CAIRIBU

Collaborating for the Advancement of Interdisciplinary Research in Benign Urology

CAIRIBU IC Interactions Core

The New NIH Data Management and Sharing Mandate

(effective January 25, 2023)

Issued by the Office of the Director of the National Institutes of Health (NIH), the final NIH Policy for Data Management and Sharing (DMS; outlined in NOT-OD-21-013) goes into effect 1/25/2023 for:

- Competing grant applications submitted to NIH after 1/25/2023
- Proposals for contracts submitted to NIH on or after 1/25/2023
- NIH Intramural Research Projects conducted on or after 1/25/2023
- Other funding agreements that are executed on or after 1/25/2023

Briefly, a DMS plan describes data management, preservation, and sharing of scientific data and metadata. During the awardee's funding period, compliance with the plan will be reviewed by the appropriate NIH Institute, Center, or Office official. **The NIH recommends that DMS plans be 2 pages or less in length.**

SEE NEXT PAGE FOR AN EXAMPLE OF AN ACCEPTABLE FORMAT
It will take you step-by-step through all of the information you need to provide

Elements of a good data management plan means ensuring that data are findable, accessible, interoperable, and reusable (FAIR). Specific elements your plan should describe include:

- Where you will store your data (specific repositories)
- How you will organize multiple data files
- Formats you will use for your data
- Metadata that others need to understand, reuse, and search for your data
- How your data will be preserved for the life of the experiment and beyond (including retaining access to digital assets after graduate students and postdocs have left the laboratory)
- How you will facilitate data sharing*

** Data generated from NIH-sponsored research may be published as a separate journal article that describes the data in detail for those who wish to re-use it.*

DKNET RESOURCES FOR CREATING DMS PLANS (all available at https://dknet.org/rin/research-data-management)

1. Archived webinars and recordings about creating and sustaining a FAIR biomedical data ecosystem, FAIR data principles, and more
2. Short tutorial video for preparing a DMS plan and finding data repositories
3. Curated list of data repositories for publishing your data – *very helpful for completing "Element 4A" on next page*
4. Tools and resources for creating effective DMS plans, including a "FAIR Data Wizard" (coming soon)

OTHER RESOURCES

1. **California Digital Library Data Management Planning Tool**: an online tool for creating DMS plans AND dozens of sample plans prepared by other investigators
2. **Loyola-Marymount University Research Data Management**: a set of questions about what should go into the plan
3. **MIT Libraries Data Management Resources**: general information about DMS plans and description of tools and services available from MIT Libraries
4. **NIH sample DMS plans**: including for clinical and/or MRI data from human research participants, genomic data from human research participants, genomic data from non-human sources, secondary data analyses, technology development, gene expression analysis from non-human model organisms, and human survey data
5. **NIH instructions for writing DMS plans**: requirements and detailed instructions by DMS plan section

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DATA MANAGEMENT AND SHARING PLAN

If any of the proposed research in the application involves the generation of scientific data, this application is subject to the NIH Policy for Data Management and Sharing and requires submission of a Data Management and Sharing Plan. If the proposed research in the application will generate large-scale genomic data, the Genomic Data Sharing Policy also applies and should be addressed in this Plan. Refer to the detailed instructions in the application guide for developing this plan as well as to additional guidance on sharing.nih.gov. **The Plan is recommended not to exceed two pages**. Text in italics should be deleted. There is no "form page" for the Data Management and Sharing Plan. The DMS Plan may be provided in the *format* shown below. **Do not include hypertext (e.g., hyperlinks and URLs) in the DMS Plan attachment**

Element 1: Data Type

A. Types and amount of scientific data expected to be generated in the project:
Summarize the types and estimated amount of scientific data expected to be generated in the project,

B. Scientific data that will be preserved and shared, and the rationale for doing so:
Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.

C. Metadata, other relevant data, and associated documentation:
Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.

Element 2: Related Tools, Software and/or Code

State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they can be accessed.

Element 3: Standards

State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources, and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist.

Element 4: Data Preservation, Access, and Associated Timelines

A. Repository where scientific data and metadata will be archived:
Provide the name of the repository(ies) where scientific data and metadata arising from the project will be archived; see Selecting a Data Repository).

B. How scientific data will be findable and identifiable:
Describe how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools.

C. When and how long the scientific data will be made available:
Describe when the scientific data will be made available to other users (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) and for how long data will be available.

Element 5: Access, Distribution, or Reuse Considerations

A. Factors affecting subsequent access, distribution, or reuse of scientific data:

NIH expects that in drafting Plans, researchers maximize the appropriate sharing of scientific data. Describe and justify any applicable factors or data use limitations affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, and any other considerations that may limit the extent of data sharing. See Frequently Asked Questions for examples of justifiable reasons for limiting sharing of data.

B. Whether access to scientific data will be controlled:

State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval).)

C. Protections for privacy, rights, and confidentiality of human research participants:

If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures).

Element 6: Oversight of Data Management and Sharing

Describe how compliance with this Plan will be monitored and managed, frequency of oversight, and by whom at your institution (e.g., titles, roles).