

## NIH Office of Intramural Research (OIR) Intramural Data Management and Sharing Plan Template

Intramural NIH research that involves the generation of scientific data is subject to the [2023 NIH Policy for Data Management and Sharing](#). The policy requires submission of a Data Management and Sharing (DMS) Plan, and compliance with the approved plan.

For all ongoing and new intramural research associated with a ZIA (and not included in a clinical protocol) that will be conducted on or after January 25, 2023, the investigator/project lead must submit a DMS plan prior to January 25, 2023. After that date, new and revised plans can be submitted throughout the year but must be included and approved as part of the annual reports process.

For research associated with a clinical protocol submitted for IC initial scientific review on or after January 25, 2023, a DMS plan must be submitted along with other protocol materials. For prior protocols, a DMS plan must be submitted as part of the quadrennial review.

If the proposed research will generate large-scale genomic data, the Genomic Data Sharing Policy also applies and should be addressed in the DMS Plan. The DMS plan incorporates the Data Sharing Plan elements required under the 2015 intramural Human Data Sharing Policy. The Intramural DMS plan template aligns with the recommended template developed by NIH for the extramural research community, available [here](#).

Additional guidance on the DMS policy is available at [sharing.nih.gov](https://sharing.nih.gov) and in the [OIR Sourcebook](#). Contact [sharing@nih.mail.gov](mailto:sharing@nih.mail.gov) for questions about NIH Sharing Policies including the new Data Management and Sharing Policy. The NIH Library offers one-on-one and group [consultations](#), as well as courses and additional services. The [DMP Tool](#), a service of the University of California, provides additional guidance and sample language. Some of the DMP Tool example answers are provided. These are provided as examples only and it is optional for investigators to use this language.

***Requested Information***

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**Investigator/Project Lead:**

**Project / Protocol Title(s):**

**ZIA Number(s):**

***Element 1: Data Type***

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**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.*

*NIH defines scientific data 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, such as laboratory specimens.*

**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.*

*NIH expects that researchers will take steps to maximize scientific data sharing, but recognizes that certain factors (i.e., ethical, legal, or technical) may necessitate limiting sharing to some extent. Foreseeable limitations should be described. See [Frequently Asked Questions](#) for examples of justifiable reasons for limiting sharing of data*

**C. Metadata, other relevant data, and associated documentation:**

*Briefly list 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. Indicate if none.*

***Element 2: Related Tools, Software and/or Code***

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*State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data. If so, provide the name(s) of the needed tool(s) and software and specify how they can be accessed. Indicate if none.*

***Element 3: Data Standards***

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*For DMS plans associated with clinical protocols, answer Element 3A and 3B. Other plans should answer only Element 3B.*

*Data standards refer to community-accepted approaches to methods of organizing, documenting, and formatting data to aid in data aggregation, sharing and reuse, and could refer to common data elements (CDEs), data dictionaries, data models, vocabulary, etc. Metadata standards (e.g., DataCite, DublinCore) are also data standards. Determining which standards are relevant to specific data may depend on the data repository where the data will be submitted as well as the standards adopted by the specific scientific community and/or by specific NIH ICs. Refer to: <https://fairsharing.org/> that makes over 1,600 standards searchable.*

**A. Data standards for clinical protocols – Common Data Elements (CDEs):**

*Describe what Common Data Elements (CDEs) will be used. Justify if CDEs are not used.*

*CDEs allow data to be collected in the same way across multiple research studies and are defined unambiguously in both human and machine-computable terms. NIH has established a “Common Data Element (CDE) Resource Portal” (<http://cde.nih.gov/>) to help investigators identify CDEs when collecting data, particularly for clinical research, and when developing protocols and case report forms.*

**B. Data standards for all plans:**

*State what additional common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources; 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 proposed research. Plans not associated with a clinical protocol should describe the use of Common Data Elements here, if applicable. Indicate if no consensus standards exist.*

*A standard specifies how data and related materials should be stored, organized, and described. For research data, the term typically refers to the use of specific and well-defined formats, schemas, vocabularies, and ontologies in the description and organization of data. Some repositories require the use of specific standards.*

#### ***Element 4: Data Preservation, Access, and Associated Timelines***

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**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. Note that submission of a study to ClinicalTrials.gov meets the requirements of FDAAA but does not fulfill the requirements of the Data Management and Sharing Policy.*

*For additional guidance see [Selecting a Data Repository](#) and [Repositories for Sharing Scientific Data](#). For some programs and types of data, NIH and/or IC policy may designate specific data repositories to be used. For data generated from research for which no data repository is specified by NIH, researchers are encouraged to select a data repository that is appropriate for the data generated from the research project. Primary consideration should be given to data repositories that are discipline or data-type specific to support effective data discovery and reuse. If no appropriate discipline or data-type specific repository is available, researchers should consider other options, including [generalist repositories](#) and PubMed Central, which can accept small datasets (2 GB or less) along with the submitted manuscript.*

**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, and if known, for how long data will be available. Scientific data must be made available no later than the time of an associated publication (when the publication first appears, either online or in print), or by the end of the project/protocol, whichever comes first.*

**Element 5: Access, Distribution, or Reuse Considerations**

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**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***

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

At Tufts University, compliance with the DMSP will be overseen by relevant units at the department, school, and central levels, including Tufts Technology Services, the Office of the Vice Provost for Research, and departmental- and school-based administrative leadership. Compliance oversight is performed annually at the time of submission of the RPPR, at a minimum.

***Element 7: Other Elements (if applicable)***

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*Include IC-specific or other additional information here. Indicate if not applicable.*