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NIH Data Management & Sharing Policy Budgeting and Application Tips and Tricks (or Treat?)

Presenters:
Christi Keene, University of Chicago
Melissa Korf, Harvard Medical School
Jim Luther, Yale University

Welcome and Agenda

- Learning Objectives
- Policy Background and Overview
- Application Requirements
- Writing the DMS Plan
- Budgeting Considerations
- Other Implementation Considerations
- Resources

Learning Objectives

- Ensure stakeholders from a variety of perspectives are aware of policy requirements
- Share tips and tricks to enable research administrators to provide the most effective support to their researchers

Poll: What type of role are you in?

- Research Administration – General
- Research Administration - Pre Award
- Research Administration - Post Award
- Contracts/DTUA
- Library
- Research computing
- Tech transfer
- Other

Poll: How familiar are you with the NIH Data Management and Sharing Policy?

- Very; I know it like the back of my hand!
- I know enough to be dangerous
- Just starting to learn more about it
- What Data Management and Sharing Policy?

NIH DMS POLICY BACKGROUND AND OVERVIEW

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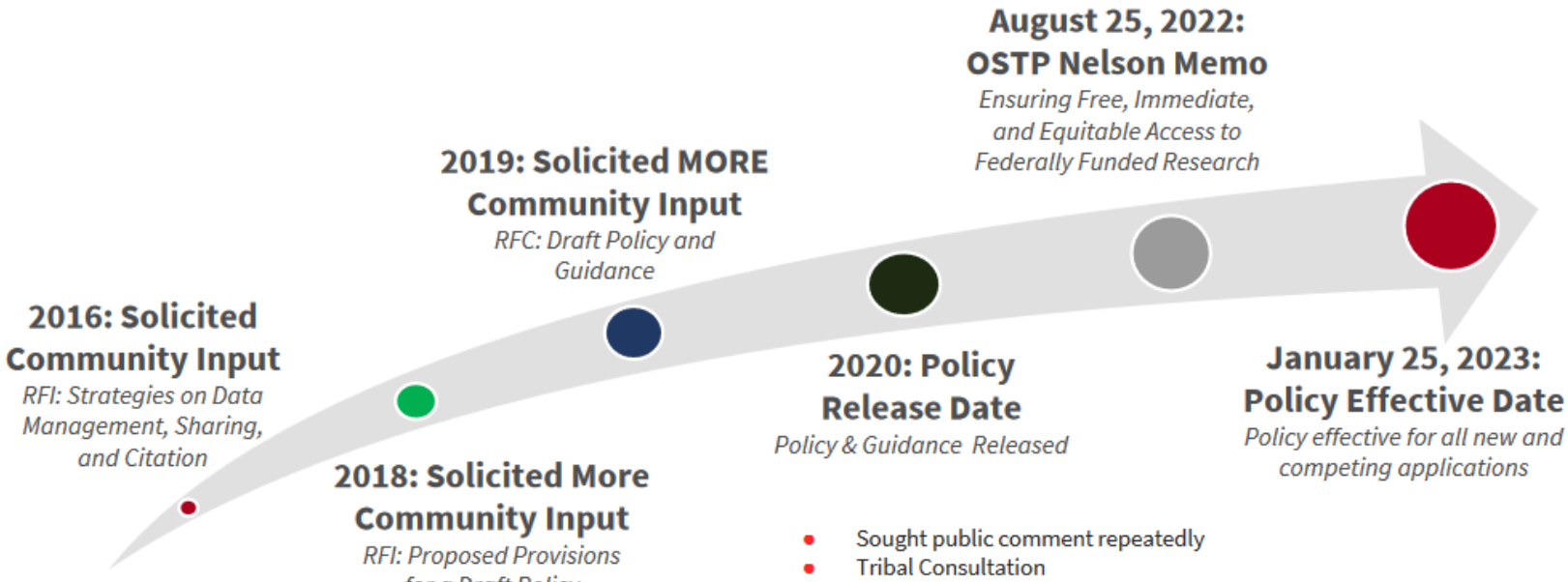
NIH Data Management and Sharing Policy Timeline



2022: Ensuring Free, Immediate, and Equitable Access to Federally Funded Research

In accordance with this memorandum, OSTP recommends that federal agencies, to the extent consistent with applicable law:

