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](https://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.

Public reporting burden for this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0001 and 0925-0002). Do not return the completed form to this address.

**Element 1: Data Type**

1. **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,*

1. **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.*

1. **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**

1. **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*](https://partnershealthcare.sharepoint.com/sites/phrmResources/c/Pages/Develop%20Your%20Data%20Management%20and%20Sharing%20Plan%20%28DMS%20Plan%29.aspx#Choosing%20a%20Repository)*).*

***MGB Guidance: Click*** [***here***](https://partnershealthcare.sharepoint.com/sites/phrmResources/c/Pages/Develop%20Your%20Data%20Management%20and%20Sharing%20Plan%20%28DMS%20Plan%29.aspx#Accepted/Recommended%20Repositories) ***to access the list of MGB approved repositories.***

1. **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.*

1. **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**

1. **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. Be sure to review both MGB policy and NIH information below.*

**MGB Guidance:** *The NIH acknowledges there may be limitations or restrictions to sharing Scientific Data based on legal, ethical, or technical reasons (e.g., due to participant privacy concerns, lack of informed consent, IP or future commercialization concerns, or agreement/contractual restrictions).* ***Be sure to review the following before writing this section:***

***“***[***MGB Policy on Limitations and Restrictions for Data Sharing under the NIH Data Management and Sharing Policy***](https://grcarcher.partners.org/default.aspx?requestUrl=..%2fGenericContent%2fRecord.aspx%3fid%3d29118165%26moduleId%3d65)***”***

[***NIH Justifiable Reasons for Limiting Sharing of Data***](https://sharing.nih.gov/faqs#/data-management-and-sharing-policy.htm?anchor=56549)

***The examples listed in Element 5C. may be used and adjusted to fit the circumstances of your data.***

1. **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).)***

1. **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).*

***MGB Examples***

***Example Text 1: Sharing of data according to MGB Limitations and Restrictions Requirements***

Scientific Data derived from humans will be protected through de-identification, removal of information that may be used to infer the identity of individuals and shared under controlled-access conditions as required by institutional policy.

 ***[If the data were collected, generated or acquired from a source that was covered by a Certificate of Confidentiality (CoC), add the following language:]***

The Scientific Data that will be shared are also protected by a Certificate of Confidentiality

***Example Text 2: Restricted sharing due to Informed Consent restriction***

The ***[describe data]*** Scientific Data will not be shared as it was collected under an Informed Consent Document that pre-dated the 2023 NIH DMS Policy and prohibited sharing outside of our institution, even when de-identified.

***Example Text 3: Restricted sharing due to agreements/contracts***

The ***[describe data]*** Scientific Data will not be shared as it was ***[collected under a sponsored agreement/acquired under a Data Use Agreement] [that pre-dated the 2023 NIH DMS Policy and]*** that prohibited sharing outside of our institution, even when de-identified.

***Example Text 4: Informed Consent described broad/open sharing of de-identified data from participants***

The [describe data] were collected with consents that allow broad/open data sharing. The [repository] requires the completion of a Data Use Agreement which prohibits any redistribution or attempts to re-identify research participants.

**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). If applying to NIDDK, see specific requirements* [*here*](https://www.niddk.nih.gov/research-funding/research-resources/data-management-sharing/guidance-writing-dms-plan#oversight) *and use Heather Cosier, Chief Compliance Officer as the named Institutional Official.*

***MGB Template Text: (Note, do not copy and paste wording for this section from external sample plans such as from the NIH or other institutions. Please use the text below for all MGB proposals.)***

Dr. [Name of Principal Investigator(s) will oversee the overall management and sharing of data during the study. Dr. [Name of Contact PI] will ensure that data management and sharing progress will be reported in annual progress reports submitted by Mass General Brigham, including details from all participating sites. Mass General Brigham Research Management will check to make sure this section of the progress report has been completed before submission to the NIH.

Should changes to the DMS plan become necessary, [Name of Contact PI] will work with the Mass General Brigham Research Management Office to request prior approval.

Mass General Brigham's Office of Research Compliance will periodically audit the NIH-approved data sharing and management plans for adherence to NIH and Mass General Brigham policy.

***[If there are collaborating institutions, add this paragraph to specify how data management and sharing responsibilities will be divided:]***

Mass General Brigham will be responsible for the [management and/or sharing] of the [name specific datasets]. [Name of the collaborating institution] will oversee the [management and/or sharing] of the [name specific datasets]. Mass General Brigham will include data management and sharing terms and conditions in the subaward to [Name of the Collaborating Institution] to ensure this obligation is passed down. [Insert any language regarding additional oversight by collaborating institution].