THE UNIVERSITY OF ARIZONA Research Innovation & Impact

Federal Data Management Plans (DMPs)

Purpose

Numerous Federal Sponsors and Agencies require a Data Management Plan (DMP) to be submitted with their funding applications. This document provides an overview and links to the data management and sharing policies of select federal agencies that commonly support human subjects research projects. Visit the University of Arizona Data Management Plans website for more information about Funding Agency Requirements.

National Institutes of Health (NIH)

Starting January 25, 2023, NIH will require a Data Management and Sharing (DMS) plan for all NIH funded/supported/conducted research (including new projects, renewals and competing grants) that results in the generation of **scientific data**. The new 2023 policy replaces the 2003 data sharing policy, and it requires a more detailed plan that needs to be submitted with all NIH applications regardless of the amount of funding; however, the policy remains flexible to allow for justified (legal, ethical local, etc.) limitations.

The new policy defines **scientific data** as recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data is used to support scholarly publications. The policy makes it clear that **scientific data does not include** laboratory notebooks, preliminary analyses, completed case report forms (CRFs), drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects such as specimens.

More information about the elements of the 2023 NIH DMS plan can be found on the NIH Data Management & Sharing website. A brief summary is provided below:

The DMS plan should be 2 pages long and include information about the following six (6) elements:

1. Data Type
2. Related Tools, Software and/or Code
3. Standards
4. Data Preservation, Access, and Associated Timelines
5. Data Sharing Agreements, License, and Other Use Limitations
6. Oversight of Data Management

The DMS plan needs to be as specific as possible, and it can be modified as needed. When developing the plan, investigators need to specify:

- What data will be shared (imaging, survey; raw data or derived; data form; etc.);
- Sharing limitations/reuse considerations (legal, ethical, technical, consent, DUA, GDPR limitations, etc.);
- When the data will be shared (as soon as possible; i.e., no later than publication or end of award);

- Information about the de-identification process (PID);
- Access control (open or restricted based on risk);
- How long the data will be available (establish a minimum time); and
- How participants will be informed a repository will be used and how data will be shared.

NIH Data Repository Expectations: De-identified data can be deposited into any repository, as long as the repository meets the FAIR principles and allows the data to be **findable, accessible, inter-operable and reusable**. The NIH Data Sharing Resources website lists several types of data sharing platforms. UArizona's ReDATA Research Data Repository is a free service offered by the University of Arizona Libraries. The ReDATA repository meets all applicable data archiving and sharing requirements and also provides assistance with maintenance, quality control, and compliance.

National Science Foundation (NSF)

Investigators are expected to share with other researchers, at no more than incremental cost and within a reasonable time, the primary data, samples, physical collections, and other supporting materials created or gathered in the course of work under NSF grants.

- NSF requires a DMP supplementary document of no more than two pages labeled "Data Management Plan", which describes how the proposal will conform to NSF policy on the dissemination and sharing of research results as stated in the Grant Proposal Guide.
- This supplementary document should describe how the proposal will conform to NSF policy on the dissemination and sharing of research results.
- NSF requires principal investigators who publish peer-reviewed journal articles or juried conference papers to deposit a copy of the item (either the final accepted version or the version of record, as defined in NSF's public access plan) in the NSF Public Access Repository (NSF-PAR). Datasets archived in a repository can optionally be attached to NSF-PAR by adding the dataset's DOI to PAR. See Research.gov webpage about Public Access.
- Data management requirements and plans specific to the Directorate, Office, Division, Program, or other NSF unit, relevant to a proposal as applicable.
- For journal articles and juried conference proceedings resulting from awards made for proposals submitted, on or after January 25, 2016, either the final accepted version of the manuscript or the publisher's version of record must be submitted.

The NSF DMP may include information about:

- The types of data, samples, physical collections, software, curriculum materials, and other materials to be produced in the course of the project;
- The standards to be used for data and metadata format and content (where existing standards are absent or deemed inadequate, this should be documented along with any proposed solutions or remedies);

- Policies for access and sharing, including provisions for appropriate protection of privacy, confidentiality, security, intellectual property, or other rights or requirements.
- Policies and provisions for re-use, re-distribution, and the production of derivatives; and
- Plans for archiving data, samples, and other research products, and for preservation of access to them.

See the Dissemination and Sharing of Research Results - NSF Data Management Plan Requirements for more information about the NSF DMP expectations.

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) expects investigators and their institutions to provide plans for submitting grant-related human subjects data to a NIAAA-sponsored data repository, the NIAAA Data Archive (NIAAADA). This policy applies to all NIAAA funded projects regardless of the amount of funding. It does not apply to scientific conference grants (R13 & U13), education grants (R25), fellowships (F); training (T), or small business (SBIR/STTR) awards.

The NIAAA Data Archive ($NIAAA_{DA}$) repository houses and shares human subjects' data generated by NIAAA-funded research.

- NIAAA-funded investigators conducting applicable human subjects research are expected to submit de-identified, individual-level data to this data archive. NIAAA expects raw data to be deposited close to the time it is collected, generally every 6 months until data collection is complete.
- Non-NIAAA funded investigators with alcohol-related data are welcome to deposit their data to the $NIAAA_{DA}$.
- NIAAA-DA serves as the designated repository for all genomic data funded by NIAAA unless NIAAA agrees to a different data archive during the negotiation of the terms and conditions of the grant award.
- The data in the $NIAAA_{DA}$ are catalogued and will be shared with the general research community 2 years after the grant end date on the initial Notice of Award. However, if a manuscript using study data is accepted for publication prior to the 2-year embargo, the study data specifically used in that manuscript will be shared with the general research community at the time of publication.
- In addition, when data is uploaded, each study participant will need an associated Global Unique ID, or GUID.

