Town Hall: NIH Data Management & Sharing Policy
Session 2

Friday, November 18, 2022

2-3pm EST

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Panelists

- William Berger, Assistant Vice President, Sponsored Projects Administration

- Moacir P. de Sa Pereira, Research Data Librarian, University Libraries

- Roger LeFort, Assistant Director for Research Integrity and Compliance, Office of Research Compliance & Training

- Naomi Schrag, Vice President for Research Compliance, Training and Policy, Office of Research Compliance & Training

- Stephanie Scott, Director of Policy & Research Development, Sponsored Projects Administration

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data-management@columbia.edu

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Agenda

- Recap of Session 1
  - Slides available at https://research.columbia.edu/nih-data-management-and-sharing-plan-2023
- Allowable Costs for Data Management & Sharing
- Budget Forecasting
- Forms-H
- Budgets and Budget Justifications
- Resources
- Q&A

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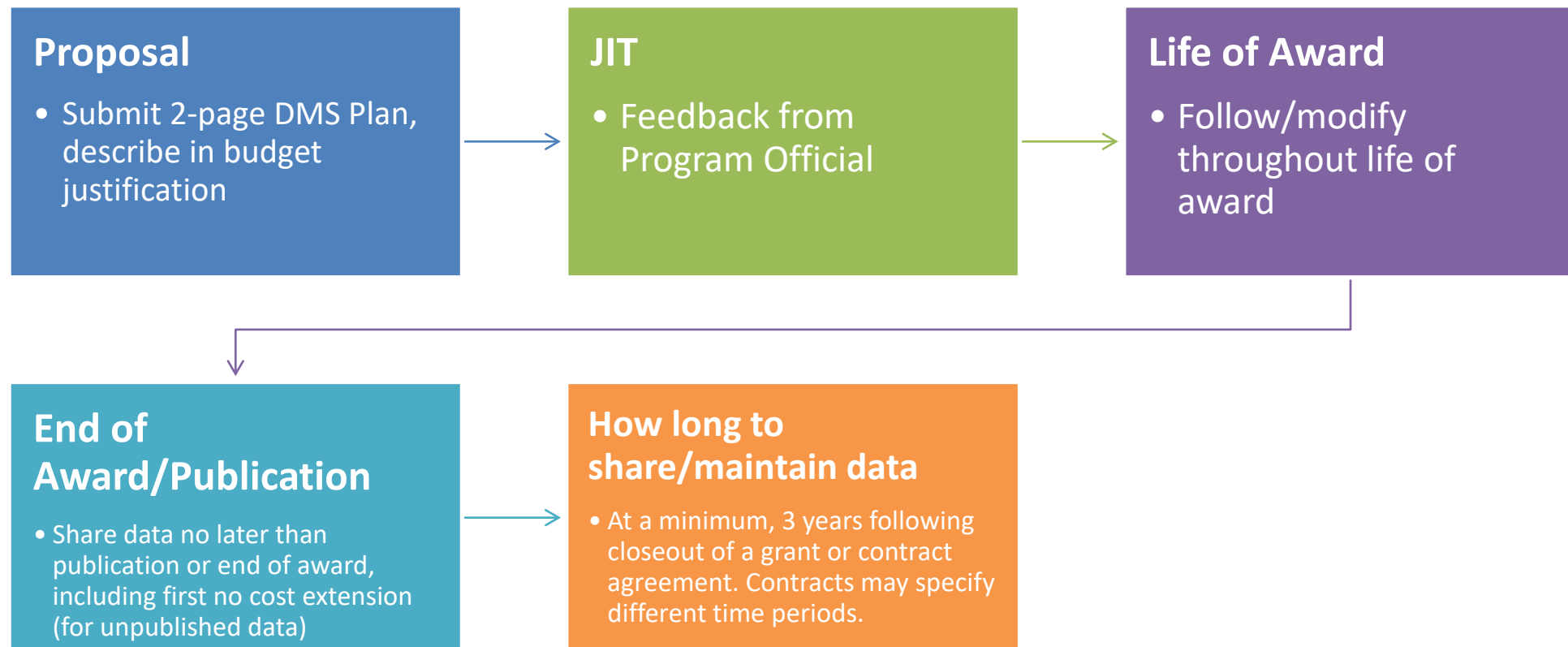The DMSP policy has **two main requirements:**

1. <u>Submission of a two-page data management and sharing plan:</u> Research proposals without a Plan will not be considered for funding.