1. Update their public access policies as soon as possible, and no later than December 31st, 2025, to make publications and their supporting data resulting from federally funded research publicly accessible without an embargo on their free and public release;
2. Establish transparent procedures that ensure scientific and research integrity is maintained in public access policies; and,
3. Coordinate with OSTP to ensure equitable delivery of federally funded research results and data.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20502

August 25, 2022

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

FROM: Dr. Alondra Nelson
Deputy Assistant to the President and Deputy Director for Science and Society
Performing the Duties of Director
Office of Science and Technology Policy (OSTP)

SUBJECT: Ensuring Free, Immediate, and Equitable Access to Federally Funded Research

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2023: The Year of Open Science

NIH DMS Policy Highlights

- Replaces the 2003 NIH Data Sharing Policy, which only required a DMS Plan for projects over $500K in annual direct costs
- Applies to new and competing applications submitted for due dates on or after January 25, 2023; does **not** apply retroactively to currently active awards
- Costs associated with data management and sharing are allowable in budgets
- Unless data sharing is integral to the program and specified in the FOA, peer reviewers will not be asked to comment on the DMSP or provided with a copy of the separate DMSP Attachment
- Reviewers ***will*** comment on the reasonableness of the budgeted costs, but these comments will not impact the overall score
- Program staff will assess the DMS Plan and request any changes that may be needed at JIT.
- DMS Plans may be updated during the annual RPPR process or through the Prior Approval Module; however, changes must be approved prior to implementation
- **Goal:** To promote positive change in data management and sharing culture

DMS Plan Submission and Review

Plan Submission

With application

Brief Plan description in Budget Justification

Full Plan as separate attachment

Plan Assessment

Peer reviewers comment on (not score) budget

NIH program staff assess Plans

Plans revisions may be requested at JIT

Plan Compliance

Incorporated into Terms and Conditions

Monitored at regular reporting intervals and updates included in annual RPPR

Compliance may factor into future funding decisions

APPLICATION REQUIREMENTS

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Application instruction highlights

- Forms-H application package released as part of policy implementation
- Added new “Other Plan(s)” section to enable the DMSP to be attached as a single pdf
- Optional DMS Plan format page developed to align with the required elements of a DMS Plan
- Sample plans and other tips on writing a DMS Plan are available via https://sharing.nih.gov

Budget Justification

- Must provide a brief summary of the type and amount of scientific data to be preserved and shared and the name of the selected established repository(ies) for each data type.
- Even though direct costs associated with data management and sharing activities may be spread across multiple budget categories, this section is required and includes general cost categories needed to implement the DMS Plan as proposed (curation, developing supporting documentation, local data management activities, repository fees, etc.), including an amount for each category and a brief explanation.
- ***This summary is what reviewers will be able to review; they will not have access to the full submitted DMSP. This section should communicate to reviewers that the PI has developed an appropriate DMS Plan and understands what will be needed to implement data management and sharing best practices.***
- The recommended length of this section of the justification is no more than half a page.

Setting timeline expectations when DUAs are involved

When generating data, consider:

- How many sites are involved?
- How sensitive is the data being collected/used?
- Are all sites collecting the same or different data?
- Is there a single IRB?
- Are all sites working in the same cloud environment or each their own data storage?

When acquiring data, consider:

- Have you worked with the data provider before?
- How large is the data set?
- If any regulatory requirements apply to the data, does your institution have a compliant environment?

Best practices with subrecipients

- Prime PI should discuss roles and responsibilities with regards to DMS activities with any subrecipients while preparing the proposal
    - Element 6 of the DMS Plan (Oversight of Data Management and Sharing) can be used to outline the roles and responsibilities
- Subrecipient should review (and ideally approve) the DMS Plan prior to proposal submission to avoid issues at award stage
- Incorporate complete DMS Plan into the subaward agreement (or include a statement that the subrecipient has no role in the DMS activities)

WRITING THE DMS PLAN

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Required elements of an NIH DMS Plan

Element 1: Data Type

Identify data to be preserved and shared; accompanying metadata, other relevant data, and associated documentation to be made available

Element 2: Related Tools, Software, and/or Code

Tools and software needed to access and manipulate data

Element 3: Standards

The standards, if any, that will be applied to the scientific data and associated metadata (i.e., data formats, data dictionaries, data identifiers, definitions, unique identifiers, and other data documentation)

