**NIH Data Management and Sharing Policy Need to Know**

The National Institute of Health issued the Data Management and Sharing Policy, effective January 25, 2023, to promote the sharing of scientific data. The DMS Policy applies to **all** research, funded, or conducted in whole or in part by the NIH, that results in the generation of scientific data. This includes research funded or conducted by extramural grants, contracts, Intramural Research Projects, or other funding agreements regardless of NIH funding level or funding mechanism. The DMS Policy does not apply to research and other activities that do not generate scientific data, including training, infrastructure development, and non-research activities.

The DMS Policy requires:

* **Submission of a** **Data Management and Sharing Plan** outlining how scientific data and any accompanying metadata will be managed and shared, considering any potential restrictions or limitations.
* **Compliance with the awardee’s plan** as approved by the NIH ICO.

The NIH ICO may request additional or specific information to be included within the Plan to meet expectations for data management and data sharing in support of programmatic priorities or to expand the utility of the scientific data generated from the research.

Data Management and Sharing Plans should explain **how scientific data generated by research projects will be managed and which of these scientific data and accompanying metadata will be shared**. Elements of a data management and sharing plan include:

* Data Type
* Related tools, software and/or code
* Standards
* Data preservation, access, and associated timelines
* Access, distribution, or reuse considerations
* Oversight of data management and sharing

The NIH encourages data management and sharing practices to be consistent with the FAIR (Findable, Accessible, Interoperable, and Reusable) data principles. These principles make it easier for computers to process and analyze datasets, which is important when reusing or repurposing datasets for secondary research. Visit [FAIR Principles - GO FAIR (go-fair.org)](https://www.go-fair.org/fair-principles/) for more information.

**Data management and sharing should be addressed in the informed consent form and process**, including communicating with prospective participants how their scientific data are expected to be used and shared. Carilion Clinic’s IRB has developed appropriate language to include in the informed consent form to address sharing of scientific data. The NIH and Carilion Clinic recognize that not all human subject data can be shared openly, even if de-identified. Explain the appropriate rationale for not sharing human subject data or consider only sharing aggregate data.

The NIH strongly encourages the use of established repositories to the extent possible for preserving and sharing scientific data. Carilion Clinic **does not** have an institutional repository nor the ability to create DOIs for data sets. If your project is a collaboration with Virginia Tech, consider utilizing Virginia Tech Data Repository: <https://data.lib.vt.edu/>. Other generalist options include Harvard’s Dataverse <https://support.dataverse.harvard.edu/> which will generate the DOI for you.

**Researchers should make their data accessible as soon as possible.** The NIH requires researchers to share their data by the end of award or simultaneous to publishing.

The NIH recognizes that making data accessible and reusable for others may incur costs. The NIH has outlined **reasonable and allowable costs** that may be included in NIH budget requests including:

* Curating data and developing supporting documentation, including formatting data according to accepted community standards; de-identifying data; preparing metadata to foster discoverability, interpretation, and reuse; and formatting data for transmission to and storage at a selected repository for long-term preservation and access.
* Local data management considerations, such as unique and specialized information infrastructure necessary to provide local management and preservation (e.g., before deposit into an established repository).
* Preserving and sharing data through established repositories **(Carilion Clinic’s recommendation)**, such as data deposit fees necessary for making data available and accessible. For example, if a Data Management and Sharing Plan proposes preserving and sharing scientific data for 10 years in an established repository with a deposition fee, the cost for the entire 10-year period must be paid prior to the end of the period of performance. If the Plan proposes deposition to multiple repositories, costs associated with each proposed repository may be included.

**It is the responsibility of the Principal Investigator and or Co-Investigators to implement and monitor compliance with the data management aspects of the approved DMS plan.** Investigators can report compliance with the DMS Plan and or updates on the DMS Plan through the annual Research Performance Progress Report (RPPR). Non-compliance may result in enforcement action and affect future funding decisions.

In short, Investigators need to:

* Make the Data Management and Sharing Plan a high priority when considering and or initiating NIH grant applications.
* Familiarize yourself with the resources available: [Data Management and Sharing Policy | Data Sharing (nih.gov)](https://sharing.nih.gov/data-management-and-sharing-policy).
* Consider all the costs you might need to budget for: [Budgeting for Data Management & Sharing | Data Sharing (nih.gov)](https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing/budgeting-for-data-management-sharing#after)
* Familiarize yourself with the FAIR Principles: [FAIR Principles - GO FAIR (go-fair.org)](https://www.go-fair.org/fair-principles/).
* Familiarize yourself with various data repositories: [Repositories for Sharing Scientific Data | Data Sharing (nih.gov)](https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/repositories-for-sharing-scientific-data)**.**
* Familiarize yourself with Carilion Clinic’s resources including this document, the Data Management and Sharing Sample Template for Human Subject Clinical Research Data, information on the IRB website, and myprojectmypath.

**Resources**

* [Data Management and Sharing Policy | Data Sharing (nih.gov)](https://sharing.nih.gov/data-management-and-sharing-policy)
* [Budgeting for Data Management & Sharing | Data Sharing (nih.gov)](https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing/budgeting-for-data-management-sharing#after)
* [Writing a Data Management & Sharing Plan | Data Sharing (nih.gov)](https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing/writing-a-data-management-and-sharing-plan#after)
* [Data Management | Data Sharing (nih.gov)](https://sharing.nih.gov/data-management-and-sharing-policy/data-management)
* [Protecting Participant Privacy When Sharing Scientific Data | Data Sharing (nih.gov)](https://sharing.nih.gov/data-management-and-sharing-policy/protecting-participant-privacy-when-sharing-scientific-data)
* [Repositories for Sharing Scientific Data | Data Sharing (nih.gov)](https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/repositories-for-sharing-scientific-data)