2. <u>Compliance with the approved plan.</u> Failure to provide updates in grant reporting may result in enforcement actions, including the addition of special terms and conditions or award termination. Failure to deposit data after the end of the funding period may negatively influence future opportunities.

Effective Date: Applies to **competing grant applications** that are submitted to NIH for January 25, 2023, and subsequent receipt dates and **all proposals for contracts** that are submitted to NIH on or after January 25, 2023. Applies only to projects that result in the generation of "scientific data."

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NIH DMSP Policy | Applicability and Timing

Applicability: Applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of **scientific data**, regardless of funding level.

- *Does not include projects that do not generate scientific data, e.g.,*
- *Training (T), Fellowships (Fs), Construction (C06), Conference Grants (R13), Resource (Gs), and Research-Related Infrastructure Programs (e.g., S06)*

Proposal
- Submit 2-page DMS Plan, describe in budget justification

JIT
- Feedback from Program Official

Life of Award
- Follow/modify throughout life of award

End of Award/Publication
- Share data no later than publication or end of award, including first no cost extension (for unpublished data)

How long to share/maintain data
- At a minimum, 3 years following closeout of a grant or contract agreement. Contracts may specify different time periods.

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Maintaining and Sharing Data

Length of Time to Maintain Data

"Per Section 8.4.2 of the NIH Grants Policy Statement, grantee institutions are required to keep the data for 3 years following closeout of a grant or contract agreement. Contracts may specify different time periods. Please note that the grantee institution may have additional policies and procedures regarding the custody, distribution, and required retention period for data produced under research awards."

Data Preservation and Sharing Timelines

"Shared scientific data should be made accessible as soon as possible, and no later than the time of an associated publication, or the end of performance period, whichever comes first. Researchers are encouraged to consider relevant requirements and expectations (e.g., data repository policies, award record retention requirements, journal policies) as guidance for the minimum time frame that scientific data should be made available, which researchers may extend."

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NIH DMS Plan | Assessment of DMS

Assessment by NIH Program Staff

- Peer review will not see or review DMS Plans but will consider any related budget items
- DMS Plans are **NOT** part of scored peer review criteria unless specifically noted in the Funding Opportunity Announcement
- Peer Review will see the budget justification, which may include up to a half-page on data management and sharing costs.
- NIH Program Staff will review the DMS Plan for acceptability and may request modifications prior to award as appropriate
- Plans must be approved by the funding institute prior to award

Just-in-Time Review

If DMS Plan provided in the application cannot be approved based on the information provided, applicants will be notified that additional information is needed through the Just-in-Time (JIT) process.

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Allowable Costs for Data Management and Sharing

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Definitions

Data Management
- The process of validating, organizing, protecting, maintaining, and processing scientific data to ensure the accessibility, reliability, and quality of the scientific data for its users.

Data Sharing
- The act of making scientific data available for use by others (e.g., the larger research community, institutions, the broader public), for example, via an established repository.

Data Management and Sharing Plan (DMS Plan)
- A plan describing the data management, preservation, and sharing of scientific data and accompanying metadata.

Glossary | grants.nih.gov. (n.d.). Retrieved November 15, 2022, from https://grants.nih.gov/grants/glossary.htm#DataManagement

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Budgeting for Data Management

- Data management happens throughout the life of the project. This is not an activity that can be deferred until the end of the project period, or when there is a manuscript ready for publication. Researchers need to document relevant metadata and properly store data and metadata from day 1 of the project.

- Learn about Good Research Data Management (GRDM) at:

- https://research.columbia.edu/content/data-management

- Data management and sharing related costs should be budgeted throughout the project period.

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Separation of Budgets

Budgets need to differentiate 2 sets of costs:

1) Routine conduct of research/Costs of doing research:
   - Costs associated with *collecting* or otherwise *gaining access to research data* (e.g., data access fees)

   vs.

2) Data management and sharing

See NIH's [Supplemental Information to the NIH Policy for Data Management and Sharing: Allowable Costs for Data Management and Sharing](#) (NOT-OD-21-015)

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Direct vs. F&A (NOT-OD-21-015)

- "Consistent with [45 CFR 75.403](#) and the [NIH Grants Policy Statement Section 7.4](#), budget requests must not include infrastructure costs that are included in institutional overhead (e.g., Facilities and Administrative costs) or costs associated with the routine conduct of research."

- "Costs may not be double charged or inconsistently charged as both direct and indirect costs."

