Policies

Administration of sponsored programs requires compliance with applicable UNMC and sponsor policies.

The order of precedence is as follows:

- Award terms & conditions
- Program guidelines
- Sponsor/Agency terms & conditions
- Uniform Guidance

Plus any applicable state or institutional regulations.

Questions or concerns about conduct that may violate UNMC policies and procedures or any law or regulation may be shared with the Institutional Compliance Office.

- UNMC-specific Policies
- Sponsor-specific Policies
- F&A Rates Policy
- Use of Embryonic Stem Cells
- NDAA Whistleblower Notice
- NIH Data Management & Sharing Policy

UNMC-specific Policies

A partial listing of frequently referenced policies related to grants and contracts administration are described below. A complete catalog of UNMC policies can be found on the UNMC Policies & Procedures Wiki.

Conflict of Interest	***Policy #8010*** UNMC identifies, manages, and if necessary, reduces potential conflicts of interest to maintain the public's trust in UNMC's teaching, research, patient care, and service mission.
Contracts	***Policy #8009*** The Board of Regents delegates the administrative authority to approve and execute certain types of university contracts.
Sponsored Project Cost Share	***Policy #6104*** Cost share committed on sponsored projects is to be limited to the minimum amount necessary to meet sponsors' requirements.
Sponsored Programs Costing	***Policy #6100*** Direct costs must be reasonable, allocable, allowable, and treated consistently in budgeting and expending.
Effort Certification	***Policy #6105*** UNMC uses the Effort Certification Report as its method of documenting employee effort performed on sponsored projects.
Export Control	***Policy #8005*** Export controls, set forth in regulations administered by several federal agencies, impose access, dissemination, and participation restrictions on the transfer and retransfer of "controlled" information and on the export and re-export of tangible items.
Institutional Base Salary	***Policy #6102*** UNMC's Institutional Base Salary (IBS) represents combined salary from UNMC and its affiliate practice plans, UNMC Physicians and Nebraska Pediatric Practice.
Outside Employment	***Policy #1049*** UNMC employees may be employed by other external organizations, provided such activities do not interfere with their regular duties at UNMC or create a conflict of interest.
SBIR & STTR Program Participation	***Policy #3002*** UNMC encourages the commercialization of applied research by faculty and staff and supports collaboration between its entrepreneurial researchers and outside companies.

Service Centers	***Policy #6107*** Service centers can result in charges to sponsored projects. Billing rates should be designed to recover the direct operating costs of providing the goods/services on an annual basis, excluding all unallowable costs.
Subrecipient	***Policy #6108*** When UNMC subcontracts part of an award to another organization, UNMC remains fully responsible to the sponsor for the entire award.
Cost Transfer	***Policy #6106*** Although it is preferable to charge costs to the correct account when they are incurred, cost transfers may occasionally be necessary and must be properly documented and processed within a reasonable time.

One Chart Compliance with 21 CFR Part 11

The electronic medical records are maintained within the One Chart powered by EPIC System which is installed and operated by Nebraska Medicine. This system is run as a closed system as defined by 21 CFR 11.10. Download the 21 CFR 11 compliance document.

Nebraska Medicine Policies

Policies for our hospital partner can be found here (select "Go to keyword search" and type "Research" locate research-specific policies).

Sponsor-specific Policies

Federal	
Uniform Guidance	Effective December 26, 2014 the Office of Management and Budget combined eight circulars into the single "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."

Sponsor	
NIH Grants Policy Statement	The National Institutes of Health Grants Policy Statement is intended to make available to NIH grantees, in a single document, the policy requirements that serve as the terms and conditions of NIH grant awards.
HHS Grants Policy Statement	The Department of Health and Human Services Grants Policy Statement is intended to make available, in a single document, the general terms and conditions of HHS discretionary grant and cooperative agreement awards.
NSF Award and Administration Guide	The Award and Administration Guide sets forth National Science Foundation policies regarding the award and administration of grants and cooperative agreements.

F&A Rates Policy

UNMC Facilities and Administration (F&A) Rates

(formerly known as Indirect Cost Rates)

The full recovery of F&A costs (up to the level allowed by the sponsor's written policy) is expected on all grants and contracts.

Current F&A Rates & Agreement

Definitions

TDC (Total Direct Cost): All costs that can be specifically identified with a particular project and can be assigned to that project with a high degree of accuracy.

MTDC (Modified Total Direct Costs):

- Includes salaries and wages, fringe benefits, materials and supplies, services, travel, and subgrants and subcontracts up to the first $25,000 of each subgrantor subcontract (regardless of the period covered by the subgrant or subcontract)
- Excludes equipment (defined as having a useful life of over one year and an acquisition cost of $5,000 or more per unit), capital expenditures, charges for patient care and tuition remission, rental costs, scholarships and fellowships, as well as the portion of each subgrant and subcontract in excess of $25,000

F&A is charged on either a TDC or MTDC basis.

F&A Waivers are considered on a case-by-case basis by the Vice Chancellor for Research. Download the F&A Waiver Form.

Use of Embryonic Stem Cells

In accordance with all Federal Guidelines, the University of Nebraska and Board of Regents policy, the Scientific Research Oversight Committee (SROC) must review and approve all research using hESC lines and **ONLY** lines from the NIH Human Embryonic Stem Cell Registry are allowed. Cell lines which are not on this registry are not allowed to be used for NU System research. The NIH Registration Number for a proposed stem cell line must be cited on your application for hESC use when submitting your application to the SROC.

More information about these procedures can be found in the SROC chapter of the IRB Guidebook.

