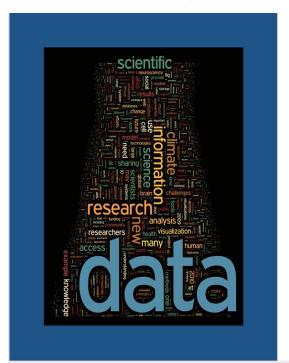
From Webinar Series Part1 (8/11/22)



DMS Policy: Scope

Applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of "scientific data".

"Scientific data" is defined 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."

Potential Examples of Scientific Data

Scientific data will vary depending on the project and the context.

Scientific data might include:

Single-cell RNA sequencing (scRNA-seq) of T lymphocytes or other immune cells in a study of HIV/AIDS

Electrophysiological recordings and fMRI images in a study of a rodent model of PTSD

Step activity from a wearable device in a study of cardiovascular health





Exclusions from the DMS Policy

Scientific data do not include:

- Data **not** necessary for or of sufficient quality to validate and replicate research findings,
- · Laboratory notebooks,
- · Preliminary analyses,
- · Completed case report forms,
- Drafts of scientific papers,
- Plans for future research,
- · Peer reviews,
- · Communications with colleagues, or
- Physical objects, (e.g., laboratory specimens)

NIH FAQ When should scientific data be shared?

Scientific data should be made accessible as soon as possible, and no later than the time of an associated publication or the end of the performance period of the extramural award that generated the data. Specifically, the DMS Policy expects scientific data to be shared by the earlier of two timepoints:

• The time of an associated publication: Scientific data underlying peer-reviewed journal articles should be made accessible no later than the date on which the article is first made available in print or electronic format.

OR

• The end of the performance period: Scientific data underlying findings not disseminated through peer-reviewed journal articles should be shared by the end of the performance period unless the grant enters into a no-cost extension. If a no cost extension is permitted, then the recipient should share the data by the end of the extended performance period. These scientific data may underlie unpublished key findings, developments, and conclusions; or findings documented within preprints, conference proceedings, or book chapters. For example, scientific data underlying null and negative findings are important to share even though these key findings are not always published. Researchers should be aware that some preprint servers may require the sharing of data upon preprint posting, and repositories storing data may similarly require public release of data upon preprint posting.

See the FAQ "Do SBIR/STTR projects have to share scientific data under the DMS Policy?" for more information on the data sharing expectations for SBIR/STTR awards.

NIH Institutes, Centers and Offices (ICOs), Notice of Funding Opportunities (NOFOs), funding opportunity announcements (FOAs), and other NIH policies (e.g., the Genomic Data Sharing Policy) may specify earlier expectations for data sharing timelines, in which case, the data should be made available as required by those expectations.

(Updated 7/26/22)

NIH FAQ What are justifiable reasons for limiting sharing of data?

NIH expects that researchers will take steps to maximize scientific data sharing, but may acknowledge in Plans that certain factors (i.e., ethical, legal, or technical) may necessitate limiting sharing to some extent. Foreseeable limitations should be described in DMS Plans. Per the supplemental information "Elements of an NIH Data Management Sharing Plan," a compelling rationale for limiting scientific data sharing should be provided and will be assessed by NIH. Potential examples of justifiable factors include:

- informed consent will not permit or will limit the scope or extent of sharing and future research use
- existing consent (e.g., for previously collected biospecimens) prohibits sharing or limits the scope or extent of sharing and future research use
- privacy or safety of research participants would be compromised or place them at greater risk of re-identification or suffering harm, and protective measures such as de-identification and Certificates of Confidentiality would be insufficient
- explicit federal, state, local, or Tribal law, regulation, or policy prohibits disclosure
- restrictions imposed by existing or anticipated agreements (e.g., with third party funders, with partners, with repositories, 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)
- datasets cannot practically be digitized with reasonable efforts

Examples of reasons that would generally not be justifiable factors limiting scientific data sharing include:

- · data are considered to be too small
- data that researchers anticipate will not be widely used
- data are not thought to have a suitable repository

See the FAQ "If researchers are reusing existing, shared data to generate new datasets, are they expected to reshare the primary data they incorporated into their new analysis?" for more information on the DMS Policy's expectations for sharing primary data accessed during the course of a study.

NIH respects and recognizes Tribal sovereignty and American Indian and Alaska Native (Al/AN) communities' data sharing concerns, and NIH has proposed additional consideration when with working with Tribes in the draft supplemental information on "Responsible Management and Sharing of Al/AN Participant Data."