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Incurring of Costs (NOT-OD-21-015)

All allowable costs submitted in budget requests must be incurred (e.g., curation fees, data repository fees) **during the performance period**, even for scientific data and metadata preserved and shared beyond the award period.

For instance, if a DMS plan proposes preserving and sharing scientific data for 10 years in an established repository with a deposition fee, *the cost for the entire 10-year period must be paid before the end of the period of performance*.

TIP: Consult upfront with respective repository about options for long-term storage, preservation and sharing.

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Allowable Costs, per NOT-OD-21-015

1. **Curating data and developing supporting documentation,** including formatting data according to accepted community standards; de-identifying data; preparing metadata to foster discoverability, interpretation, and reuse; and formatting data for transmission to and storage at a selected repository for long-term preservation and access.

2. **Local data management considerations,** such as unique and specialized information infrastructure necessary to provide local management and preservation (e.g., before deposit into an established repository).

3. **Preserving and sharing data through established repositories,** such as data deposit fees necessary for making data available and accessible. For example, if a **Data Management and Sharing Plan** proposes preserving and sharing scientific data for 10 years in an established repository with a deposition fee, the cost for the entire 10-year period must be paid prior to the end of the period of performance. If the Plan proposes deposition to multiple repositories, costs associated with each proposed repository may [14] be included.

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Allowable Costs, breaking it down

Reasonable, allowable costs may be included in NIH budget requests for:

- Curating data (time and effort)
- Developing supporting documentation (time and effort)
- Formatting data according to accepted community standards, or for transmission to and storage at a selected repository for long-term preservation and access (time and effort)
- De-identifying data (time and effort)
- Preparing metadata to foster discoverability, interpretation, and reuse (time and effort)
- Local data management considerations, such as <u>unique</u> and <u>specialized</u> information infrastructure necessary to provide local management and preservation (for example, before deposit into an established repository). (project-specific data storage)
- Preserving and sharing data through established repositories, such as <u>data deposit fees</u>.
  - If the Data Management & Sharing (DMS) plan proposes deposition to multiple repositories, costs associated with each proposed repository may be included.

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Unallowable Costs

- **Budget requests must NOT include:**
  - Infrastructure costs that are included in institutional overhead (for instance, Facilities and Administrative costs)
    - Sharepoint
    - Lab servers/computers used for multiple projects
    - IT services
  - Costs associated with the routine conduct of research, including costs associated with collecting or gaining access to research data.
  - Costs that are double charged or inconsistently charged as both direct and indirect costs

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What is Data Curation?

Data curation is the ongoing processing and maintenance of data throughout its lifecycle to ensure long term accessibility, sharing, and preservation. Data curation is composed of research data management and digital preservation to make data finable and understandable. - *Paraphrased from: National Library of Medicine, NIH. (n.d.). Data Curation | NNLM. Retrieved November 13, 2022, from* [*https://www.nnlm.gov/guides/data-glossary/data-curation*](https://www.nnlm.gov/guides/data-glossary/data-curation)

Who normally does data curation? Multiple people may be involved throughout the project.

- The PI is responsible, but can also delegate some of these tasks – time & effort/allowable costs

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What is free?

- DMPTool, an interactive on-line tool used to create a data management plan, https://dmptool.org/

- NIH-supported Scientific Data Repositories (double check, some *may* include fee structures, but many are free), Dryad, some Research Data Storage options.

- Consultation services offered by Research Data Services | Libraries and the ReaDI Program
  - Help with writing a DMS Plan
  - Strategies for documentation and data management
  - Workshops on the principles of data management
  - Connect you to additional resources

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Budget Forecasting

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Budget Forecasting Resources

The National Academies of Science, Engineering, and Medicine has developed a resource "Forecasting Costs for Preserving, Archiving, and Promoting Access to Biomedical Data" that may be useful when budgeting for data management and sharing costs.

Cost Drivers Workbook – customizable Word doc

NAS' Cost Drivers Workbook

A. Content (details)			
Category	**Cost Driver**	**Decision Points/Issues**	**Relative Cost Potential (Low, Medium, High)**
A.1	Size (volume and number of items) > size = higher costs	1. How many files will be in a single data submission?	
		2. How large is an average data submission in total?	
		3. Are the data sizes likely to stay stable over the life of the resource?	
		4. What is the total amount of data expected?	
		5. In what kind of medium will data be captured in the short and long terms?	
A.2	Complexity and Diversity of Data > complexity + diversity = higher	1. How complex is the underlying structure of the data?	
		2. How are the included data to be organized?	

