

---

# NIH Data Management and Sharing Policy

**Presentation for College of Liberal Arts and Sciences**

January 18, 2023

# Agenda

---

- UI Implementation Group
- Effective Date
- Research Covered by the 2023 Data Management and Sharing Policy
- Definition of Scientific Data
- Timeline for Sharing Data
- Data Management and Sharing Plan Format and Submission
- Repositories for Sharing Scientific Data
- Budgeting for Data Management and Sharing Costs
- Proposal Review and Plan Compliance
- Protecting Privacy and Informed Consent
- Resources
- Questions

# UI NIH Data Management and Sharing (DMS) Policy Implementation

UI working group includes representatives from the following offices:

- Office of the VP for Research – Jennifer Lassner
  - Division of Sponsored Programs – Wendy Beaver, Lynn Hudachek, Jessica Boyle
  - Human Subjects Office – Michele Countryman
- Office of General Counsel
- UI Libraries Research Data Services – Sara Scheib, Brian Westra
- IT Research Services – Joe Hetrick, Gabby Perez
- University of Iowa Healthcare Data Governance Task Force – Boyd Knosp
- Information Security and Policy – Zach Furst, Kirk Corey

Link to [UI Partners in Data Management and Sharing](#)

# NIH Data Management and Sharing Policy

---

→ Effective Date:

- **January 25, 2023** (replaces 2003 Data Sharing Policy)

→ Policy Requirements:

- **Submit** a [Data Management and Sharing Plan](#) outlining how scientific data and any accompanying metadata will be managed and shared, considering any potential restrictions or limitations.
- **Comply** with the Data Management and Sharing Plan approved by the funding Institute or Center (IC).

→ In alignment with the new NIH DMS policy, the NIMH released a revised [Data Sharing Policy](#) that applies to all grant applications and awards that involve human subject research submitted on or after January 25, 2023.

→ Refer to [NIH DMS policy overview](#);

# Research Covered by the 2023 DMS Policy

---

- The Data Management and Sharing Policy applies to all NIH-supported research that results in the generation of “**scientific data**”. The Policy applies for proposals submitted to NIH on or after January 25, 2023, for:
  - grants,
  - contracts, and
  - other transactions.
- For grant proposals, refer to the NIH List of Grant [Activity Codes Subject to the Data Management and Sharing Policy](#)

# Definition of Scientific Data

---

→ "Scientific data" is defined as:

***"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, (e.g., laboratory specimens).

# Timeline for Sharing Data

---

- No later than the time of a **publication of findings** in a peer-reviewed journal OR at the **end of the award**, whichever comes first.
- For how long should data be shared?
  - The appropriate time frame varies across disciplines.
  - Consider relevant requirements and expectations as guidance for the minimum time frame for which scientific data should be made available.
    - Data repository policies
    - Award record retention requirements
    - Journal policies
- Refer to [NIH Data Preservation and Sharing Timelines](#)

# Elements of a Data Management and Sharing Plan

---

## → Data type

- Identifying data and metadata/documentation to be preserved and shared

## → Related tools, software, code

- Tools and software needed to access and manipulate data

## → Standards

- Standards to be applied to scientific data and metadata

## → Data preservation, access, timelines

- Repository to be used, persistent unique identifier, and when/ how long data will be available

## → Access, distribution, reuse considerations

- Description of factors for data access, distribution, or reuse

## → Oversight of data management and sharing

- At the University of Iowa, the PI is responsible for monitoring compliance with the Plan. At the link below, NIH Samples F, G, H, and I include text for Element 6 where the PI is responsible for oversight.

→ Refer to [Writing a Data Management & Sharing Plan](#) (link includes sample plans) and this [Checklist](#)



# Data Management and Sharing Plan Format

---

- Plans should be 2 pages in length.
- An optional [Data Management and Sharing Plan format page](#) is available.
  - A final fillable version is incorporated into the NIH Application Form Instructions.
- For grant proposals applicants must use FORMS-H application packages for due dates on or after Jan. 25, 2023.
  - See [High-level Summary of Form Changes in FORMS-H Application Packages](#) for a full list of form changes.
  - Application guides for FORMS-H application packages are posted to the [How to Apply - Application Guide](#) page.
- Applications subject to NIH's Genomic Data Sharing (GDS) Policy should also address GDS-specific considerations within the elements of a DMS Plan
  - See [NOT-OD-22-189](#) and [Writing a Data Management & Sharing Plan](#).

