From: research.listserv@mssm.edu <research.listserv@mssm.edu>
Sent: Thursday, January 5, 2023 9:03 AM rev. 12/18/23
Subject: [GCO-Library] **Advice for**
Element 5: Access, Distribution, or Reuse Considerations and
Element 6: Oversight of Data Management and Sharing

Icahn School of Medicine at Mount Sinai

Research Guidance & Education

Guidance from Kris Alpi, Associate Dean of Libraries & Information Sciences and Allison Gottlieb, Sponsored Programs Eduation and Communications Director, GCO

Dear Research Community,

In this communication, we focus on the last two elements of the Data of the NIH Data Management and Sharing Plan: Element 5: Access, Distribution, or Reuse Considerations; and Element 6: Oversight of Data Management and Sharing.

https://www.vecteezy.com/free-vector/nature

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.

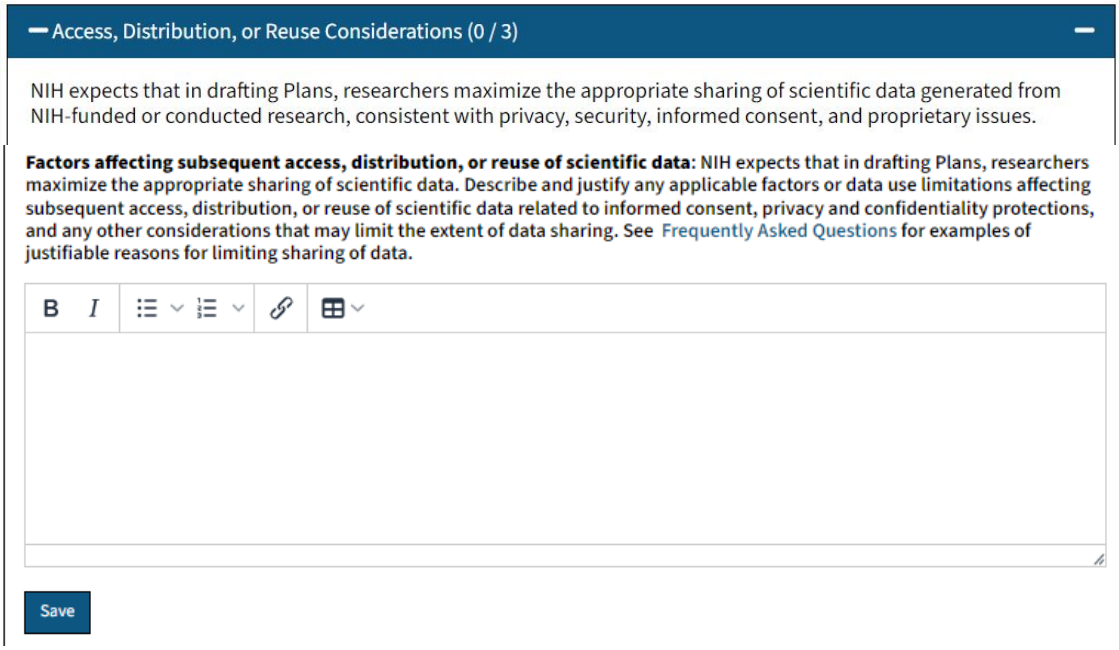
B. Whether access to scientific data will be controlled:

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).

DMPTool Screenshot: Element 5A: Access, Distribution, or Reuse Considerations > Factors affecting subsequent access, distribution, or reuse of scientific data



Our comments: Your comments here for human subjects data should parallel the information in your overall proposal and conform with any language required by your funding agency. Informed consent language must describe data sharing plans--see example for NIMH studies sharing through the National Data Archive repository. Examples also available from ICPSR. If you do not have consent to share individual data without an agreement, you may still share the codebook and metadata about the type and extent of data for which access is limited. If your limitations are technical due to size or structure of the data, consider a conversation with the Mount Sinai High-Performance Computing Minerva group about your options.

