IU Research Data Management Plans Working Group

The NIH Final Policy on Data Management & Sharing: What you need to know

INDIANA UNIVERSITY

Agenda

1. Background
   - Working Group Aims & Members
   - Session Goals
2. NIH Data Management & Sharing Policy
3. Implementation & Support @ IU
4. Q&A

SECTION 1

Background

IU RDMP Working Group Aims

- Inform all stakeholders about the Final NIH Data Management & Sharing (DMS) Policy.
- Invite input from stakeholders to identify specific challenges, opportunities, and supports needed to comply with funder policies, including the NIH DMS Policy.
- Identify potential mechanisms for a sustained conversation between stakeholders about data management and sharing more broadly, including funder, publisher, and institutional requirements.

IU RDMP Working Group Members

- Julie Aders, Sr. Data Administration Program Manager
- Heather Coates, Data Steward for Research Data & Associate Librarian
- Levi Dolan, NLM Associate Fellow, Ruth Lilly Medical Library
- Ethan Fridmanski, Data Services Librarian, Herman B Wells Library
- Marcia Gonzales, Senior Associate General Counsel
- Katie Gray, Associate Director for Research Administration, Proposals & Awards
- Beth Johnson, University Director, HRPP
- Alicia Libla, University Director, Research Contracting (formerly Katie Morris)
- Claire Tempel, HIPAA Privacy Officer & Data Steward for Health Data
- Beth Whipple, Assistant Director of Research and Translational Sciences for Ruth Lilly Medical Library

Goals

1. Inform everyone affected by this new policy
2. Gather input about how this policy may affect research at IU

SECTION 2

Final NIH Policy for Data Management and Sharing (NOT-OD-21-013)

Policy & Supplemental Information

NOT-OD-21-013 – Final NIH Policy for Data Management and Sharing

NOT-OD-21-014 – Supplemental Information… Elements of an NIH Data Management and Sharing Plan

NOT-OD-21-015 – Supplemental Information… Allowable Costs for Data Management and Sharing

NOT-OD-21-016 – Supplemental Information… Selecting a Repository for Data Resulting from NIH-Supported Research

NOT-OD-20-013 – Request for Public Comments on a DRAFT NIH Policy for Data Management and Sharing and Supplemental DRAFT Guidance

NOT-OD-22-195 – New NIH "FORMS-H" Grant Application Forms and Instructions…

NOT-OD-22-198 – Implementation Changes for Genomic Data Sharing Plans...

NOT-OD-23-012 – New Grant Application Instructions Now Available

[new] NIH Website on Scientific Data Sharing: https://sharing.nih.gov/

Policy Background

2015 – release of the 2015 Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research

2016 - requested public comments on data management and sharing strategies and priorities (NOT-OD-17-015)

2018 - solicited public input on proposed key provisions that could serve as a foundation for a future NIH policy (NOT-OD-19-014)

2019 - released a draft proposal for a future data management and sharing policy in the Federal Register (84 FR 60398).

2020 – released Final Policy for Data Management & Sharing (NOT-OD-21-013)

Key Policy Details [1 of 5]

- Effective Date: January 25, 2023
- Submission of Data Management & Sharing (DMS) Plan at the time of application
- Scope - “The DMS Policy applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of scientific data.”
  - Section III. Scope “The DMS Policy does not apply to research and other activities that do not generate scientific data, including training, infrastructure development, and non-research activities.”

Key Policy Details [2 of 5]

- Compliance - Extramural Awards: The DMS Plan will become a Term and Condition of the Notice of Award.
    - As things change during the conduct of the project, revised and updated DMS Plans can/should be submitted.
- DMS Plan should describe the plan for managing and sharing the resulting scientific data
    - If you do not plan to share, provide a rationale for why data sharing is not possible

Key Policy Details [3 of 5]

New definition of Scientific Data

- “The recorded factual material commonly accepted in the scientific community as **of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications**. Scientific data do not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens.”