# Repository Selection

---

- **NIH ICs may designate specific data repository(ies)** – *read the funding announcement for IC requirements or recommendations.*
  - Refer also to [NIH Institute and Center Data Sharing Policies](#).
- NIH strongly encourages the use of established repositories to the extent possible for preserving and sharing scientific data.
  - As outlined in NIH's [Supplemental Policy Information: Selecting a Repository for Data Resulting from NIH-Supported Research](#), using a quality data repository generally improves the FAIRness (Findable, Accessible, Interoperable, and Re-usable) of the data.
- If NIH does not require or recommend a repository, the PI selects one:
  - Refer to Selecting a Data [Repository](#) and [Repositories for Sharing Scientific Data](#).
  - See UI Libraries Research Data Services' [guide to selecting a repository](#), or [contact them](#) for assistance.

# Allowable Costs

---

→ Reasonable costs allowed in budget requests:

- Curating data
- Developing supporting documentation
- Formatting data
- De-identifying data
- Preparing metadata
- Preserving/sharing data through repositories
- Local data management considerations

→ **Allowable costs must be incurred during the performance period.**

→ Unallowable 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)

→ Refer to [Budgeting for Data Management and Sharing](#)

# Proposal Review and Plan Compliance

---

## → Review of Data Management and Sharing Plans

- NIH program staff review and approve Data Management and Sharing Plans.
- Plans are not part of the scored peer review criteria unless specified in the Funding Opportunity Announcement.
- Plans can be revised at Just-In-Time stage.

## → Compliance after the Project is Funded

- Data Management and Sharing Plan is incorporated into the award terms and conditions.
- University of Iowa PI monitors compliance with the approved Data Management and Sharing Plan (i.e., manages and shares data as described in the approved Plan).
- PI reports progress on the approved Plan in the Research Performance Progress Report (RPPR).
- NIH reviews compliance annually.
- Changes to the Plan require NIH prior approval.

→ Refer to [Review](#) of DMS Plans

# Protecting Privacy When Sharing Human Subjects Data

- Refer to [NIH Supplemental Information](#) for a basic framework when considering how to protect privacy.
- Provides principles, best practices, and considerations for determining whether to control access to data.
  - De-identify to the greatest extent.
  - Explicit consent is required when sharing personal data openly.
  - Sharing via controlled access can help to protect privacy.
  - Some NIH-supported repositories and a few others can provide restrictions to data access.

# Informed Consent

---

The Data Management and Sharing Plan in the proposal must be congruent with:

- Section X of the IRB application;
- What a subject is told in the informed consent document regarding what will happen to their data in the future; and
- The ClinicalTrials.gov record (when registration is required).

NIH Resource: [Informed Consent for Secondary Research with Data and Biospecimens](#): Points to Consider and Sample Language for Future Use and/or Sharing.

→ The UI IRB is considering changes to the template future use section of the informed consent document as recommended by NIH.



# Resources

# NIH Resources

---

→ **NIH Scientific Data Sharing Website:** <https://sharing.nih.gov/>

- Guidance and resources including policy decision tool, [FAQs](#), training/webinars, [News & Events](#).
- NIH continues to update the content.

→ **National Library of Medicine NIH Data Management and Sharing Requirements [Webinar Series](#)**

- The recorded webinar series introduces the basics of data management and the new requirements for data management and sharing that will be in place beginning in 2023. The introduction is followed by three webinars providing “practitioner perspectives” – i.e., data librarians sharing their opportunities, barriers, methods, and successes as they work toward improving data management practices at their institutions, and a recap/Q&A session.



# UI Workshops

---

## → **University Libraries NIH Data Management and Sharing Plans Workshop**

This session will help you create a useful and well-written plan that meets the requirements and can be put into practice in your project. We'll dig into each section of a plan, including: describing the types of data for your proposed project; standards for data and metadata; selecting a repository; addressing preservation and access requirements; and considerations for access, reuse and redistribution. Examples and UI and NIH resources will be discussed. Bring a draft plan if you have one, and the FOA to which you are responding.

→ [Sign up preferred](#), but drop-ins welcome.

- Wednesday, February 8th 2023, 10:00 - 11:00 am, ZOOM
- Thursday, March 9th 2023, 3:00-4:00 pm, ZOOM
- Tuesday, April 4th 2023, 10:00 - 11:00 am, ZOOM
- Wednesday, May 3rd 2023, 2:00 - 3:00 pm, ZOOM

# UI Web Resources

---



[UI NIH Data Management & Sharing website](#)



[UI DMS Reference Guide](#)



[UI Research Data Services](#)

# CLAS Resources

---

- College of Liberal Arts and Sciences Grant Support Office
- General email: [CLAS-GSO@uiowa.edu](mailto:CLAS-GSO@uiowa.edu)

**IOWA**

**College of Liberal Arts  
and Sciences**

Grant Support Office

# For assistance:

---

- Contact your [UI Partners in Data Management and Sharing](#) with questions.
- If you're not sure which office can best assist you, email [nih@uiowa.edu](mailto:nih@uiowa.edu).

# Questions?

---