- Allows you to document responses to important decision points

- Remove questions N/A to your research

- User Guide

- Video

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Questions to ask

- Is there a fee for the repository? Consult about long-term costs.
- Will you need dedicated staff time for any data management and sharing functions to meet the requirements of the repository? Hire new staff?
  - Should be justified in the Budget Justification (more on that later)
- Is your NIH budget modular or non-modular?
  - FORMS-H
- Do you have **subrecipients**, and will they be responsible/need to budget for DM&S?
  - How will they collaborate with you on meeting sharing requirements?
  - Will they be collecting data? Will they need to budget for some data curation costs? How will they share their data with you? Who will be responsible for uploading data into the repository? Should be discussed and worked out in the DMS Plan.

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Data Management & Sharing (DMS) Plan for budgeting

- While developing the DMS Plan, use each element to factor in the associated costs

- There is no one-size-fits-all model

- Costs will vary widely by discipline, type of data, amount of data, the length of time for sharing the data, amount of time it will take to curate the data in a format that can be findable and reused by the research community.

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Consult with…

- Other colleagues in the scientific community (including the lessons they learned)

- CUIT/CUIMC IT, the Libraries, Roger LeFort (ReaDI Program) as necessary.
  - See Columbia's Research Data Storage Options, includes associated costs
  - Email data-management@columbia.edu as questions come up

- After selecting a data repository for sharing data, consult with the data support staff associated with the selected repository (and refer to the instructions for depositing data into the repository) to estimate the amount of time and resources necessary to prepare the data for deposit.

- Picking the repository is a great first step in creating the budget. It drives many of the other costs.

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Selecting a Repository

Selecting a Repository for Data Resulting from NIH-Supported Research

- The DMS Policy does not currently mandate any particular repository for data, but some individual NIH institutes have specified required repositories (e.g., NIMH).

- NIH encourages researchers to select the repository that is most appropriate for their data type and discipline. A [Generalist repository](#) can also be used if researchers are unable to find a repository that suits their data.

https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/repositories-for-sharing-scientific-data

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Research Data Storage Options

Principal investigators should establish a research data management system for their projects including procedures for storing "working data" collected during the conduct of the research. The PI should communicate these procedures to all group members. The procedures should ensure that the PI is able to access all data produced by the research group and must meet all applicable security requirements.

Below is a list of options for the storage of digital research data. A glossary of the terms used in the summary is located at the end of this document.

UNIT	SERVICE	FREE	UNLIMITED	MUTABLE	BACKUPS	VERSION CONTROL	PI/RHI SECURE	PHI CERTIFIED SECURE	ACCESS CONTROL	SHARABLE	ARCHIVAL PRESERVATION	LONG-TERM STORAGE	PUBLIC ACCESS
CUIT	LionMail Drive	Yes	No	Yes	Yes	No	No	No	Yes	Yes	No	No	No
	Amazon Web Services (AWS)	Free Tier	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	Google Cloud Platform (GCP)	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes
	Secure Data Enclave (SDE)	No	No	Yes	No	No	Yes	Yes	Yes	No	No	No	No
	Microsoft Azure	Free Tier	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	No	No
	Globus (data transfer)	Yes	N/A	N/A	No	N/A	No	No	Yes	Yes	No	N/A	No
	Columbia Data Platform	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
	Box	Free Tier	Unlimited Tier	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	No
CUIMCIT	CUIMC IT Storage	No	Unlimited Tier	Yes	Yes	Yes*	Yes	Yes	Yes	Yes	No	Yes*	Yes*
	CUIMC IT FTP Server	No	No	Yes	No	No	Yes*	Yes*	Yes	Yes	No	No	No
	SharePoint Online – Office 365	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	Virtual Servers	No	No	Yes	Yes	N/A	Yes*	Yes*	Yes	Yes	No	No*	No
Libraries	Academic Commons	Yes	No	No	Yes	Yes*	No	No	No	Yes	Yes	Yes	Yes
	Dryad	Yes	Yes	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes

UPDATED – 10.26.2022 - Roger Lefort

DMS Plan | NIH Required Elements

1. Data type

- Identifying estimated type and amount of data to be generated (i.e., modality, level of aggregation, and degree of data processing)
- Which data to be preserved and shared
- Accompanying metadata, other relevant data, and associated documentation to be made available

