Key Points: NIH Data Management and Sharing Policy

Overview

The National Institutes of Health (NIH) has announced a Policy for Data Management and Sharing (NOT-OD-21-013). The policy focuses on “…maximizing the appropriate sharing of scientific data generated from NIH-funded or conducted research, with justified limitations or exceptions.” Starting on January 25, 2023, all grant submissions to the NIH must include a Data Management and Sharing (DMS) Plan.

Key points: Planning and budgeting

- Requires submission of DMS plans at the time of application for research that results in the generation of scientific data
- May allow costs associated with data management and data sharing to be included under the budget for a proposed project

  Example expenses: curating data and developing supporting documentation, local data management considerations, preserving and sharing data through established repositories NOT-OD-21-015 & Budgeting for Data Management & Sharing

- Newly defines 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.”

- Promotes thoughtful practices in sharing human participants’ data

  Three concepts: 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 NOT-OD-22-213 & NOT-OD-22-214 (American Indian/Alaska Native)

- Requires data sharing as soon as possible

  “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 the award/support period, whichever comes first.”

- Encourages data retention

  “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. ” “NIH encourages researchers to make scientific data available for as long as they anticipate it being useful for the larger research community, institutions, and/or the broader public.” NOT-OD-21-014

- “Strongly encourages the use of established repositories to the extent possible” NOT-OD-21-016
- Allows that data security is best addressed by institutions and repositories preserving and sharing the data

Key points: Submission and review

- Provides for peer review of proposed budgets to inform NIH regarding “reasonable costs”

  “The final DMS Policy maintains NIH Program Staff assessments of Plans’ merits. However, peer reviewers may comment on the proposed budget for data management and sharing, although these comments will not impact the overall score…Over time, and through these reviews, we hope to learn more about what constitutes reasonable costs for various data management and sharing activities across the NIH portfolio of research.”
Key points: Implementation

• Requires compliance with the awardee's plan as approved by the NIH ICO

“During the funding period, compliance with the Plan will be determined by the NIH ICO…After the end of the funding period non-compliance with the NIH ICO-approved Plan may be taken into account by NIH for future funding decisions for the recipient institution”

• Expects DMS plans to be revised when necessary and “reviewed by the NIH ICO during regular reporting intervals or sooner”

Key elements of a Data Management & Sharing Plan (NOT-OD-21-014)

A data management plan must include the following information:

• data type – including estimated amount of data generated or used and description of what data will be preserved and shared

• related tools, software, or code - indication of whether specialized tools are needed to access or manipulate shared scientific data to support replication or reuse, name(s) of the needed tool(s) & software

• standards - indication of what standards will be applied to the scientific data and associated metadata

• 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

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

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

Tools and resources:

Write a data management plan
DMPTool (login via Touchstone)
NIH Format (DMPTool is better; use NIH- GEN DMSP (forthcoming 2023))
25 questions to help you start thinking (AHRQ)
NIH: Writing a data management & sharing plan and FAQ

Choosing a data repository

Some programs, types of data, Institute, Office, or FOA may identify particular data repositories to be used, and “primary consideration should be given to data repositories that are discipline or data-type specific to support effective data discovery and reuse.” Desirable characteristics (NOT-OD-21-016):

• Unique persistent identifiers (DOI)
• Clear use guidance

• Long-term sustainability
• Security and integrity

• Metadata
• Confidentiality

• Curation and quality assurance
• Common format

• Free and easy access
• Provenance

• Broad and measure reuse
• Retention policy

View some NIH-supported repositories. Please contact Data Management Services for further guidance.
Supplemental Information & NIH resources not mentioned above

NOT-HG-21-023 - Notice Announcing NHGRI Guidance for Third-Party Involvement in Extramural Research
NOT-HG-21-022 - Notice Announcing the National Human Genome Research Institute's Expectation for Sharing Quality Metadata and Phenotypic Data
NOT-OD-21-015 – Supplemental Information to the NIH Policy for Data Management and Sharing: Allowable Costs for Data Management and Sharing
NOT-OD-22-189 – Implementation Details for the NIH Data Management and Sharing Policy
NIH Data Management and Sharing Policy resources – Planning and Budgeting; Data Management; Sharing Scientific Data
FAQ – FAQs for the NIH Policy for Data Management and Sharing (DMS Policy)

MIT Resources

Data Management Services (DMS): We work with you on managing research data: from helping you to develop data management plans, through advising on effective data management during research, to recommending data sharing and publication options. Contact data-management@mit.edu.

MIT InfoProtect: This new program is based on classifying Institute research data and administrative information according to the risk posed by the loss of confidentiality, integrity, or availability of the information.

Office of Strategic Alliances and Tech Transfer (OSATT): Help with Data Use Agreements (DUAs) & Certificates of Confidentiality (COCs)

More MIT Resources

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