Q&A With the OPERA –Data Management & Sharing and Disclosures

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DATA MANAGEMENT & SHARING

National Institutes of Health
Office of Extramural Research

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

- Now effective for all competitive (Type 1 and Type 2) applications
- **Requirements:**
    1. **Submission** of Data Management & Sharing Plan
    2. **Compliance** with ICO-approved Plan
- **Scope:** All NIH-supported research generating *scientific data*
- **Elements of a DMS Plan:**
    - Data type
    - Related tools, software, code
    - Standards
    - Data preservation, access, timelines
    - Access, distribution, reuse considerations
    - Oversight of data management and sharing
- **Timelines:**
    - **When to share data:** No later than the time of an associated publication or end of award (for unpublished data), whichever comes first

Pre-Award

Plan submitted at the time of application

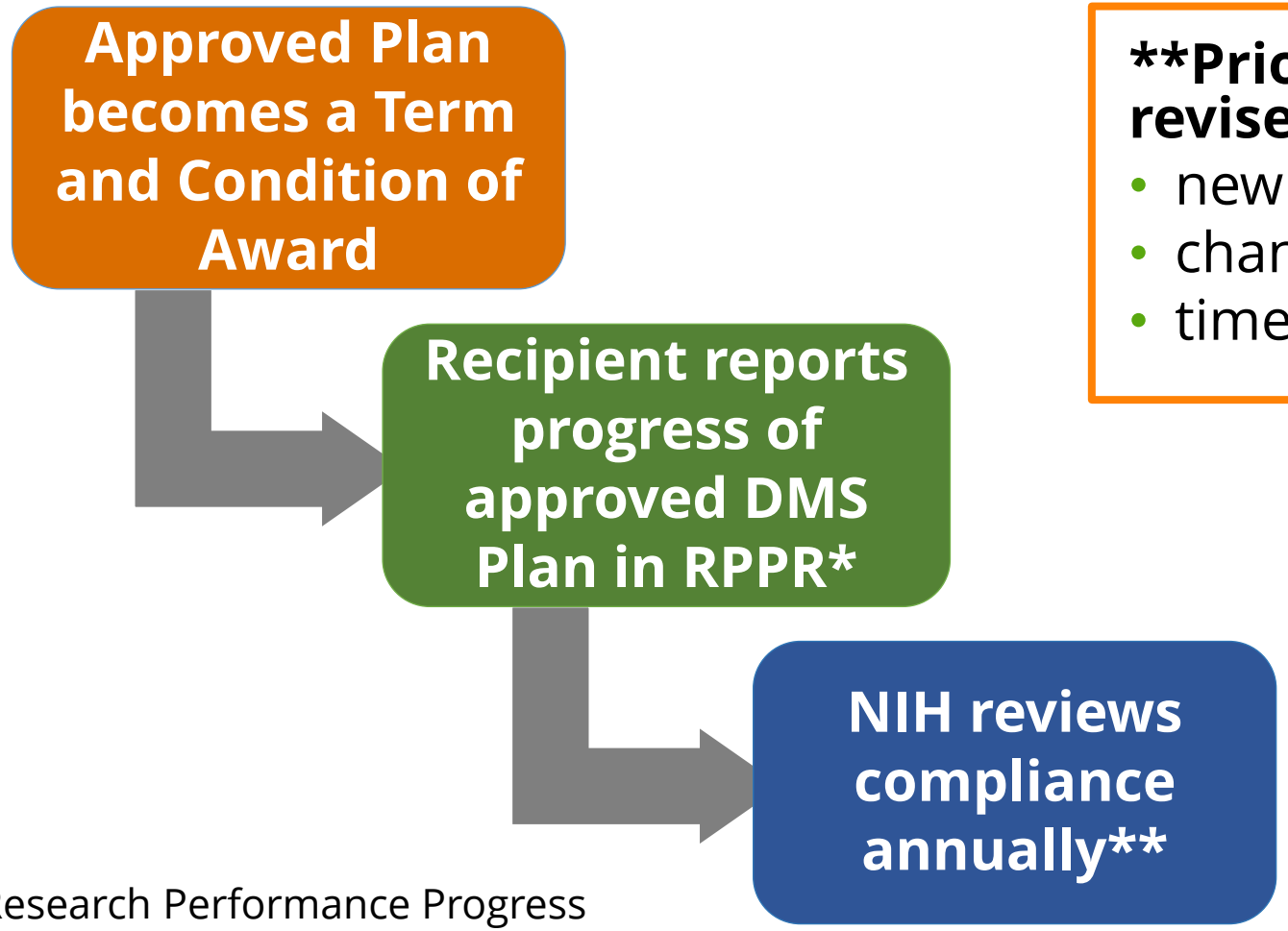
- Not included in peer review, unless data sharing is integral to the project design and specified in the Funding Opportunity Announcement.

