NIDDK Webinar 1 Q&A

Q1. Can you give examples of limitations to data sharing?

The NIH DMS Policy recognizes that there are justifiable ethical, legal, and technical factors that may limit the sharing of scientific data or in some cases, preclude sharing entirely. Investigators should list and describe all factors that affect data access, distribution, or reuse in the Access, Distribution, or Reuse Considerations element of their DMS Plan.

Additional resources:

- <u>Frequently Asked Questions (FAQs): What are justifiable reasons for limiting sharing of data?</u> | Data Sharing (nih.gov)
- <u>FAQs: Considerations for Scientific Data Derived from Human Participants | Data Sharing</u> (<u>nih.gov</u>)
- <u>Understanding the New NIH Data Management and Sharing (DMS) Policy (16:45)</u> YouTube
- Q2. Can you provide guidance on data sharing where data is restricted or under Intellectual Property protection?

NIH recognizes that there may be existing or anticipated agreements (such as a Data Use Agreement [DUA] or a <u>Data Use Limitation [DUL]</u> with third-party funders, research partners, repositories, or HIPAA-covered entities) that may be necessary to conduct the proposed research. Although such agreements may appropriately impose limitations on data sharing, careful consideration is required to maximize data sharing to the extent possible. Investigators should list and describe all factors that affect data access, distribution, or reuse.

Additional resources:

- FAQs: What are justifiable reasons for limiting sharing of data? | Data Sharing (nih.gov)
- FAQs: Do SBIR/STTR projects have to share scientific data under the DMS Policy? | Data Sharing (nih.gov)
- FAQs: Am I expected to share all data generated during my research? | Data Sharing (nih.gov)

• Q3. How much time should principal investigators (PIs) plan on devoting to data management, including planning, collecting, curation, and submission?

Time for DMS plan development and ongoing oversight is project and situation dependent. Investigators are encouraged to consider the nature of the proposed research, additional processing steps that may be needed for sharing data (original or secondary data), as well as the expertise on the research team. Leveraging institutional resources, including data librarians, and drawing on prior experience from similar research or pilot studies may be informative. Investigators are encouraged to consult with institutional resources early in the DMS planning process for project-specific needs and consider if these resources may be of use during the project (see Q4).

Q4. Is it advisable for PIs to request a budget for librarian assistance?

For in-depth work like curation or ongoing data management throughout the life of the project, it may be appropriate to enlist the services of a data librarian. Support for librarian time, provided it is for <u>allowable costs</u>, can be included in the budget. Consulting institutional resources early in the planning process may be informative in budgeting and planning for DMS activities.

Additional resources:

• FAQs: How do I budget effort for personnel whose duties are included and budgeted as part of the Data Management and Sharing Plan? | Data Sharing (nih.gov)

Q5. What are examples of allowable DMS costs?

NIH recognizes that DMS activities may have associated costs beyond the regular conduct of research. <u>NOT-OD-21-015</u> outlines allowable costs that investigators can include in the budget to support DMS activities, including data curation and deidentification, formatting data according to accepted community standards or for deposition in the selected repository(ies), data deposition fees, and local data management (including cloud storage) prior to depositing into an established repository. Costs that are incurred as part of doing research, such as obtaining the data or data analysis, building local or cloud data infrastructure that are included in overhead, and disseminating research findings (e.g., publication costs) are not appropriate for inclusion in the DMS budget.

Additional resources:

- Budgeting for Data Management & Sharing | Data Sharing (nih.gov)
- Forecasting Costs for Preserving, Archiving, and Promoting Access to Biomedical Data | National Academies a
- FAQs: Budget/Costs | Data Sharing (nih.gov)