Welcome!

Today’s session will begin shortly. There will be no audio sound until the session begins.
Zoom Webinar Reminders

• Zoom technical support at 1-888-799-9666, option 2
• Audio will be streamed through your speakers
• Submit questions at any time in the Q&A box at the bottom of your screen
• Webinar recording, slides, and session summaries posted shortly after the event at thefdp.org

*If you are a member of the press, please identify yourself and your publication in the chat or Q&A.
NIH Implementation of the New Data Management and Sharing Policy

MICHELLE G. BULLS, DIRECTOR
NIH OFFICE OF POLICY FOR EXTRAMURAL RESEARCH ADMINISTRATION (OPERA)
SEPTEMBER 12, 2022
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 Efforts to Reduce Administrative Burden: The DMS Demonstration Pilot Project

- FDP collaboration with NIH OPERA, OER 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 and DMPTool: 12/22-12/23
  • 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: Cost Policies: 1/23-12/23
  • 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 – feedback to NIH and community
Additional Efforts to Reduce Recipient Administrative Burden

• A preview version of the recommended but optional Data Management and Sharing Plan format page is available now and a final fillable version will be available by Fall 2022, with instructions incorporated into the NIH Application Form Instructions.

• Applicants subject to both the DMS and GDS policies will submit one DMS plan that will include their Genomic Data Sharing (GDS) plan.

• Requested direct costs to support the activities proposed in the DMS Plan will be indicated as “Data Management and Sharing Costs” in the application budget, allowing recipients to request costs up front.

• Peer reviewers will not review or score a DMS Plan unless it is integral to the project design and tied to a scored review criterion.

• NIH will permit applicants to revise their DMS plan when needed through the Just-in-Time process prior to award.

• Applicants can describe any limitations to sharing data in the DMS Plan.

• Applicants can select a data repository of their choosing (see NOT-OD-21-016), unless the funding opportunity requires use of a specific data repository.
Assessment of the DMS Plan and Budget

Applications will provide DMS costs upfront in the budget and budget justification sections of their applications (or as specified in the Funding Opportunity Announcement (FOA)).

Program staff at the proposed IC will assess DMS Plans to ensure the Elements of a DMS Plan have been adequately addressed and to assess the reasonableness of those responses.

Peer reviewers may provide comments on the reasonableness of the proposed budget for DMS contained in the budget justification, but these comments will not impact the score. Peer reviewers will not be provided with the separate DMS Plan attachment unless sharing data is integral to the project design and specified in the FOA.

If data sharing is integral to the project and specified in the FOA, program staff will still assess the adequacy of the DMS Plan, but peer reviewers will also be able to view the DMS Plan attachment and will factor that information into scores as outlined in the FOA evaluation criteria.

Applications selected for funding will only be funded if the DMS Plan is complete and acceptable.
  • If the submitted DMS Plan is not acceptable, applicants may be notified that additional information is needed through the Just-in-Time process.
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
Questions?

Division of Grants Policy:
  • E-Mail: GrantsPolicy@mail.nih.gov

Division of Grants Compliance & Oversight:
  • E-Mail: GrantsCompliance@mail.nih.gov

Systems Policy Branch
  • E-Mail: OPERAsystemspolicy@mail.nih.gov

Division of Extramural Inventions and Technology Resources:
  • E-Mail: Inventions@nih.gov

Questions about NIH Sharing Policies including the new Data Management and Sharing Policy:
  • E-Mail: Sharing@nih.gov