing costs” and projected annual costs to institutions. Both efforts seek to assist institutions and researchers in implementing the NIH policy and provide avenues to address cost and other factors. ■



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NIH OPERA: Before we go, I have a couple questions for my FDP colleagues about the recipient organization perspective. How are recipient organizations working to support researchers in this initiative?

FDP Pilot Co-Chairs: Keeping in mind each recipient organization is structured differently, we have already seen the value of librarians, research computing centers, and research administrators at all levels coming together to provide resources for faculty. Some of these resources and services include reviewing DMS Plans for completion prior to submission, identifying repositories, describing metadata standards, and providing budgeting tools. We’ve seen organizations create shared email addresses to provide a single point of contact for questions. Others have developed a matrix for faculty to quickly identify which office is best able to answer specific questions.

NIH OPERA: What benefits do you and your organizations hope to receive from the pilot?

FDP Pilot Co-Chairs: The pilot has been such an amazing opportunity to collaborate with our NIH colleagues in the pursuit of our shared goals and a testament to what a unique organization like FDP can achieve. Promoting data management best practices and maximizing the appropriate sharing of scientific data are both so important to ensuring the success of the research enterprise, and we have been impressed by our NIH colleagues’ commitment to pursuing these goals in a way that works for all stakeholders. From a more practical perspective, the pilot presents a critical opportunity to work with our NIH colleagues to test out various strategies to resolve implementation challenges and find out what will work the best for all involved before anything becomes final. Many thanks to our FDP and NIH colleagues for this wonderfully successful collaboration! ■

For more information on the new NIH Data Management Sharing Policy and associated NIH resources, see <https://sharing.nih.gov>.

For more information on the FDP NIH DMS Pilot, see <https://thefdp.org/default/fdp-nih-data-management-and-sharing-pilot>.

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