Required elements of an NIH DMS Plan

Element 4: Data Preservation, Access, and Associated Timelines

Proposed Repository to be used consistent with Supplemental Information on Repository Selection, persistent unique identifier and when/how long data will be available

Element 5: Access, Distribution, and Reuse Considerations

Description of factors potentially affecting data access, distribution, or reuse (related to informed consent or privacy and confidentiality protections); Whether access to human data will be controlled; any restrictions imposed by federal, Tribal, or state laws, regulations, or policies

Element 6: Oversight of Data Management and Sharing

Indicate how compliance with the Plan will be monitored and managed; Titles and roles of those responsible for overseeing data management and sharing; Frequency of oversight

What is the FDP?

FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

FDP mission:

Association of federal agencies, academic and nonprofit research institutions, and research policy organizations that work together to streamline the administration of federally sponsored research and foster collaboration to enhance the national research enterprise, while maintaining high standards of stewardship and accountability.

Researchers doing research, not administration

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Federal Demonstration Partnership (FDP) NIH DMS Pilot

- Phase 1: NIH DMS Plan Template Pilot
  - We will test the effectiveness and usability of two DMS Plan templates developed in collaboration with representatives from participating ICs:
    - **Alpha Template** is a prescriptive template designed to limit the need for free text entry
    - **Bravo Template** aims to provide detailed prompts as well as more options to include free text responses as necessary.
  - We will gather data from the researcher/faculty perspective as well as the NIH program perspective.
  - Support Providers can also submit their feedback
  - See the pilot webpage for more information: https://thefdp.org/demonstrations-resources/nih-data-management-sharing-pilot/
- Phase 2: Cost Policies
  - Planning phase has begun!

Interested in joining?

The Pilot is still accepting new participating organizations!

Email NIHDMSPilot@thefdp.org to request a copy of the pilot MOU for review and signature