NIH Guidance

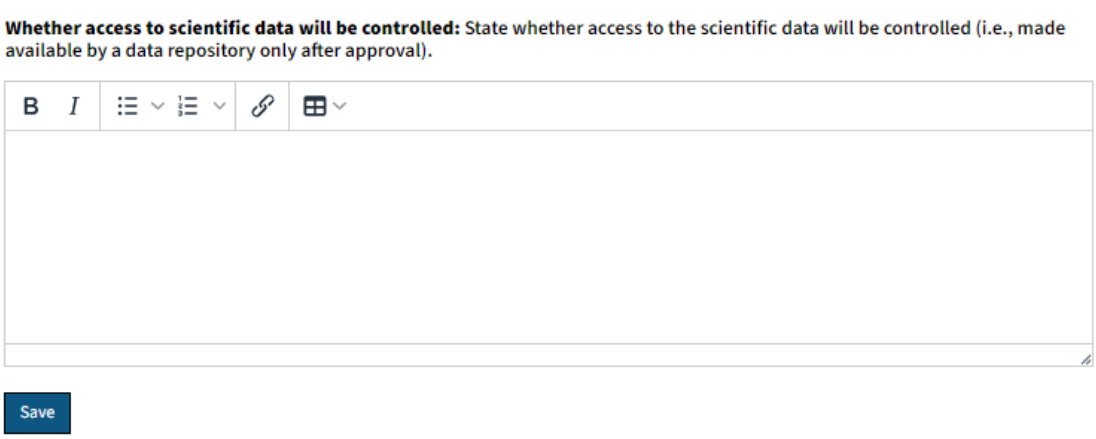
Genomic data may have further considerations to address. The NIH now expects a single data-sharing plan at the time of funding application to satisfy both the Genomic Data Sharing (GDS) Policy and the DMS Policy (per NOT-OD-22-198).

Additional Guidance

Some data may require extra preparation before they can be shared. This is the section to describe what legal, ethical, or technical issues will require limiting the sharing of your data. Examples may include existing legal limits such as data licenses or use agreements, issues of proprietary IP development, technical limits about the size or structure of the data, or ethical issues for human subjects privacy.

Key issues in justification of human subjects data specifically may be informed consent (e.g., disease-specific limitations, particular communities' concerns) or privacy and confidentiality protections (i.e., de-identification, Certificates of Confidentiality, and other protective measures). Specific steps for human subjects data preparation can be addressed in the protections for privacy subquestion below.

DMPTool Screenshot: Element 5B: Access, Distribution, or Reuse Considerations > Whether access to scientific data will be controlled