The NIAAA Data Management Plan is expected to be a 4-page MS Word document that includes a signature line for the PI's, AOR and NIAAA. The use of the $NIAAA_{DA}$ Data Sharing Plan (DSP) template is strongly encouraged. For more information see the January 9, 2023 NIAAA Data Sharing Guidelines, and the NIAAA Data Archive ($NIAAA_{DA}$) website.

The National Institute of Mental Health (NIMH)

NIHM funded studies are required to deposit all raw and analyzed data (including, but not limited to, clinical, genomic, imaging, and phenotypic data) from experiments involving human subjects into this infrastructure. The policy applied to all NIMH funded projects, except fellowships (F), K, training (T), small grants (R03), small business (SBIR/STTR) awards; or AIDS-related projects.

The resource sharing plan portion dealing with data must include:

- A summary of the data that will be shared;
- A description of the standard(s) and/or data dictionaries that will be used to describe the data set; and
- The proposed schedule to validate that the data are compliant with the data dictionary that is being used.
- Researchers are strongly encouraged to use clinical and phenotypic data collection instruments/data dictionaries that have already been defined rather than create new versions of those data dictionaries.
- The general expectation is that data from NIMH funded awards will be submitted to NDA every 6 months. Within 6 months of the original award, awardees will provide a Data Submission Agreement signed by the principal investigator and an institutional business official.
- Data will be shared with the research community when papers using the data have been accepted for publication or at the end of the award period (including the first no cost extension), whichever occurs sooner.

More information about the Notice of Data Sharing Policy for the National Institute of Mental Health can be found on the NIH website. NIMH has issued guidance for data harmonization.

National Heart, Lung, and Blood Institute (NHLBI)

The NHLBI Supplement to the NIH Policy for Data Management and Sharing (NIH DMS Policy) is effective as of May 25, 2023. This NHLBI Supplement replaces the previous NHLBI Policy for Data Sharing from Clinical Trials and Epidemiological Studies. It also harmonizes with the Final NIH Policy for Data Management and Sharing. Please refer to the NIH DMS Policy for details on its requirements and compliance.

NHLBI acknowledges that not all research will be immediately subject to the new NHLBI Supplement during the transition period on and after May 25, 2023. Research applications, awards, and intramural research projects not required to comply with the new NHLBI Supplement on and after May 25, 2023, should continue referring to the NHLBI Policy for Data

Sharing from Clinical Trials and Epidemiological Studies for data sharing expectations and compliance monitoring until notified otherwise.

NHLBI Data Repository Expectations: NHLBI-supported researchers are expected to share scientific data through existing NIH-supported Scientific Data Repositories or other repositories that have the desired characteristics described in the Supplemental Information to the NIH Policy for Data Management and Sharing. NHLBI encourages submission of data into NHLBI BioData Catalyst (BDC), especially for data from studies that must comply with NHLBI's Accrual of Human Subjects (Milestones) Policy and for those projects supported by funding opportunity announcements that encourage data deposition into BDC. For data submitted to repositories other than BDC, an appropriate globally-unique, persistent identifier with sufficient metadata should be shared with NHLBI to promote FAIR principles and populate a master index for data generated from all NHLBI-supported research.

Please see the NHLBI website for more information about the NHLBI Supplement to the NIH DMS Policy.

HSPP/IRB Requirements:

- If your sponsor/funding agency requires a Data Management Plan (DMP), a copy of the approved DMP needs to be uploaded with the IRB submission in eIRB.
- Complete the Data Management Plan section in the IRB Protocol for Human Subjects Research and make sure information is consistent with the DMP. Include information about what data/metadata will be shared (imaging, survey; raw data or derived; protocol, data form; etc.), what repository will be used (if known), and how will data be stored (in a de-identified or identifiable format), etc.
- Discuss limitations on subsequent use of shared de-identified scientific data, and whether or not the shared data needs explicit limitations on subsequent use.
- If the study is planning to share or store data from Native American participants, make sure to thoroughly answer the repository question in the Appendix for Native Americans form. The community consultation discussions with Native American tribes should include information on future use and sharing of research data. These conversations are expected to happen prior to submission of the DMP to the funder. In addition, researchers who are conducting research with Native American Populations, should also review the HSPP Guidance on Research Involving Native American or International Indigenous Populations and the NIH Supplemental Information about the Responsible Management and Sharing of American Indian/Alaska Native Participant Data.
- HSPP expects all existing NIH funded studies renewed after January 25, 2023, to update their impacted IRB protocols and study materials with the DMP information.

Informed Consent Considerations:

- Address data management and sharing plans during the informed consent process to ensure prospective participants understand how their data will be managed and shared. Include information about how the subject's data will be managed and used in future research; what repository will be used to store the participant's data (if known); what data will be stored/shared; and if there are any limitations placed on subsequent use of data. Outline the steps that you will take to protect the privacy, rights, and confidentiality of prospective participants (i.e., through de-identification, Certificates of Confidentiality, and other protective measures).
- Is there a way for participants to withdraw their data? If so, state how this is done. If not, let participants know that once the data is shared, it can't be withdrawn.
- Include data storage and future use considerations for data originating from Native American Tribes and/or Indigenous Populations.

See the Informed Consent for Secondary Research with Data and Biospecimens NIH guidance document for more information. This guidance document should be used to ensure that the consent language is sufficient and appropriate.

Additional Data Management Plan (DMP) Resources:

- University of Arizona Libraries NIH Data Management and Sharing Policy
- University of Arizona Data Management Plan Overview and DMP Tool
- HSPP Data Management webpage
- HSPP Guidance Document: Repositories- Storing Research Information for Future Use