**Participation is not limited to FDP member organizations*

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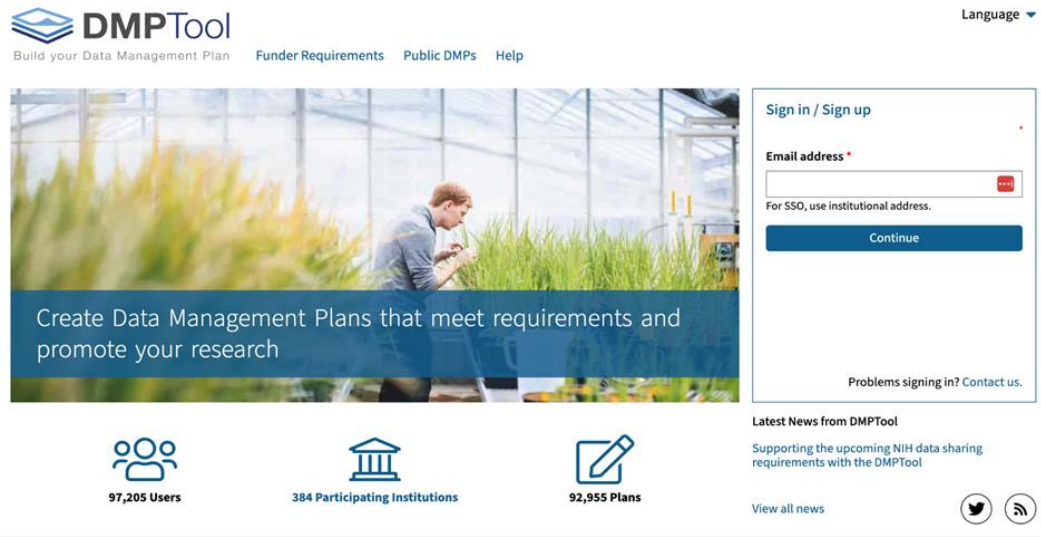
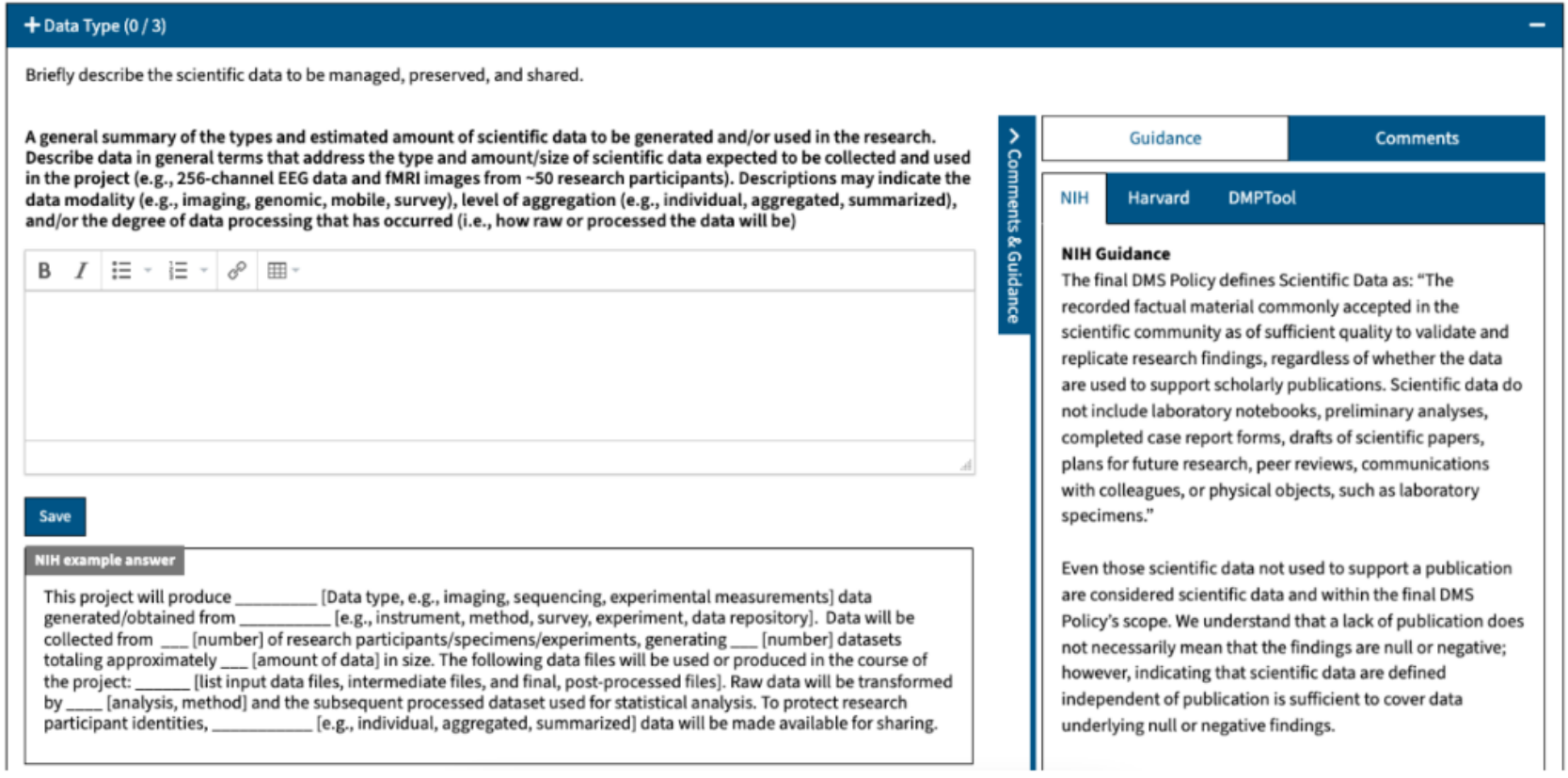
DMPTool

