NIH Data Management and Sharing (DMS) Policy Readiness Webinar

January 17, 2023

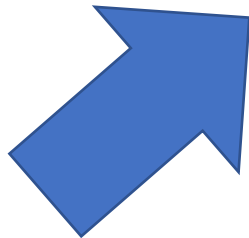*"Countdown to effective date – January 25, 2023"*

Reminder: Register for February COGR Meeting!

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Upcoming Meeting and Webinar Information

Upcoming Virtual Meeting:

February 28-March 3, 2023

Register Here

Meeting Materials

Register in the COGR Member Portal

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Speakers

Krystal Toups, *Director, Contracts & Grants Administration*

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

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

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Purpose of Webinar

Agenda

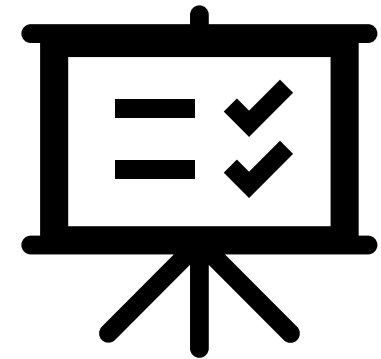- ✓ DMS To-Date (COGR's Advocacy and Resources)

    Krystal Toups

- ✓ Costing Angle

    David Kennedy
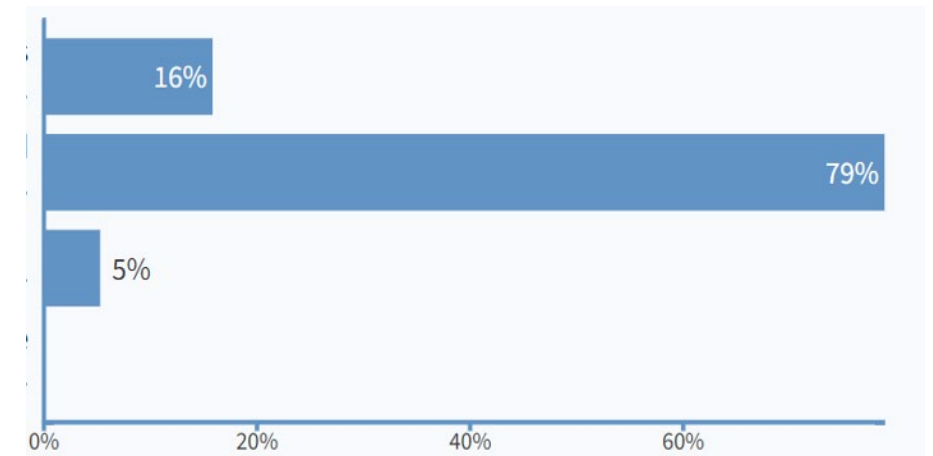
- ✓ NIH Implementation

    Michelle Bulls

- ✓ Q&A

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An Association of Research Institutions

DMS To-Date
(COGR's Advocacy and Resources)

October 2022 - Level of Readiness for January 25th?

- **WHEN WE ASKED THIS AT THE OCTOBER COGR MEETING: What is your level of "readiness" for the NIH DMS implementation?**

  - We're just starting this work at my institution 16%
  - We're underway and making progress 79%
  - We've got this. We'll be ready 5%
  - I don't know, but I hope someone else is on this 0%

- **Update – What is your level of "readiness" now?**

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What is your level of "readiness" for the NIH DMS implementation, Today?

A. We're just starting this work at my institution.

B. We're underway and making progress.

C. We've got this.

D. I don't know, but I hope someone else is on this.

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DMS To-Date (COGR's Advocacy and Resources)

Policy

Engagement & Partnerships

Implementation & Learning

✓ Partnerships with Associations
  • FDP, ARL & Other Associations
✓ COGR Membership, Workgroups, & Partners
✓ Engagement & Partnership with NIH

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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

Comment Letters to NIH

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Immediate Priorities and Considerations

January 2023

#1 Issue Budgeting & Costing
- Single Budget Line Item
- Real Costs of Burden
- Limitations

Chapter 4 (Three Parts)
Part I: Analysis
Part II: Institutional Considerations
Part III: DMS Survey Results