2. Related tools, software, code

- Tools and software needed to access and manipulate data

3. Standards

- 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)

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4. Data preservation, access, and associated timelines

- Proposed repository to be used consistent with <u>Supplemental Information on Repository Selection</u>
- How data will be findable and accessible (e.g., persistent unique identifier)
- When data will be made available and for how long

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

6. Oversight of data management

- Describe how compliance with the DMS Plan will be monitored and managed

Note(s):

- Data management responsibilities extend beyond just the PI or researcher(s) who create or collect the data. Various parties involved in the research process (including collaborators) must play a role in ensuring good quality data stewardship throughout the life of the project. It will be essential that roles and responsibilities of data management be clearly defined and assigned, rather than assumed.

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A Note about the Genomic Data Sharing (GDS) Policy

- Special instructions for developing the DMS Plan for data subject to the GDS Policy.

- https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing/writing-a-data-management-and-sharing-plan#data-management-and-sharing-plan-format

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FORMS-H

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FORMS-H: Notice [NOT-OD-23-012](#), issued 10/26/22

- FORMS-H application packages are currently being posted to all active funding opportunity announcements (FOAs). Expect to complete this process by late December 2022.
- All FORMS-G application forms packages will be updated with a close date of January 24, 2023.

If the intended due date is...	You must use...
On or before **January 24, 2023**, including: - Applications submitted for due dates on or before January 24, 2023 - Applications submitted under [NIH Late Policy](#) 2-week window of consideration for intended due dates on or before January 24, 2023 - Applications submitted by February 1, 2023 under NIH [Continuous Submission Policy](#) for the January 7, 2023 AIDS intended due date	FORMS-G application package
On or after **January 25, 2023**, including: - Applications submitted for due dates on or after January 25, 2023 - All application types (New, Resubmission, Renewal, Revision) - Applications submitted early for intended due dates on or after January 25, 2023	FORMS-H application package

When preparing application in ASSIST

https://grants.nih.gov/grants/guide/ApplyButtonSplash.cfm?dest=https://public.era.nih.gov/assist

Submitting to a due date on or after January 25, 2023?

- Use FORMS-H application forms

Submitting to a due date before January 25, 2023?

- Use FORMS-G application forms

See NOT-OD-22-195 to learn more.

Choose Package for FOA #: PA-20-185

FOA INFORMATION

FOA Number:	PA-20-185
Opportunity Title:	NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)
Offering Agency:	National Institutes of Health

Competition ID	Competition Title	Opening Date	Closing Date	Select Package
FORMS-G	Use for due dates on or after January 25, 2022	10/26/2021	05/07/2023	Select
FORMS-H	Use for due dates on or after January 25, 2023	10/26/2022	05/07/2023	Select

Close

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FORMS-H Instructions

New FORMS-H instructions posted:

https://grants.nih.gov/grants/how-to-apply-application-guide.html

Application Form Instructions

Determine the Correct Application Instructions for Your Activity Code

Application Instructions	Description	SF424 (R&R) - Version G (Due dates BEFORE Jan. 25, 2023)	SF424 (R&R) - Version H (Due dates ON/AFTER Jan. 25, 2023)
G General Instructions	Comprehensive guidance for research, training, fellowship, career development, multi-project, and small business applications	HTML / PDF	HTML / PDF
Filtered Application Instructions			
R Research Instructions	Guidance for research only Activity Codes: Research (R), including Research Education (R25), and equivalent Cooperative Agreements (U)	PDF	PDF
K Career Development Instructions	Guidance for career development only Activity Codes: Individual Career Development (K), excluding Institutional Career Development (K12, KL2, KM1)	PDF	PDF

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Significant Changes - Research Instructions

PHS 398 Research Plan Form

- New item 11 in the Research Plan - "**Other Plan(s)",** with instructions for applicants submitting Data Management and Sharing (DMS) Plans.

- Renumbered form fields.

- Applications subject to Genomic Data Sharing (GDS) Policy should no longer include a GDS Plan in item 10, under the Resource Sharing Plan(s)

  - Instead, Genomic Data Sharing should be provided as part of the new Data Management and Sharing Plan uploaded to the <u>new item 11</u>.

  - Resource Sharing Plan(s) (item 10) now limited to <u>Sharing Model Organisms</u>, and <u>Research Tools Policy</u>.

- Clarified instructions for renewal or resubmission applications involving changes between single PD/PI to or from multiple PD/PIs.