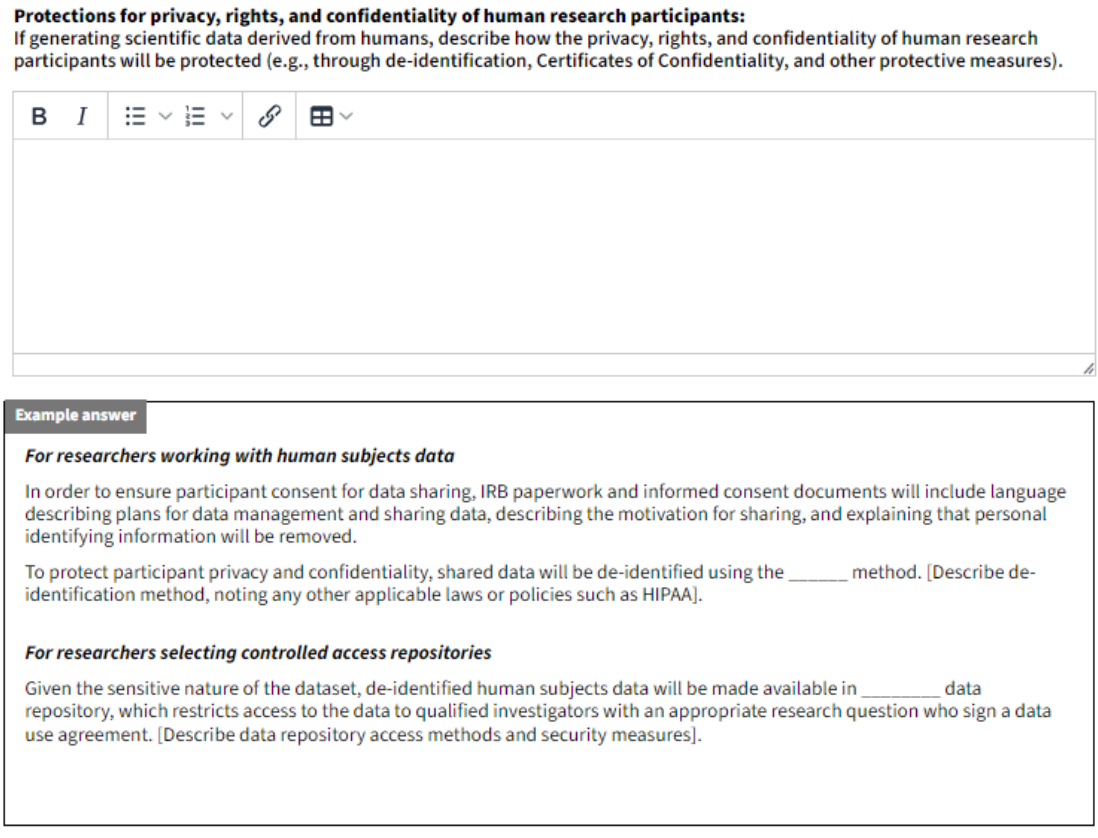


Our comments: Only control your data when necessary for the reasons described earlier in your proposal. Do not use controls for the purpose of delayed release. If data can be public after a length of time or event, use an embargo period to delay making data public, e.g. deposit it and get the data ID and citation, but indicate that it will not be released until publication or a certain date.

Additional guidance

Check the repository you intend to use to find out more about whether and how the repository supports controlled access.

DMPTool Screenshot: Element 5C: Access, Distribution, or Reuse Considerations > Protections for privacy, rights, and confidentiality of human research participants



Our comments: Your response on control of access for human subjects data should parallel the information in your overall proposal and conform with any language required by your funding agency. See examples of [restricted use study language at ICPSR](#).

Additional Guidance

Certain kinds of data, especially human subjects data, require extra preparation before they can be shared to ensure participant privacy. In this section, you will describe your approach to preparing human subjects data for sharing and note any additional restrictions or policies that will impact access to your data. If you are working with human subjects you should also describe how you will address data management and sharing in your informed consent process. You will also need to describe your methods for ensuring privacy and confidentiality, including how you will de-identify your data. If you have decided that a controlled access repository (where researchers must apply to access data) is a better fit for your data than an open repository, you should describe the repository's access procedures. Finally, if there are any other laws, policies, or existing agreements that impact your ability to share your data they should be described here.

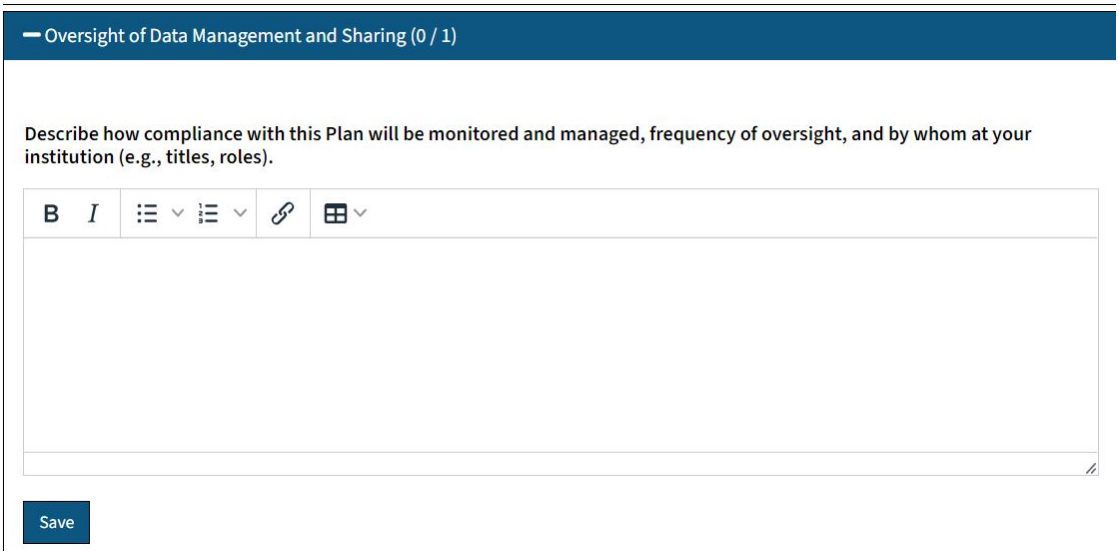
Issues to consider:

- *Any restrictions imposed by federal, Tribal, or state laws, regulations, or policies, or existing or anticipated agreements (e.g., with third-party funders, with partners, with Health Insurance Portability and Accountability Act (HIPAA) covered entities that provide Protected Health Information under a data use agreement, through licensing limitations attached to materials needed to conduct the research).*
- *Any other considerations that may limit the extent of data sharing.*

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).

