2023 NIH Policy for Data Management and Sharing
Briefing Sheet for UO Researchers and Research Community

SUMMARY:
The National Institutes of Health (NIH) has issued a new Policy for Data Management and Sharing effective for proposals submitted on or after January 25, 2023. The new policy will require a Data Management and Sharing Plan (DMSP) for ALL NIH-funded projects, an expansion from the current requirement for projects over $500K in annual direct costs. Proper data management and sharing are critical research practices to accelerate scientific advancement and support scientific integrity. The new policy will implement numerous compliance requirements with the aim of fostering a significant cultural shift towards more widespread adoption of best practices for data management and sharing.

For more information: NIH Scientific Data Sharing Website

REGULATIONS:
Applicable Policies (Released October 2020 and effective January 25, 2023)

1. NIH-OD-21-013 – Final NIH Policy for Data Management and Sharing
2. NOT-OD-21-014 – Supplemental Information: Elements of an NIH Data Management and Sharing Plan
3. NOT-OD-21-015 – Supplemental Information: Allowable Costs for Data Management and Sharing
4. NOT-OD-21-016 – Supplemental Information: Selecting a Repository for Data Resulting from NIH-Supported Research
5. NOT-OD-22-189 – Implementation Details for the NIH Data Management and Sharing Policy
6. NOT-OD-22-195 – New NIH "FORMS-H" Grant Application Forms and Instructions Coming

POLICY OBJECTIVE: Maximize research outcomes (taxpayer dollars) while supporting rigor & reproducibility through leading a "cultural shift that makes data sharing the norm." It also emphasizes the importance of good data management practices and establishes the expectation for maximizing the appropriate sharing of scientific data generated from NIH-funded or conducted research, with justified limitations or exceptions. This Policy applies to research funded or conducted by NIH that results in the generation of scientific data. Review previous NIH-wide policies under "Background and History."

BACKGROUND AND HISTORY:

- 2003 Policy on Data Sharing (In effect until January 2023)
  - Applies to grants > $500k direct costs per year; requires a plan for "timely release and sharing" of data.
- 2008 NIH Public Access Policy
  - Requires all NIH-funded researchers to submit or have submitted to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscript.
  - To be made publicly available no later than 12 months after the official date of publication.
- 2013 OSTP Memo: "Increasing Access to the Results of Federally Funded Scientific Research"
  - Each Federal agency with over $100 million in R&D expenditures must develop a plan to support increased public access to results of funded research inclusive of peer-reviewed manuscripts and articles and research data.
  - As of November 2021, all 20 Federal departments and agencies subject to the Memo comply; several agencies with R&D below $100 million have also adopted these principles.
- 2015 NIH Genomic Data Sharing (Applies to large-scale human or non-human genomic data)
  - Establishes expectations for the protection of human data and informed consent.
  - All submissions of large-scale human genomic data to an NIH-designated data repository (e.g., dbGaP) must include a certification by the responsible Institutional Official(s) of the submitting institution.

NEW POLICIES:

- **Effective January 25, 2023** (policies developed by specific NIH Institutes, Centers, and Offices (ICOs) may implement effective dates prior to January 2023)
- For guidance on applications for receipt dates **BEFORE** January 25, 2023, see the 2003 NIH Data Sharing Policy
- **Applies to all research that generates scientific data**
- NIH ICOs are expected to issue more specific supplemental requirements for Data Management and Sharing Plans (DMSPs), for example, regarding new standards for the interoperability of data sets.
- Requirements: **DMSPs are required as part of proposals submitted to NIH**. A DMSP should reflect the proposed approach to data management and sharing at the time it is prepared and be updated during the award/support period to reflect any changes in the management and sharing of scientific data (e.g., new scientific direction, new repository option, timeline revision). An optional Data Management and Sharing Plan format page will be provided. Use of this form is recommended, but DMSPs generated using other approaches will be accepted.
    - Required Plan Elements: see NOT-OD-21-014
        - Data Type: Describe the scientific data to be managed, preserved, and shared
        - Related Tools, Software, and/or Code: Indicate whether specialized tools are needed to access or manipulate shared scientific data to support replication or reuse
        - Standards: Indicate what standards will be applied to the data and associated metadata
        - Data Preservation, Access, and Associated Timelines: Plans and timelines for data preservation and access, including the name of the repository(ies) where scientific data will be deposited.
        - Access, Distribution, or Reuse Considerations: Describe any applicable factors.
        - Oversight of Data Management and Sharing: Indicate how compliance with the Plan will be monitored and managed, the frequency of oversight, and by whom (e.g., titles, roles).