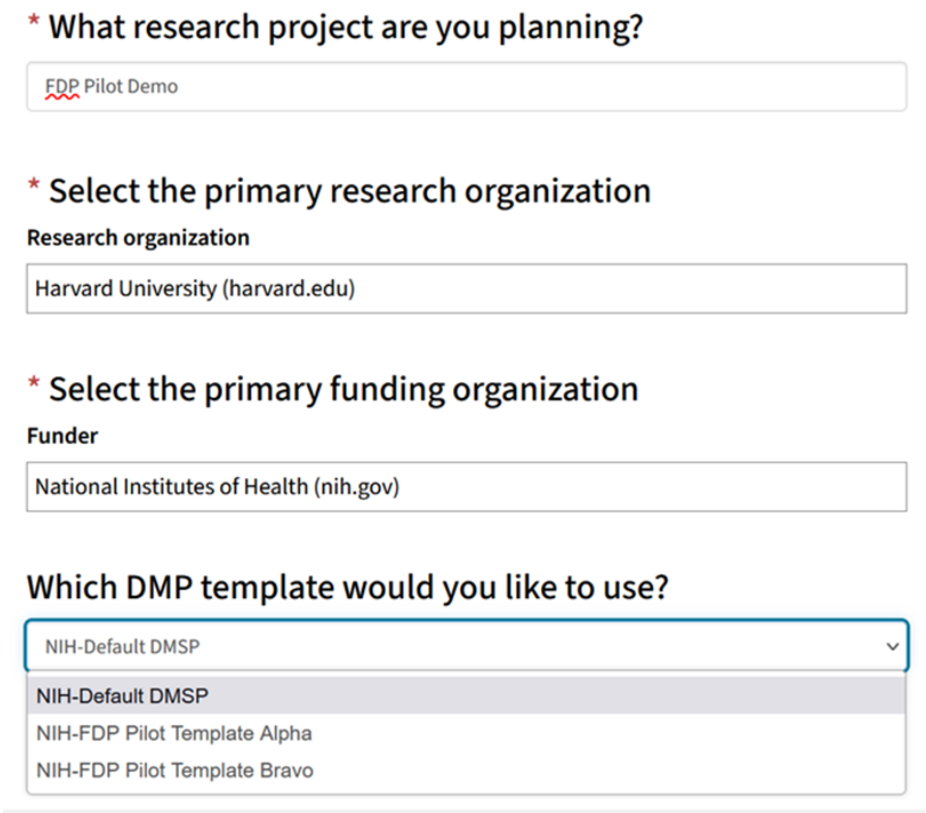
- Free, open source, community-supported application with over ten years of use
- A communication vehicle that supports data stewardship between librarians and researchers at scale
- Funder-specific templates that institutions can customize to ensure that their requirements are considered
- Best practice guidance to ensure DMPs are structured and optimized
- A mechanism for registering a DMP ID



DMPTool: NIH-Default DMSP



FDP Pilot Templates in DMPTool



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Poll: Does your institution support (secured behind single sign on) the use of DMPTool?

- Support it? We require it!
- Yes
- No
- Not sure

BUDGETING

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NOT-OD-23-161 issued July 31, 2023

- “Effective for applications submitted for due dates on or after October 5, 2023, NIH will no longer require the use of the single DMS cost line item. NIH recognizes that DMS costs may be requested in many cost categories. Therefore, in line with our standard budget instructions, DMS costs must be requested in the appropriate cost category…”
- “…NIH will require applicants to specify estimated DMS cost details within the “Budget Justification” attachment of the R&R Budget Form or “Additional Narrative Justification” attachment of the PHS 398 Modular Budget Form, pursuant to the instructions...”

Direct vs Indirect Costs

- Per the NIH Supplemental Information: Allowable Costs for Data Management and Sharing: "…budget requests must not include infrastructure costs that are included in institutional overhead (e.g., Facilities and Administrative costs)…"
- **A direct cost** is a cost that can be identified specifically with a particular final cost objective or can be directly assigned relatively easily with a high degree of accuracy (2 CFR 200.413). A direct cost usually involves a single unit of cost and a single benefiting cost objective.