COGR's NIH Data Management and Sharing Policy Readiness Guide

Chapter 1	Starting the Conversation: A Briefing Document (Joint Release with the Association of Research Libraries)
Chapter 2	NIH Policy Matrix: Policies, Supplements, and FAQs (Excel Download)
Chapter 3	Roles and Responsibilities At Your Institution (Institutional Considerations & Worksheet (Excel Download, NEW)
Chapter 4	Budgeting & Costing Part I: COGR's Review of the Final NIH Policy for Data Management and Sharing

-------Upcoming Chapters-------

Chapter 4	Budgeting & Costing Part II: Institutional Considerations
Chapter 5	Culture Change
Chapter 6	Data Management and Storage
Chapter 7	Data Management and Sharing Plans
Chapter 8	Human Subjects Research
Chapter 9	Research Security and Data Sharing
Chapter 10	Monitoring and Compliance

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Costing Angle

COGR Review of the Final NIH Policy for Data Management and Sharing: Budgeting & Costing

The *COGR Review* was shared with NIH in late December …

… the tightrope to walk is a <u>sense of urgency now</u> and what can be addressed in the <u>FDP Pilot</u>

1. Leveraging "Just-in-Time"
2. Limitations of a Single Line Budget Request
3. Limitations of the Cost Estimator Tool
4. Clear Guidance Around Repositories
5. Perceptions Around Proposing DMS Costs
6. Alleviating the Modular Award (and Other Budget Cap) Squeeze
7. "Default" Budget Factors should be Considered

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COGR Review of the Final NIH Policy for Data Management and Sharing: Budgeting & Costing
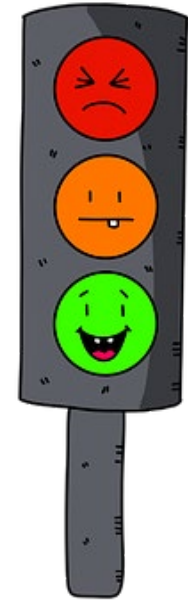
Continued ...

8. Distinguishing between Labor and Non-labor Costs is Imperative

9. Simplifying Effort Reporting Expectations

10. Personnel with "Significant" DMS Responsibilities

11. Allowability of Post-performance DMS Costs is Essential

12. NIH Confidence in Institutional Cost Models

13. "Low" and "High" Data Density Programs

14. Expectations for Monitoring and Oversight

15. Standards for Enforcement and Audit

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COGR Survey on Burden & DMS

Do you expect this activity will create new administrative burden at your institution (N=34)?

- 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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COGR Survey on Burden & DMS

With new <u>administrative burden</u> comes <u>cost burden</u>:

- Survey results (N = 34) showed significant impact on:
  - Pre-Award
  - IT
  - Campus Libraries
  - Department Administration
  - Researchers/PIs/Grad Students

- Cost burden to exceed $1 million per institution?

- Smaller and emerging research institutions most at risk?

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COGR Survey on Burden & DMS

COGR found that while the full cost impact may not be fully recognized for several years, initial analysis indicates cost burden will exceed $500,000 at the central administrative level, while also exceeding the $500,000 at the academic level. The impact to Researchers and PIs is the most significant driver at the academic level. This risks a further shift of PI effort away from science and toward administrative tasks. While COGR supports the important activity of data sharing and public access to research data, the cost burden is significant, and will most adversely impact smaller and emerging research institutions.

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NIH's Implementation

NIH Implementation of the New Data Management and Sharing Policy

NIH OFFICE OF POLICY FOR EXTRAMURAL RESEARCH ADMINISTRATION (OPERA)

JANUARY 17, 2023

NIH > National Institutes of Health
Office of Extramural Research

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

- Effective for applications submitted for due dates on or after January 25, 2023 (8 days to go!)
- **Requirements:**
  1. **Submission** of Data Management & Sharing Plan
  2. **Compliance** with ICO-approved Plan
- **Scope:** All NIH-supported research generating _scientific data_
- **[Recommended 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