Key Policy Details [4 of 5]

Sharing human subjects data – “NIH promotes thoughtful practices”

- address it in the informed consent process
- any limitations on use of data should be communicated to those who are preserving and sharing the data
- consider whether controlled access is appropriate

Key Policy Details [5 of 5]

When data are expected to be shared

- “[s]hared scientific data should be made accessible as soon as possible, and no later than the time of an associated publication, or the end of the award/support period, whichever comes first.”

DMS Plan Elements [1 of 2]

1. **data type**, general description of scientific data to be managed, preserved, and shared, including the type, estimated amount of data, modality, and level of aggregation

2. **related tools, software, or code** - indication of whether specialized tools are needed to access or manipulate shared scientific data to support replication or reuse, and description of how to access the necessary tools

3. **standards** - indication of what standards will be applied to the scientific data and associated metadata

DMS Plan Elements [2 of 2]

4. **data preservation, access, and associated timelines** – name of the repository(ies), how the data will be findable and identifiable, when the data will be made available to others and for how long

5. **access, distribution, or reuse considerations** – informed consent, privacy & confidentiality protections, whether access will be controlled, any other restrictions or considerations

6. **oversight of data management and sharing** – indicate how compliance with the Plan will be monitored and managed

Choosing a data repository

- Some programs, types of data, NIH ICO, and FOA may specify particular data repository(ies) to be used
- “Primary consideration should be given to data repositories that are discipline or data-type specific to support effective data discovery and reuse.”
- If no data repository is specified, researchers are encouraged to consult the list of desirable characteristics (NOT-OD-21-016)

Allowable Costs

- Reasonable costs allowed in proposal
  - Curating data/developing supporting documentation
  - Preserving/sharing data through repositories
  - Local data management considerations
- NOT considered data sharing costs
  - Infrastructure costs typically included in indirect costs
  - Costs associated with the routine conduct of research (e.g., costs of gaining access to research data)

Please note that all cost allowability is subject to change as NIH releases more information; please continue to check the most recent NIH guidance for accurate cost information.

SECTION 3

Implementation & Support @ IU

NIH Submission & Review

- Data Management & Sharing Plans should be included as part of the Budget Justification Document
- NIH Program Staff will assess DMS Plans
- Peer Reviewers may comment on the proposed budget for data management and sharing, but the comments cannot impact the overall proposal score
- Plans can be updated prior to award based on these comments

IU Submission & Review Process

- Office of Research Administration (ORA) staff will not review the Plan for content, but will ensure it is included when required
- It is important to contact support services for advice prior to submitting the proposal to the Office of Research Administration for review
- Final Data Management and Sharing Plans WILL be incorporated into the Terms & Conditions of the Award
- Be sure you and IU can comply with the Plan

Award Management

- Applicants must use FORMS-H application packages for due dates on or after January 25, 2023
  - See High-level Summary of Form Changes in FORMS-H Application Packages
  - Application guides for FORMS-H application packages will be posted to the How to Apply - Application Guide page no later than October 25, 2022.
- DMS Plans should be updated at regular reporting intervals or sooner
- Any updates will be reviewed by NIH Program Staff
- Compliance will be monitored throughout the award and compliance may impact future funding decisions

Existing Resources & Support @ IU

1. UITS Research Technologies, https://kb.iu.edu/d/anwu
   - SecureMyResearch, https://cacr.iu.edu/projects/SecureMyResearch/index.html
2. IU Libraries
   - IU Bloomington, https://libraries.indiana.edu/data-services
   - IUPUI University Library, https://cds.ulib.iupui.edu/digitalscholarship/datasupport
   - Ruth Lilly Medical Library, https://iupui.libguides.com/iusmdataservices
3. IUSM Biostatistics & Health Data Science, https://medicine.iu.edu/biostatistics/services
4. Regenstrief Data Services, https://www.regenstrief.org/rds/

Key Areas of Support

1. Developing DMS Plans:
   https://research.iu.edu/policies/nih-data-mgmt-sharing-policy.html
   - Overview of the policy
   - IU Guidance for Developing an NIH DMS Plan (see Guidance & Support)
   - Considerations for Sharing Research Data at IU:
     https://forms.office.com/r/ssQjhtD9m3
2. Implementing DMS Plans
   - *TBD*

SECTION 4

Q&A