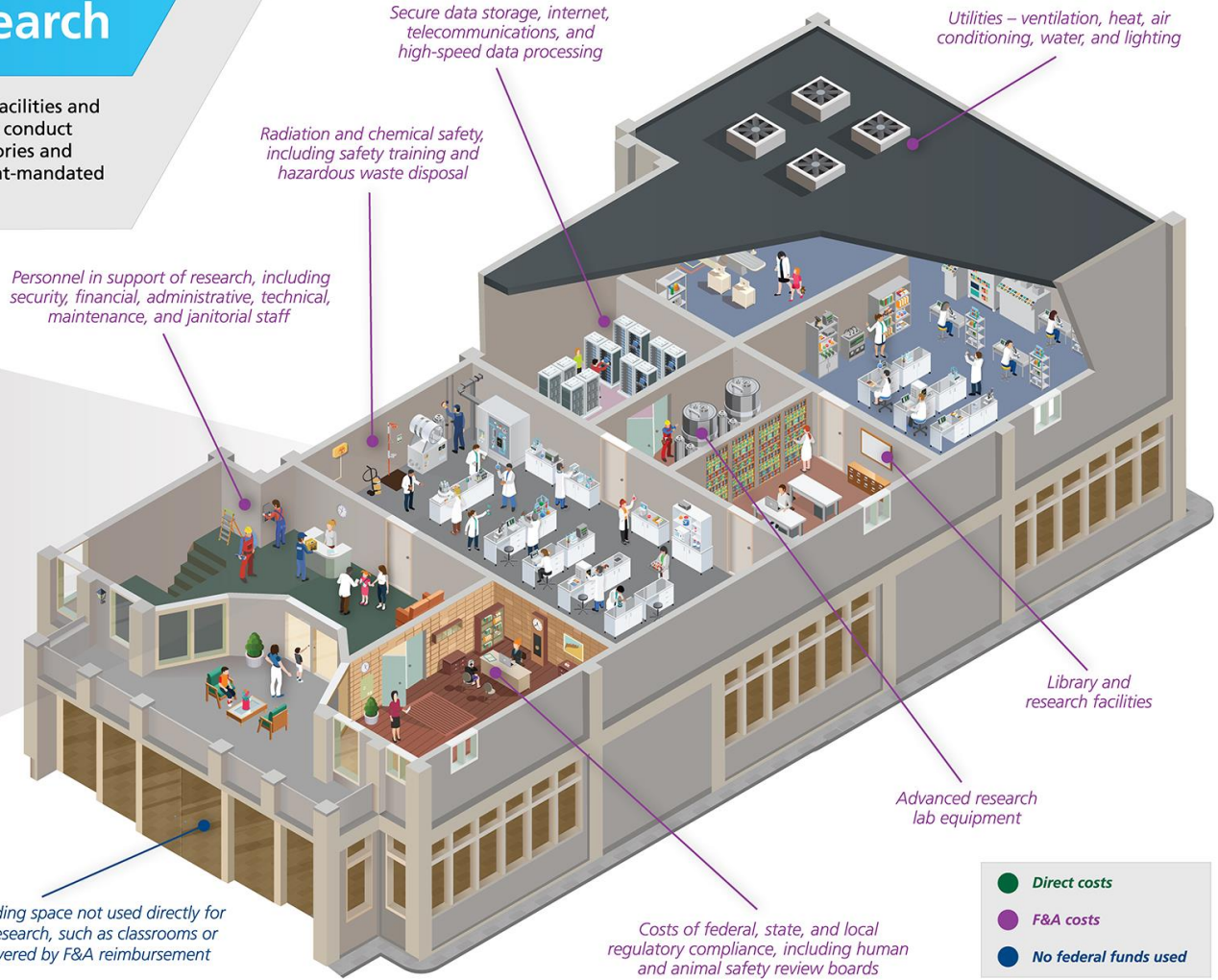
Indirect Costs (IDC, F&A, or Overhead)

- **An indirect cost** is a cost incurred for a common purpose benefitting more than one cost objective and not readily assignable to the benefitting cost objectives without effort disproportionate to the result achieved. For Institutions of Higher Education (IHEs), indirect costs are made up of Facilities and Administrative expenses and are unofficially capped at 69.9%.
  - **Facilities**: Depreciation, Interest, Operations and Maintenance, Library
  - **Administration:** General Administration and Expenses, Departmental Administration Expenses, Sponsored Projects Administration (For IHEs, capped at 26%)

Costs of Federally Sponsored Research

The total cost of federally sponsored research includes a combination of both direct and facilities and administrative (F&A) costs. Both types of expenditures are key to an institution's ability to conduct cutting-edge research. F&A consists of the construction and maintenance costs of laboratories and high-tech facilities; energy and utility expenses; and safety, security, and other government-mandated expenses. These costs are real and research cannot be conducted without them.