Plan assessed by Program Officials (PO)

- POs work with PIs to resolve issues and finalize plan based on PO assessments
- POs and PIs agree on plan, and it's resubmitted at just-in-time through the AOR if needed

Plan accepted and becomes a term and condition

Post-Award



****Prior Approval and revised plan required:**

- new scientific direction
- change in data repository
- timeline revision

***RPPR:** Research Performance Progress Report (RPPR) - Annual, Interim, and Final

NIH Efforts to Reduce Administrative Burden: The DMS Demonstration Pilot Project – Collab with Federal Demonstration Partnership (FDP)

- FDP and NIH collaboration engaging NIH Institutes and Centers and Offices (ICOs), Office of Extramural Research SMEs, the Office of Science Policy and OPERA/Compliance.
- 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.

FDP Pilot Phase 1: DMS Plan Templates

- Federal Demonstration Partnership (FDP) pilot project to test structured templates and tools for DMS Plan submission
- 2 Templates have been selected for testing
  - Discussions underway with DMPTool
- Purpose is to generate greater consistency in DMS Plan requirements across ICOs and programs, while mitigating administrative burden for researchers.
- FDP has 15-20 participants signed on so far.
- Pilot participants began using the test templates on March 1.

FDP Pilot Phase 2: Costing Policies

- Identify ways to
  - Analyze ways to maximize common cost principles
  - Identify types of costs required (e.g., key personnel, impact on budget caps/thresholds)
  - Determine how to identify additional/unforeseen costs that may be needed to meet the spirit of the DMS Policy
  - Determine feasibility of placing costs in a single category vs. throughout the budget line items
  - …and MORE (i.e., subawards, and costs after the period of performance)!

DMS FAQS

National Institutes of Health
Office of Extramural Research

Do I need to submit a DMS plan with a non-competitive renewal?

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- No, the DMS policy does not apply to non-competitive renewals (Type 5), only competing (Type 1 & 2) applications.

Do changes to the DMS plan require prior approval?

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- Significant changes to the DMS plan (e.g., new scientific direction, different data repository, or revision to timeline) require NIH prior approval.
- The updated, approved plan becomes a term and condition of award.

Does the single budget line item for DMS costs include personnel?

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- All costs for data management and sharing activities, including personnel costs, must be included in the single line item on the R&R Budget Form in section F. Other Direct Costs. This includes the salary and fringe benefits corresponding to the time it takes personnel to undertake data activities (e.g., formatting, curating, developing supporting documentation).
- Do not include personnel costs related to data management and sharing activities in section A. Senior/Key Person or section B. other Personnel.
- Supporting details, including a breakdown of any personnel effort, must be included in the budget justification.

What if I don’t anticipate any direct costs related to DMS?

What if I don’t anticipate any direct costs related to Data Management and Sharing?

- If there are no anticipated data management and sharing costs, this should be noted in the budget justification. Also include a line item titled "Data Management and Sharing Costs" in section F. Other Direct Costs of the R&R Budget Form and enter “0" in the "Funds Requested" column

How do I include DMS costs for subawards in my application?