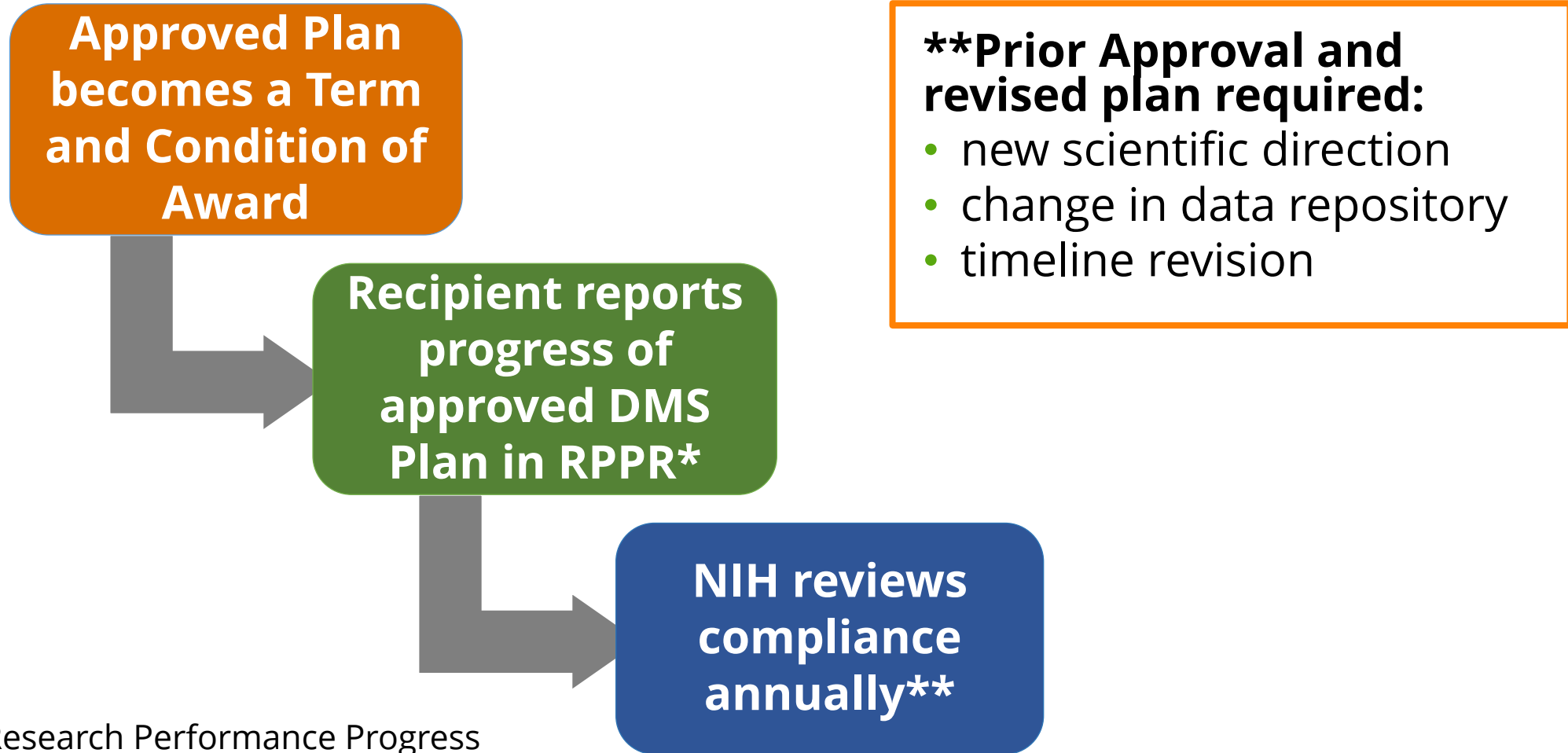**Plan submitted at the time of application**

