
NIH Data Management and Sharing Policy

Webinar for UI Campus

August 30, 2022

Agenda

- UI Implementation Group
- Effective Date
- Research Covered by the 2023 DMS Policy
- Definition of Scientific Data
- Timeline for Sharing Data
- Elements of a DMS Plan
- Repositories for Sharing Scientific Data
- Budgeting for Data Management and Sharing Costs
- DMS Plan Submission, Review, and Compliance
- 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 – Ian Arp
- 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
- IT 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).

→ The University of Iowa will continue to work through compliance requirements, especially as the NIH updates guidance and adds content to their website.

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

Research Covered by the 2023 DMS Policy

- Applies to all NIH-supported research that results in the generation of “scientific data”, regardless of funding mechanism.
 - **Competing grant applications** that are submitted to NIH for January 25, 2023, and subsequent receipt dates.
 - **Proposals for contracts** that are submitted to NIH on or after January 25, 2023.
 - **Other funding agreements** (e.g., Other Transactions) that are executed on or after January 25, 2023, unless otherwise stipulated by NIH.
 - The DMS Policy does not apply to research and other activities that do not generate scientific data, for example: training, infrastructure development, and non-research activities.
- The policy applies regardless of the proposal budget dollar amount.
- Refer to [NIH Research Covered by the 2023 DMS 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:

- Data **not** necessary for or of sufficient quality to validate and replicate research findings,
- 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:
 - Data repository policies
 - Award record retention requirements
 - Journal policies
- Refer to [NIH Data Preservation and Sharing Timelines](#)

Elements of a DMS Plan

→ Data type

- Identifying data 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

- Plan compliance will be monitored/ managed and by whom

→ Refer to [Writing a Data Management & Sharing Plan](#)

DMS Plan Format

- Plans should be no more than 2 pages in length.
- An optional [Data Management and Sharing Plan format page](#) will be provided.
- A [preview version](#) of this format page is available now.
 - A final fillable version will be available by Fall 2022 and instructions will be incorporated into the NIH Application Form Instructions. Use of this format page is recommended, but DMS Plans generated using other approaches will be accepted.
- For the University of Iowa, the PI will be responsible for monitoring compliance with the DMS Plan.

Repository Selection

- 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.
- NIH helps investigators identify appropriate repositories. Refer to Selecting a Data [Repository](#)
- **NIH ICs may designate specific data repository(ies)** – *read the funding announcement for IC requirements or recommendations.*

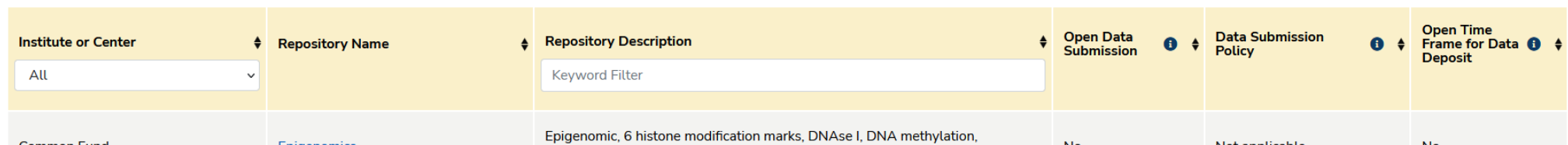
Repository Selection: NIH & Other Resources

→ Refer to [Repositories for Sharing Scientific Data](#)

→ NIH Repositories

- Filterable list of more than 70 NIH supported repositories

NIH-supported Scientific Data Repositories*



Institute or Center	Repository Name	Repository Description	Open Data Submission	Data Submission Policy	Open Time Frame for Data Deposit
All		Keyword Filter			
Common Fund	Epigenomic	Epigenomic, 6 histone modification marks, DNase I, DNA methylation,	No	Not applicable	No

→ Other Repository Resources

- [Generalist repositories](#) that accept all data types
- Nature's [Data Repository Guidance](#)
- The [Registry of Research Data Repositories](#)

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](#)

Cost Estimates

To determine available central UI resources and additional cost estimates, contact the following:

→ UI Libraries Research Data Services, lib-data@uiowa.edu, Brian Westra -

- For assistance creating data sharing plans, selecting a data repository, managing data during research projects, and publishing and preserving your research data.

→ IT Research Services, research-computing@uiowa.edu, Joe Hetrick and Gabby Perez –

- For assistance determining UI services available for storage and to meet your other research data needs.