DMPTool Screenshot: Element 6:



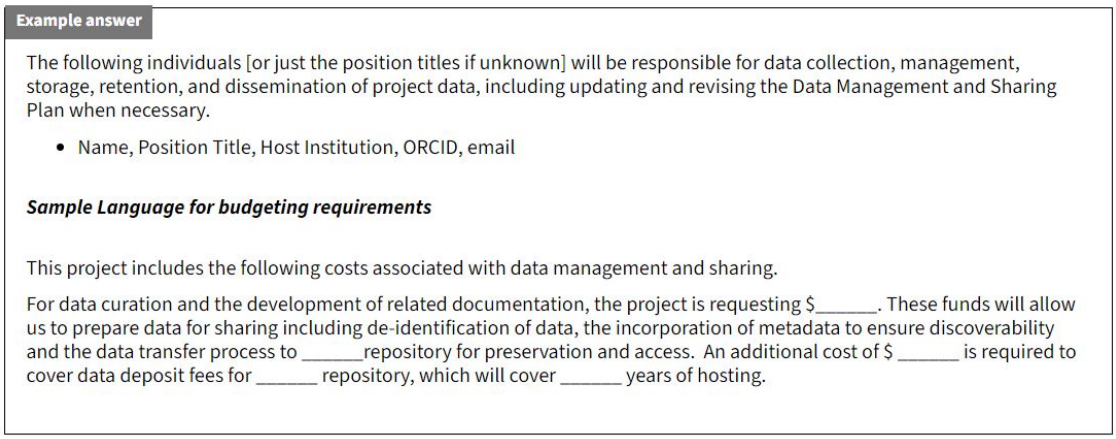
Our comments: This section should be in agreement with your grant proposal's personnel justifications stating who will do this work. The DMSP should be part of your lab notebook and all team members should be aware of the plan and their role in it. Users of LabArchives, the electronic lab notebook licensed by Mount Sinai can create, store and update the plan there. At minimum, the PI

and authors should review the plan as you prepare data and articles for publication and write the data availability statement required by the journal. Compare the statement with your DMSP and document any changes—you may need to notify your program officer if the changes are substantial. Comparing data availability statements of published funded research with original plan texts is an approach NIH could take to monitor compliance. If your department has a person who ensures data and other compliance is maintained, indicate that person's role.

Additional Guidance:

Describe how and by whom compliance with this Plan will be managed. If roles will include the addition of study personnel for data management oversight, see NIH's supplementary guidance on allowable costs for data management and sharing. Do not address the budget here. You will request funds towards DMS costs in the budget itself and you will provide a brief summary of the DMS Plan and describe the requested DMS costs in the budget justification. Please refer to this GCO-Library Communication on preparing the budget for more information.

Example Answer



Example answer

The following individuals [or just the position titles if unknown] will be responsible for data collection, management, storage, retention, and dissemination of project data, including updating and revising the Data Management and Sharing Plan when necessary.

- Name, Position Title, Host Institution, ORCID, email

Sample Language for budgeting requirements

This project includes the following costs associated with data management and sharing.

For data curation and the development of related documentation, the project is requesting $_____. These funds will allow us to prepare data for sharing including de-identification of data, the incorporation of metadata to ensure discoverability and the data transfer process to _____repository for preservation and access. An additional cost of $ _____ is required to cover data deposit fees for _____ repository, which will cover _____ years of hosting.

This completes our series on writing your data management and sharing plan. We will continue to share information about training provided by NIH and the National Center for Data Services. On January 11 at noon, Levy Library is offering a virtual workshop on Research Data Sharing: Metadata, Data Standards and Documentation Best Practices to help researchers who would like to learn more.

Please see this new section on the GCO's Application Information to find all the information, resources, and communications we have been posting.

GCO's Application Info Webpage > Data Management and Sharing Plan

The Office of Research Services Research Roadmap is another valuable resource for information.

https://researchroadmap.mssm.edu/basic-science/data-management/

https://researchroadmap.mssm.edu/investigator/document-retention-and-storage/

https://researchroadmap.mssm.edu/industry/document-retention-and-disposal/

Please let us know in the Library and the GCO any questions you may have.

Sincerely,

Allison Gottlieb

Allison Gottlieb, M.S. | Director, Sponsored Programs Education and Communications | Grants and Contracts Office

and

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