Direct costs - These expenses solely cover research and include lab supplies and equipment; salaries and stipends for researchers and graduate students; and travel costs for conducting and sharing research



AAMC

Association of American Universities
Inquiry · Innovation · Impact

AIRI
Association of Independent Research Institutes

Association of Public & Land-grant Universities

COGR
Council On Governmental Relations

Confirm your institution's approach

- Each institution may make a different decision about which costs associated with data management and sharing are included in their F&A rate negotiation.
- Certain services may be offered through a service or recharge center
  - A service or recharge center may be used when there are multiple types of costs and the users or usage is unknowable at the time costs are incurred.
  - Example: Research Computing Core
  - A fee associated with use of a service or recharge center should be included in the budget as a direct cost.

Which direct costs can be included?

- Reasonable, allowable direct costs associated with:
  - Curating data and developing supporting documentation
  - Local data management considerations
  - Preserving and sharing data through established repositories
- **Reasonable**: The cost on the award reflects what a “prudent person” would pay in a similar circumstance.
- **Allowable**: Both federal regulations and the terms of a specific award must allow for the purchase of such an item or service. Allowable direct charges to sponsored (federal and non-federal) awards must comply with both institutional policies and the terms/conditions of the award.

Working with the PI to budget appropriate costs

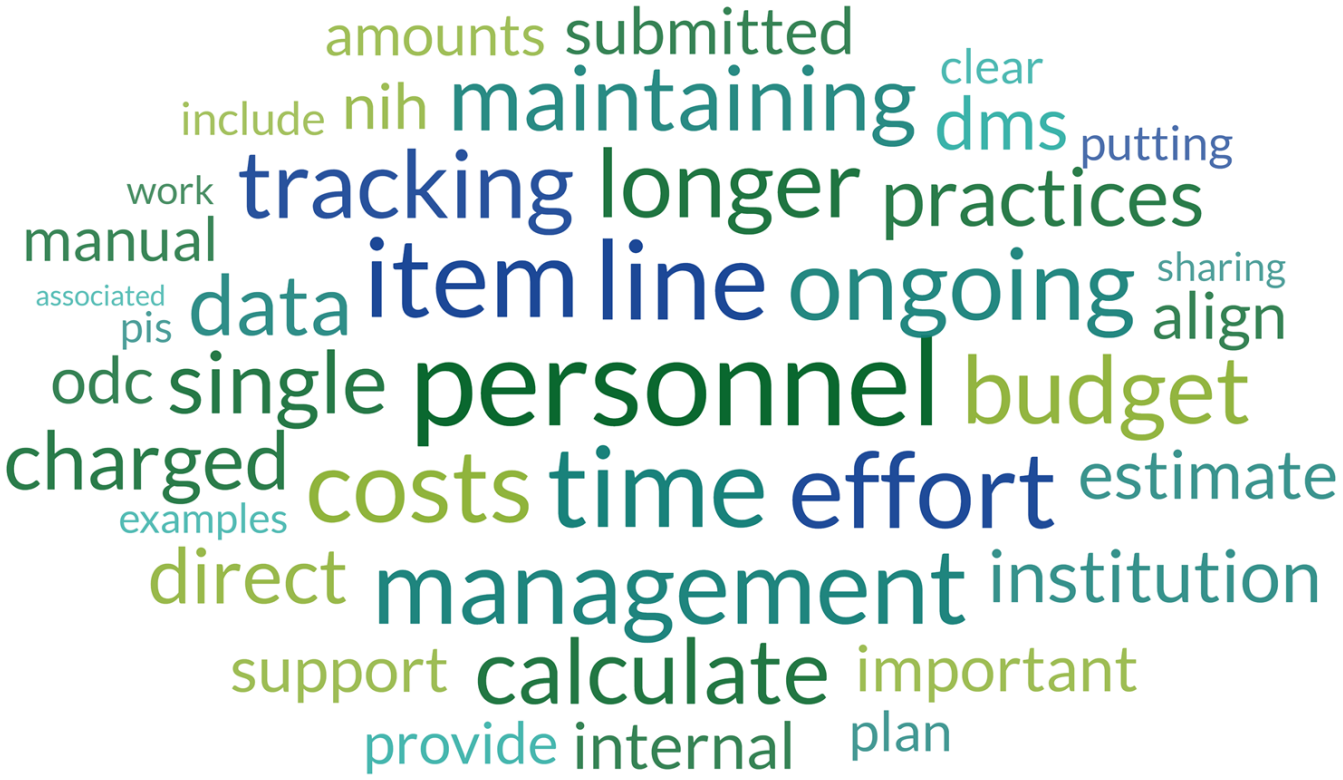
- Is there a deposit fee for any of the repositories you are planning to use?
  - Does the repository allow pre-payment via a single deposit fee or is there an annual recurring fee? (Note: If an annual fee, fees incurred after the period of performance cannot be charged to the award.)
- Will you need dedicated research personnel time to support any data management and sharing activities to meet repository requirements? If not personnel time, will you need to engage the services of a core/service center or vendor to complete:
  - Data curation?
  - Developing supporting documentation?
  - Formatting data according to accepted community standards or for transmission and storage at selected repository?
  - Preparing metadata?
  - De-identifying data?