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PHS 398 Research Plan

Introduction

1. Introduction to Application
   (for Resubmission and Revision
   applications)

   Limited to 1 page (except R25 Resubmission can be 3 pages). Required for Resubmission and Revision applications.   [View Attachment]

Research Plan Section

2. Specific Aims

   Required (except DP1, DP2, DP4, R35, R50 and X02). Limited to 1 page.   [achment]

3. *Research Strategy

   Adhere to page limits specified in Application Guide and/or FOA. Typically 6 or 12 pages; a small number of FOAs specify 30 pages.   [Attachment]

4. Progress Report Publication List

   Only allowed for Renewals and Resubmissions of renewals.   [Attachment]

Other Research Plan Section

5. Vertebrate Animals

   Required for all apps. (except S10), if Vertebrate Animals is Yes on the Other Project Information form.   [iew Attachment]

6. Select Agent Research   [_____] [Add Attachment] [Delete Attachment] [View Attachment]

7. Multiple PD/PI Leadership Plan

   Required if more than one PD/PI is specified on R&R Sr/Key Person Profile form.

8. Consortium/Contractual Arrangements   [_____] [Add Attachment] [Delete Attachment] [View Attachment]

9. Letters of Support

   Required for R36 applications.   [dd Attachment] [Delete Attachment] [View Attachment]

10. Resource Sharing Plan(s)   [_____] [Add Attachment] [Delete Attachment] [View Attachment]

11. Other Plan(s)

   FORMS-H: A single Data Management and Sharing plan must be attached, if required. See Application Guide and FOA. Recommended <= 2 pages. Typically not part of application image used for peer review; posted as separate document in eRA Commons.

12. Authentication of Key Biological and/or Chemical Resources

   Required if project involves key biological and/or chemical resources. Recommend 1 page. No system validation enforcement.

Appendix

13. Appendix

   DO NOT use Appendix attachments to circumvent page limits in other sections of the application. Applications will be withdrawn and not reviewed if they are submitted with appendix material that are not specifically listed in notice NOT-OD-17-098 or the FOA as allowed or required.

NEW - single PD/PI to or from multiple PD/PIs

Resubmission Applications: For resubmission applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for the change **in the introduction** and include the required **Multiple PD/PI Leadership Plan**.

Renewal Applications: For renewal applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for the change **in the progress report within the research strategy** and include the required **Multiple PD/PI Leadership Plan.**

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Significant Changes – Career Development Awards

PHS 398 Career Development Award Supplemental Form

- Added new item 17. Other Plan(s) and added instructions for applicants submitting Data Management and Sharing (DMS) Plans.

- Renumbered form fields.

- Applications subject to Genomic Data Sharing (GDS) Policy should no longer include a GDS Plan in item 16, under the Resource Sharing Plan(s)

  - Instead, Genomic Data Sharing should be provided as part of the new Data Management and Sharing Plan uploaded to the new item 17.

  - Resource Sharing Plan(s) (item 16) now limited to Sharing Model Organisms, and Research Tools Policy.

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OMB Number: 0925-0001
Expiration Date: TBD

Introduction

1. Introduction to Application
(for Resubmission and Revision applications)
   ☐ Required for Resubmission and Revision applications. Must not be included for New or Renewal applications. Limited to 1 page. [Attachment]

Candidate Section

2. Candidate Information and Goals for Career Development
   ☐ Required. This attachment and the Research Strategy attachment are limited to a combined total of 12 pages unless otherwise stated in the announcement. [Attachment]

Research Plan Section

3. Specific Aims
   Required. Limited to 1 page. [Add Attachment] [Delete Attachment] [View Attachment]

4. * Research Strategy
   ☐ This attachment and the Candidate Information and Goals for Career Development attachment are limited to a combined total of 12 pages unless otherwise stated in the announcement.