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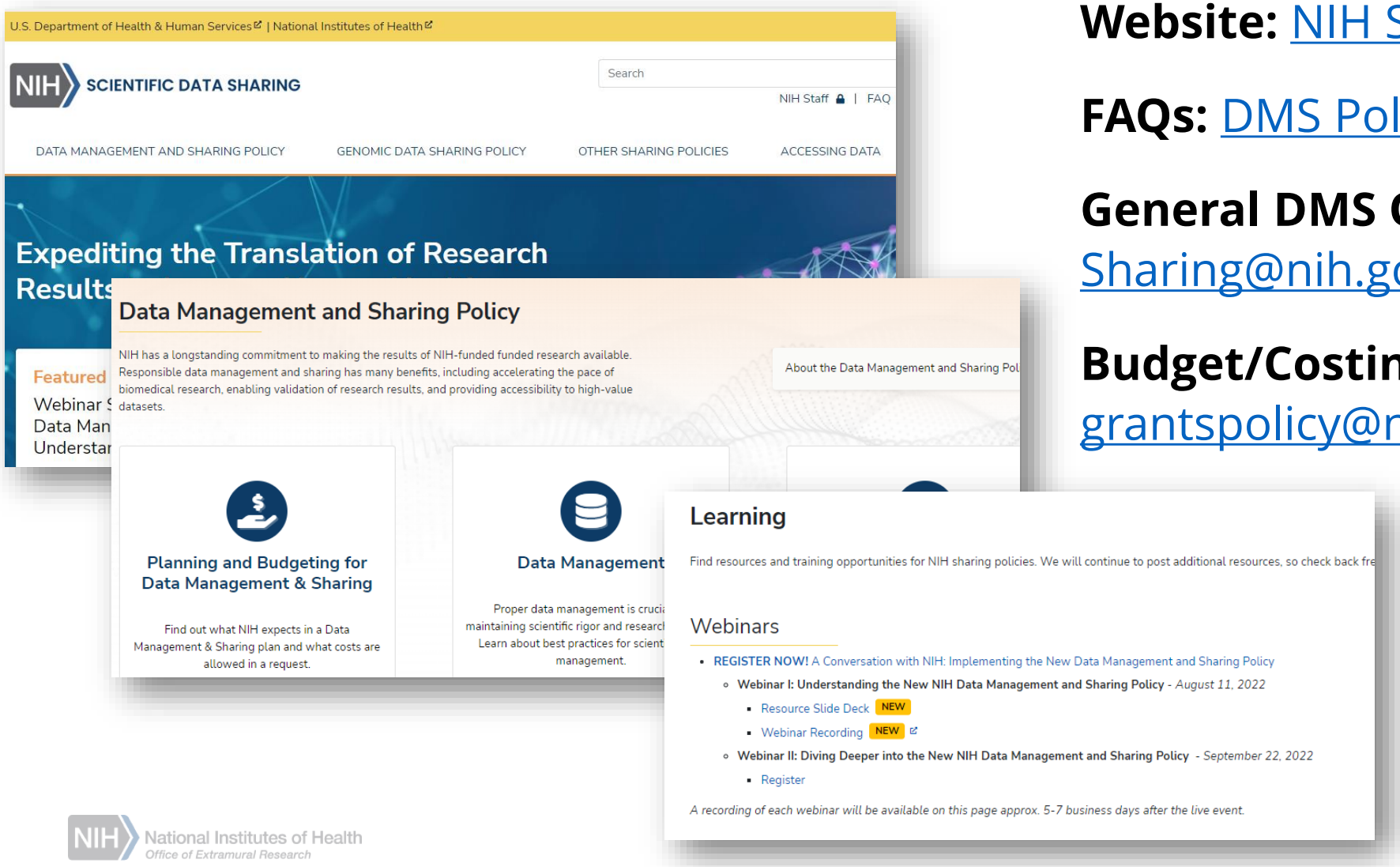
- DMS costs for each subaward must be listed as a single line item on the R&R Budget for the subaward (F. Other Direct Costs, 8-17 Other). If no DMS costs are anticipated on the subaward, the line item is not required. A DMS costs line item must still be listed on the project/parent R&R Budget Form for the parent DMS costs, including $0 if no costs are anticipated for the parent.
- For complex grant applications that involve an overall budget and multiple project/core budgets, DMS costs must be included within the applicable component(s), as outlined in the application instructions.
- For grant applications submitting a modular budget, include all DMS costs request information in the Additional Narrative Justification attachment on the PHS 398 Modular Budget Form, as outlined in the application instructions.

For More Information…



Website: [NIH Scientific Data Sharing]

FAQs: [DMS Policy FAQs]

General DMS Questions: [Sharing@nih.gov]

Budget/Costing Questions: [grantspolicy@nih.gov]

DISCLOSURES

Why are disclosures important?

Commitment Transparency

Transparency and reporting of *all* research activities, domestic and foreign

- Openness and transparency enables productive collaboration and helps ensure appropriate disclosure of potential conflicts of interest and commitment
- Failure by some researchers at NIH-funded institutions to disclose substantial contributions of resources from other organizations, including foreign governments, threatens to distort decisions about the appropriate use of NIH funds

Disclosure Requirements - References

- NDAA 223: 2021 National Defense Authorization Act (NDAA), Section 223 *Disclosure of Funding Sources in Applications for Federal Research and Development Awards*
- NSPM-33: National Security Presidential Memorandum (NSPM) on Research Security and Integrity, signed January 14, 2021
  - NSPM-33 Implementation Guidance: Outlines specific disclosure requirements for applicants

Common Format Development

- National Science and Technology Council (NSTC) Research Security Subcommittee has been working on development of Common Forms for the Biographical Sketch and Current and Pending (Other Support) for over a year.
- A Common Format was posted in the Federal Register for public comment, and the 60-day public comment period ended on October 31, 2022.
- 99 comments were received from individuals, organizations, professional societies and federal employees.

Common Thematic Areas

- Biographical Sketch
- Current and Pending (Other) Support
- Disclosure Table
- General Comments
- The accuracy of the Agency's estimate of the burden of the proposed collection
- Ways to enhance the quality, utility, and clarity of the information on respondents through use of automated collection techniques for other forms of information technology
- Ways to minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology
- Whether the proposed collection is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility.

Next Steps

- NSTC Research Subcommittee is reviewing the comment resolution.
  - Modifying and adding definitions (e.g., academic, professional and institutional appointments)
  - We will work with institutions to ensure that definitions meet the needs of our recipients, while also meeting the charge from OSTP.
- Once finalized the Common Forms will move forward for implementation.

DISCLOSURE FAQS

National Institutes of Health
Office of Extramural Research

Will NIH adopt the Common Forms as-is?

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- NIH will adopt the Common Forms with few NIH-specific instructions
- Updated forms and instructions will be available Fall 2023

Is NIH developing a SciENcv template for Other Support?

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- Yes, NIH is working with SciENcv to develop an Other Support template.
- Researchers will sign in using their eRA Commons ID and certify their forms in the system.
- Use of SciENcv may be required in FY 24.

For More Information…

Website: Other Support, Biosketch

FAQs: Other Support, Biosketch

Disclosure Questions: nihosbiosketch@nih.gov