Working with the PI to budget appropriate costs

- Where are you planning to store the data while the project is active? Is there an associated fee?
- Is there a fee associated with any tools or software you are planning to use to collect or analyze the data?
  - **Note:** If these are necessary for the ordinary conduct of research and not just the data management and sharing activities, they should be budgeted in the appropriate budget category and not in the data management and sharing line item.
- Do you have subrecipients?
  - If yes, will they be responsible and need to budget for data management and sharing activities?
- Are you a subrecipient?
  - If yes, have you discussed with the Prime PI if you will be responsible and need to budget for data management and sharing activities?
- Do you anticipate any expenses related to the DMSP after the end of the period of performance of the award? If so, how should those costs be covered as they cannot be charged to the award?

Source: Harvard NIH DMSP Budgeting and Application Instructions – Tip Sheet

FDP ThoughtExchange: key challenges related to budgeting



OTHER IMPLEMENTATION CONSIDERATIONS

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Poll: How ready do you feel to support the JIT and Awards stages?

- Ready for whatever these stages throw it as; bring it on!
- We might be ready, but are waiting to see how it goes.
- We haven’t really planned for these stages yet.
- Wait, this doesn’t end at the proposal stage?

Initial Observations – DMS Plans

- Not indicating which data goes where, for example, not using an established repository.
- Vague descriptions of which data will be shared, vague reasons for not sharing.
- Conflicting information (something described in one element is contradicted in another).
- Plans that used any template or included tables/lists were generally more successful.
- FDP Pilot Leads will be working with NIH Program Staff to continue to assess information in the plans, to better inform the future phases of the pilot and compliance activities.

With thanks to NCI and NICHD for providing initial observations of plans received by their ICs. This data is anecdotal, based on preliminary reviews of DMS plans.

If a revised DMS Plan is requested at JIT…

- Any revised DMS Plan must be submitted to NIH by the AOR
- Ensure PI has sufficient time to thoughtfully revise the DMS Plan
- Ask PI whether any changes to the budget would be needed to implement the revised DMS Plan
- Consider whether any changes impact subrecipients and, if so, confirm they are comfortable with the revisions
- When the Notice of Award is received, confirm the correct version of the DMS Plan has been incorporated

Prior Approval Requests for DMS Plan Revisions

- Prior approval may be sought via the Research Performance Progress Report (RPPR) if the timing of the changes allows
- All other requests for prior approval of revisions to the DMS Plan must be submitted via the Prior Approval Module in eRA Commons (NOT-OD-23-185)
- The revised DMS Plan should not be implemented until the appropriate prior approval is obtained

What are some indicators that prior approval is needed?

- Type(s) of data to be generated change(s)
- Change(s) in the data repository to be used
- The sharing timeline shifts
- PI may want to consult with the Program Officer prior to submitting a prior approval request and/or to confirm whether prior approval should be sought

Resources

- NIH's Scientific Data Sharing website: https://sharing.nih.gov/
- FDP Pilot website: https://thefdp.org/demonstrations-resources/nih-data-management-sharing-pilot/
- COGR's NIH Data Management and Sharing Policy Resource Page: https://www.cogr.edu/nih-data-management-and-sharing
- NDA Data Submission Cost Estimation Tool: https://nda.nih.gov/nda/data-contribution.html#cost
- Registry of Research Data Repositories: https://www.re3data.org/
- Harvard DMS Plan Budgeting and Application Instructions Tip Sheet: https://research.harvard.edu/files/2023/10/Application-Instructions-Tip-Sheet-V3_9-21-2023.pdf

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STAY WITH US!

AFTER THE SHOW

Will begin 5 minutes after the conclusion of the webinar

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