Please contact them early in the planning stages!

Plan Submission, Review, and Compliance

For Grant Proposals*

→ DMS Plan required at Proposal Stage:

- DMS Plan pdf attached to proposal (2 page limit), and
- Brief Plan description in budget justification.

→ Review of DMS Plans

- Peer Reviewers comment on (do not score) the DMS Plan budget, and
- NIH program staff assess DMS Plans.
- Plans can be revised.

→ Compliance

- DMS Plan is incorporated into the award terms and conditions;
- University of Iowa PI monitors compliance with the approved DMS Plan;
- PI reports progress on the approved Plan in the RPPR; and
- NIH reviews compliance annually. Failure to comply may result in enforcement action including special terms and conditions, termination of award, or affecting future funding.

*A similar process will apply for contracts and other transactions.

Grant Proposal Submission - FORMS-H

Applicants must use FORMS-H application packages for due dates on or after January 25, 2023.

- For full details see Notice [NOT-OD-22-195](#).

→ FORMS-H Key Changes:

- A new “Other Plan(s)” attachment field has been added to the PHS 398 Research Plan Form and the PHS 398 Career Development Award Supplemental Form.
- Applicants must attach the required DMS Plan pdf in this new field in the FORMS-H applications.
- 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 will be posted to the [How to Apply - Application Guide](#) page no later than October 25, 2022.

Contract and OTA Proposal Submission

The DMS Plan should be submitted as follows:

- For Contracts submit the DMS Plan as part of the technical evaluation.
- For Other Transaction Authority proposals refer to the funding announcement requirements.

Informed Consent

The DMS Plan in the proposal must be congruent with:

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

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.

More information will be forthcoming . . .

- NIH continues to provide additional content and updates to the website: <https://sharing.nih.gov/>
- Watch the NIH two-part webinar series: [A Conversation with NIH: Implementing the New Data Management and Sharing Policy](#)
 - Webinar I: Understanding the New NIH Data Management and Sharing Policy – recording and slides available from August 11 webinar
 - *Register now for Webinar II: Diving Deeper into the New NIH Data Management and Sharing Policy - September 22, 2022*
- Contact your [UI Partners in Data Management and Sharing](#) with questions.



Resources

NIH Resources

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

- Guidance and resources including policy decision tool, [FAQs](#), training/webinars, [News & Events](#).
- Content will continue to be updated.

→ **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 Workshop

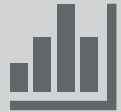
→ **University Libraries NIH Data Management and Sharing Plans Workshop –**

- 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.

- Tuesday, September 27th, 2022, 1:00-2:00pm, ZOOM
- Thursday, October 20th, 2022, 2:00-3:00pm, ZOOM
- Wednesday, November 9th, 2022, 10:00-11:00am, ZOOM

UI Web Resources



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



[UI DMS Reference Guide](#)

UI Partners in Data Management & Sharing

[Division of Sponsored Programs](#) – email nih@uiowa.edu

→ Contact the Division of Sponsored Programs with questions related to submission of proposals and DMS plans, other NIH requirements, and requests for data sharing and use agreements.

[UI Libraries Research Data Services](#). – email lib-data@uiowa.edu

→ Contact UI Libraries Research Data Services for assistance creating DMS plans, selecting a data repository, and archiving data.

[Human Subjects Office](#) – email irb@uiowa.edu

→ Contact the Human Subjects Office with informed consent or IRB application questions related to data management and sharing.

[Information Security and Policy](#) - email it-security@uiowa.edu

→ Contact the Information Security and Policy office with questions related to secure information technology systems, services, and programs including best practices and identification of architectural requirements.

UI Partners in Data Management & Sharing

[ITS Research Services](#) – email research-computing@uiowa.edu

→ Contact ITS Research Services early in the planning stages to determine UI resources available related to your research data needs.

Consultation & Workshops: <https://its.uiowa.edu/researchconsult> <https://events.uiowa.edu>

Data classification guide to IT Services: <https://its.uiowa.edu/support/article/110901>

Computation & Storage

- Research Data Collaboration Service: <https://its.uiowa.edu/rdcs>
- Research Data Storage: <https://its.uiowa.edu/rdss>
- Large Scale Storage: <https://its.uiowa.edu/lss>
- Research Remote Desktop: <https://its.uiowa.edu/rdds>
- Interactive Data Analytics & HPC: <https://hpc.uiowa.edu/resources-and-services>

Questions?