- 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

Plan accepted and becomes a term and condition

NIH National Institutes of Health
Office of Extramural Research

Post-Award

Approved Plan becomes a Term and Condition of Award

Recipient reports progress of approved DMS Plan in RPPR*

NIH reviews compliance annually**

**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 National Institutes of Health
Office of Extramural Research

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 (ICs), Office of Extramural Research SMEs 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.
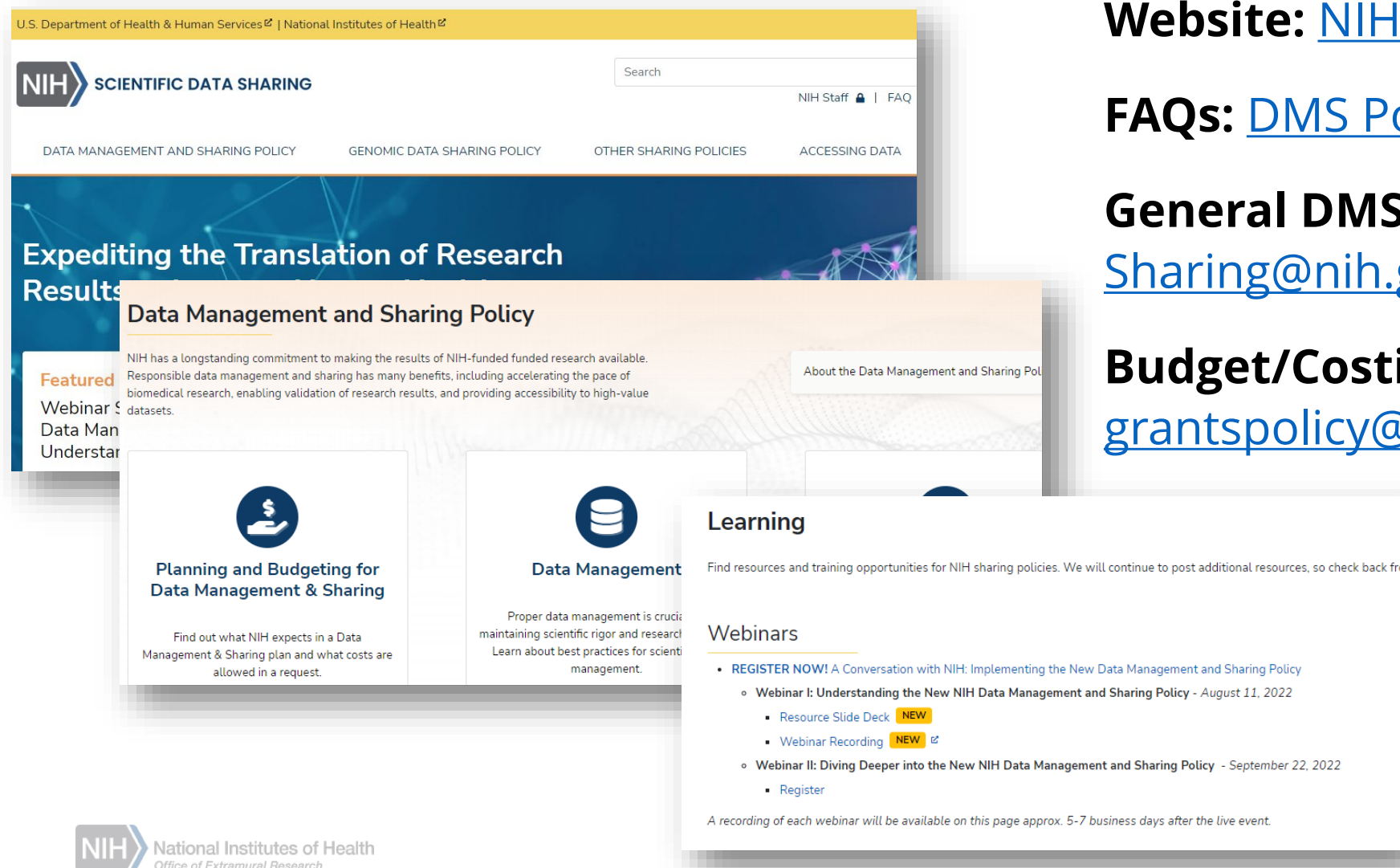
NIH National Institutes of Health
Office of Extramural Research

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 reached out to institutions to gather participants (over 60 interested so far

National Institutes of Health
Office of Extramural Research

FDP Pilot Phase 2: Costing Policies

- Identify ways to
    - Establish common cost principles
    - Identify types of costs required (e.g. key personnel, impact on budget caps)
    - 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!

For More Information...

Website: NIH Scientific Data Sharing

FAQs: DMS Policy FAQs

General DMS Questions:
Sharing@nih.gov

Budget/Costing Questions:
grantspolicy@nih.gov

Resources

- [NIH Data Management and Sharing Policy Page](#)

- [COGR's Resource Page](#)

- [COGR NIH DMS Readiness Guide](#)

- [COGR's Webinars & Additional Resources on DMS](#)

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