UO RESOURCES:

- UO FAQ for the 2023 Policy: Includes UO-focused answers based on current NIH guidance.
- NIH Data Management and Sharing Plans (2023): Overview of the NIH DMSP policy and resources, on the OVPRI website.
- Sponsored Projects Services Overview of Data Management Plans
- Innovation & Partnership Services Information on Data Management Plans
- UO Libraries Research Data Management: Support and consultation on Data Management Plans
- DMP Tool: Web-based platform providing templates to help construct Data Management Plans.

FACULTY AND INSTITUTIONAL IMPLICATIONS:

- Faculty
    - Culture change: data and data management will not be a by-product of research, but an inherent part of good scientific practice.
    - All researchers will need to become proficient in developing DMSPs and/or utilizing institution support to effectively manage data
    - Costs for data storage and data management-related personnel effort will vary from insignificant to significant depending on the project, the data produced and used during the project
    - DMSP management and monitoring will be required and audited/monitored externally
    - Training and educational offerings will be critical and should include topics such as data ethics, sensitive data, data de-identification and/or anonymization, and curating data for re-use. Training efforts could potentially be based on Responsible Conduct of Research training materials already in use at UO.

- Institution
    - Increased cost (capital and labor) to support faculty in the development, management, monitoring, and compliance oversight of DMSPs and research data.
    - Increased data storage costs, particularly after project completion
    - Increased rigor related to data management (FAIR Guiding Principles for scientific data and stewardship: Findable, Accessible, Interoperable, and Reusable)
- Examples
    1. Faculty doing non-data intensive work*
        a. Implications:
            i. Needs assistance in creating and monitoring DMSP, and with data ingestion/curation/metadata management, etc.
            ii. Does not need assistance in data storage/sharing because needs are low and data will be deposited in a publisher-provided or generalist (Dataverse, Figshare, etc.) repository at the end of the project.
            iii. *Note: there are grant mechanisms that may not require a DMSP (e.g., for training, conferences).
    2. Faculty doing low- to mid- data-intensive work
        a. Implications:
            i. Needs assistance in creating DMSP as well as monitoring of and compliance with DMSP as it is likely to change throughout the life of the award
            ii. Needs assistance with data ingestion/curation/metadata management, etc.
            iii. May need some assistance in data storage/sharing because it is likely the data will go to a disciplinary, institutional, or generalist data repository at the end of the project.
    3. Faculty doing data-intensive work
        a. Implications (discipline-dependent):
            i. Needs assistance in creating DMSP, and significant assistance in the monitoring and compliance with DMSP as it is likely to change throughout the life of the award
            ii. Needs assistance with data ingestion/curation/metadata management, etc.
            iii. Needs assistance in data storage/sharing because data for a single project may total many gigabytes or terabytes, or even grow into the petabyte range and include a variety of data types, e.g., images, DNA/RNA sequence, sensor data, etc.
            iv. Need to consider post-award data management and storage

REFERENCES AND SOURCES:

- External Guides and Recommendations:
    - AAU/APLU Guide to Accelerate Public Access to Research Data
    - COGR/ARL NIH Data Management and Sharing Readiness Guide
    - The FAIR Guiding Principles for scientific data management and stewardship
- Federal Agency Policy References and Reports:
    - NIH Data Sharing Policy
    - NIH Data Management and Sharing Activities Related to Public Access and Open Science
    - Informed Consent for Research with Data and Biospecimens
    - Selecting a Repository for Data Resulting from NIH-Supported Research
    - 2021 OSTP Public Access Congressional Report