5. Progress Report Publication List
(for Renewal applications)
   [Add Attachment] [Delete Attachment] [View Attachment]

6. Training in the Responsible Conduct of Research
   Required. Limited to 1 page. [Add Attachment] [Delete Attachment] [View Attachment]

Other Candidate Information Section

7. Candidate's Plan to Provide Mentoring
   ☐ Required for K05 and K24. Do not include for K01, K07, K08, K18, K22, K23, K25, K76, K99, K99/R00. Limited to 6 pages. [Attachment]

Mentor, Co-Mentor, Consultant, Collaborators Section

8. Plans and Statements of Mentor and Co-Mentor(s)
   ☐ Required for K01, K08, K18, K23, K25, K76, K99, K99/R00. Warning if not included for K07 or K22. Limited to 6 pages. [View Attachment]

9. Letters of Support from Collaborators, Contributors, and Consultants
   Limited to 6 pages. [Add Attachment] [Delete Attachment] [View Attachment]

Environment and Institutional Commitment to Candidate Section

10. Description of Institutional Environment
    Required. Limited to 1 page. [Add Attachment] [Delete Attachment] [View Attachment]

11. Institutional Commitment to Candidate's Research Career Development
    Required. Limited to 1 page. [Add Attachment] [Delete Attachment] [View Attachment]

12. Description of Candidate's Contribution to Program Goals
    Required for diversity-related funding opportunity announcements only. [View Attachment]

Other Research Plan Sections

13. Vertebrate Animals
    ☐ Required if Vertebrate Animals Used is Yes on the R&R Other Project Information form.

14. Select Agent Research
    [Add Attachment] [Delete Attachment] [View Attachment]

15. Consortium/Contractual Arrangements
    [Add Attachment] [Delete Attachment] [View Attachment]

16. Resource Sharing
    [Add Attachment] [Delete Attachment]

17. Other Plan(s)
    FORMS-H: A single Data Management and Sharing plan required if research will generate scientific and/or large-scale genomic data. Recommended <= 2 pages. Typically not part of application image used for peer review; posted as separate document in eRA Commons.

18. Authentication of Key Biological and/or Chemical Resources
    Required if project involves key biological and/or chemical resources. No system validation enforcement. [View Attachment]

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Modular Budgets

- Used when applying for $250,000 or less per budget period in direct costs (though FOA instructions always take precedence)

- Only the *direct costs* for a subrecipient (consortium/contractual arrangements) is factored into *eligibility* for using the modular budget format, the **total** subrecipient costs must be included in the overall requested modular direct cost amount.

- See [NIH Modular Research Grant Applications](#) for more info

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Modular Budgets – Additional Narrative Justification

- "…the Data Management and Sharing justification must be clearly labeled as "Data Management and Sharing Justification" followed by the requested dollar amount. If no cost will be incurred, enter "0" for the requested dollar amount.

- Also include a brief justification of the proposed activities that will incur costs.

- Provide a brief summary of **type** and **amount** of scientific data to be preserved and shared **and the name of the established repository(ies)** where they will be preserved and shared.

- Indicate general cost categories such as **curating data and developing supporting documentation, local data management considerations, preserving and sharing data through established repositories,** etc., including **an amount for each category and a brief explanation**.

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- The recommended length of the justification should be no more than half a page."

Source: Modular Budget Justification Instructions for FORMS-H

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Modular Budgets – Additional Narrative Justification

Cumulative Budget Information | System calculated.

1. Total Costs, Entire Project Period

Section A, Total Direct Cost less Consortium Indirect (F&A) for Entire Project Period $ [0.00]

Section A, Total Consortium Indirect (F&A) for Entire Project Period $ [ ]

Section A, Total Direct Costs for Entire Project Period $ [0.00]

Section B, Total Indirect (F&A) Costs for Entire Project Period $ [ ]

Section C, Total Direct and Indirect (F&A) Costs (A+B) for Entire Project Period $ [0.00]

2. Budget Justifications

Personnel Justification [ ] Add Attachment | Delete Attachment | View Attachment

Consortium Justification [ ] Add Attachment | Delete Attachment | View Attachment

Additional Narrative Justification [ ] Add Attachment | Delete Attachment | View Attachment

FORMS-H: If a Data Management and Sharing (DMS) plan is included, you must provide this attachment and include a section titled "Data Management and Sharing Justification" that provides a brief brief summary of DMS activities and justification for their costs.

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Detailed Budgets – the R&R Budget Form

- Use the R&R Budget Form if you are applying for more than $250,000 per budget period in direct costs (though FOA instructions always take precedence).
- **Note:** The terms "**detailed budget**" and "**R&R Budget**" are used interchangeably.

- If DMS Plan required - costs to support these activities, including personnel costs (e.g., personnel who will be curating data for the project) **must be noted as a single line item**.

- The line item must be titled "**Data Management and Sharing Costs**" (without quotation marks, but following exact phrase and spacing). The line item must only be used for Data Management and Sharing costs and cannot include or be combined with any "Other" costs.

- If no cost will be incurred, enter "0" in the "Funds Requested" column.

- Details regarding Data Management and Sharing costs **must be specified in the Budget Justification attachment (L), pursuant to the instructions**.

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F. Other Direct Costs

Funds Requested ($)

1. Materials and Supplies
2. Publication Costs
3. Consultant Services
4. ADP/Computer Services
5. Subawards/Consortium/Contractual Costs → Subaward/Consortium/Contractural Costs are not pre-populated. Include both Direct and Indirect costs.
6. Equipment or Facility Rental/User Fees
7. Alterations and Renovations
8. Data Management and Sharing Costs — **$15,000**

This is an example. Put all the related DMS costs as a single line item.

9. Up to 10 additional Other Direct Costs line items can be added. Examples of possible uses: Tuition Remission, Technical Assistance, and Patient Care Costs.
10.
11. FORMS-H: If a Data Management and Sharing (DMS) plan is included, you must include a "Data Management and Sharing Costs" line item covering DMS costs, including personnel costs (e.g., personnel who will be curating data for the project). If no cost incurred, enter 0. Type the string as requested (without quotation marks) and do not combine the line item with any "Other" costs.
12.
13.
14. If proposing the use of human fetal tissue from elective abortions, you must include a "Human Fetal Tissue Costs" item (if no cost incurred, enter 0). Type the string as requested (without quotation marks) and do not combine the line item with any "Other" costs.
15.
16.
17.

L. Budget Justification

(Only attach one file.)   [Add Attachment] [Delete Attachment] [View Attachment]

Budget Justification is required and must cover all budget periods.

FORMS-H: If a Data Management and Sharing (DMS) plan is included, you must include a section titled "Data Management and Sharing Justification" that provides a brief brief summary of DMS activities and justification for their costs.

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Detailed budget – Budget Justification

- Include a brief justification of the proposed activities that will incur costs. <mark>This summary will be reviewed by your study section.</mark>

- The Data Management and Sharing justification must be clearly labeled as "Data Management and Sharing Justification" in the within the budget justification attachment.

- Provide a brief summary of **type** and **amount** of scientific data to be preserved and shared **and the name of the established repository(ies)** where they will be preserved and shared.

- Indicate general cost categories such as **curating data and developing supporting documentation, local data management activities, preserving and sharing data through established repositories, etc., including an amount for each category and a brief explanation.**

- Specify in the justification if no costs will be incurred for Data Management and Sharing, if applicable. The recommended length of the justification should be **no more than half a page.**

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Special Instructions for Multi-project Applications

Examples include the **P01, P30, P50, P2C, U10, U19**, etc. Read the FOA's instructions very carefully!

Only one DMS Plan is needed in the Overall Component.

However, budgeting for DMS costs should be included in the Overall Component, as well as each individual component needing to include such costs.

- **Overall Component**: Include budget information for Data Management and Sharing Costs in the Overall Component

- **Other Components**: Include budget information for Data Management and Sharing Costs within the applicable component(s). Do not include a "Data Management and Sharing Plan" attachment within the components. Any component-specific information should be described within the overall "Data Management and Sharing Plan" attachment provided within the PHS 398 Research Plan Form in the Overall Component.

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Fall 2022 Town Halls scheduled:
- Session 3: Thursday, December 1, 2022; 12:30pm – 1:30pm EST

Also planning faculty-focused smaller sessions:

- Faculty Sharing Effective Data Management Practices
- DMS Plan Drafting Workshops

What other resources or outreach would be helpful?

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If you have questions about NIH's new data management and sharing policy, you may email:

data-management@columbia.edu

We will route as appropriate to SPA, Research Compliance, Libraries, or others with appropriate expertise.

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Questions?

For questions regarding…	Please contact…
• Proposal submission • Budgeting and allowable costs • NIH requirement for DMSP • Data sharing and use agreement	SPA Project Officer
• Creating a DMS plan • Selecting a data repository • Managing data during research projects • Publishing and preserving data research	Research Data Services ORCT
• Informed consent and data privacy related to DMSP • Documenting and obtaining IRB approval for DMSP	Human Research Protection Office and IRBs
• Resources available to meeting research data needs • Consultation and workshops • Computation and data storage	Research Data Services ORCT CUIT CUIMCIT
• Data security and secure information technology systems • Identification of architectural requirements • Best practices in data security	CUIT CUIMCIT

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QUESTIONS?

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