NDAA Whistleblower Notice

Pilot Program for Enhancement of Employee Whistleblower Protections

In order to encourage employees to report fraud, waste, and abuse in federally-funded programs, the National Defense Authorization Act for Fiscal Year 2013 established a pilot program for enhancing contractor employee whistleblower protections. These protections extend to all individuals working in federally-funded programs, including sponsored research.

As an employee of the University of Nebraska working on a federally-sponsored research project, you are entitled to the rights and remedies provided by the pilot program. Specifically, the University of Nebraska is prohibited from discharging, demoting, or otherwise discriminating against you as a reprisal for whistleblowing. These protections cannot be waived by any agreement, policy, form, or condition of employment.

Whistleblowing is defined as disclosing information that you reasonably believe is evidence of any of the following:

- Gross mismanagement of a federal contract or grant;
- Gross waste of federal funds;
- Abuse of authority relating to a federal contract or grant;
- A substantial and specific danger to public health or safety; or
- A violation of law, rule, or regulation related to a federal contract or grant (including the competition for, or negotiation of, a contract or grant).

In order to qualify for whistleblower protection under the pilot program, your disclosure must be made to one of the following persons or entities:

- A member of Congress or a representative of a congressional committee;
- An Inspector General that has oversight over contracts awarded for, or on behalf of, the federal agency concerned in the contract or grant;
- The Government Accountability Office;
- A federal employee responsible for contract or grant oversight or management at the relevant agency;
- An authorized official of the Department of Justice or other law enforcement agency;
- A court or grand jury; or
- A management official or other employee of the contractor, subcontractor, grantee, or subgrantee who has the responsibility to investigate, discover, or address misconduct.

If you believe that you have been discharged, demoted, or otherwise discriminated against as a reprisal for whistleblowing related to a federal contract or grant, you may submit a complaint to the Inspector General of the agency concerned. Procedures for making disclosures can be found on the Office of the Inspector General's Whistleblower Hotline (http://www.oig.doc.gov/pages/hotline.aspx). Keep in mind that you cannot file a complaint more than three years after the date on which the alleged reprisal took place.

You may also contact the UNMC Chief Compliance Officer at (402)559-6767 or report your concern through the UNMC Compliance Hotline at 1-(866) 568-5430.

More information may be found at:

http://uscode.house.gov/view.xhtml?req=(title:41%20section:4712%20edition:prelim)

NIH Data Management & Sharing Policy

The National Institutes of Health (NIH) announced a new data management & sharing (DMS) policy to foster good data stewardship. This page includes information and resources for UNMC researchers to help them prepare, create, and submit a DMS Plan with their NIH applications, including:

- an overview on the new policy and to whom it applies
- information about data types and repositories
- UNMC-specific tools, templates, and resources for writing and submitting your DMS Plan and budget with your NIH application
- a list of frequently asked questions, as well as recorded webinars and other resources

Since January 25, 2023, the policy requires that all application types (new, resubmission, renewal, and revision) that generate Scientific Data, regardless of funding level, include a detailed plan for how the data will be managed and shared during the entire funding period.

NOTE: The new DMS Policy does not apply to funded NIH projects that do not generate scientific data, such as applications for Training (Ts), Fellowships (Fs), Construction (C06), Resources (Gs), etc.

> **For each of the categories below, click the arrow to expand the content.**

Overview: What's New?

The National Institutes of Health (NIH) has issued a new Data Management and Sharing Policy (DMS Policy) starting January 25, 2023.

The new policy requires a Data Management and Sharing Plan (DMS Plan) for ALL NIH-funded projects that generate scientific data. Previously, the NIH only required a DMS Plan for projects over $500,000. This policy places proper data management and reusability of data at the center of research practices so that we can all advance scientific findings and support the integrity of those findings. This policy helps researchers use best practices in data management and sharing to facilitate the shift to open science and open data.

The NIH has also created a website dedicated to Scientific Data Sharing, but these pages on the SPA website aim to provide UNMC-specific information for our researchers while also summarizing the information from the NIH. Below, we include upcoming and recorded webinars (given by UNMC, NIH, or others), as well as provide links to other resources.

Types of Data

There are two “large bucket” categories of data that most researchers work with on a regular basis: quantitative and qualitative data.

In the biomedical sciences, quantitative data is used to provide measurements, calculate change over time, and generally used in raw data gathering. This raw data can then be used as the basis of statistical analyses.

Qualitative data is often thought of as social sciences data because many researchers in the social sciences use surveys and oral responses—in other words, natural language—as the basis of analyses. However, researchers in the sciences often use these same techniques when describing a particular set of data or when mapping data geographically.

Both types of data are used in the sciences, and both can be used as the basis for primary data and secondary data.

Quantitative Data

When using a variable that can be counted, measured, and given a numerical value, it is considered a type of quantitative data. Quantitative variables can answer the “how” questions: “how many,” “how much,” or “how often.”

Many researchers will also call quantitative data “numerical,” because of its capacity to measure and thus bridge empirical observation with mathematical expression. Because of the relationship between observation and mathematical expression, a researcher uses statistical analyses in experiments to find significant differences that can be replicated using similar methods.

There are two main types of quantitative or numerical data: discrete and continuous.

Discrete data is usually defined as a type of data that can be counted. These data cannot be made more precise, and so they involve integers, or numbers that cannot be made divisible. A classic example of a discrete data type would be a member of a family: you cannot have 1.3 or 4.2 children in a family. Another example might be how many doctor visits one may have in a year.

Continuous data can be divisible into smaller parts using decimal points. Continuous data, when graphed, create a distribution of values on a continuum. A classic example of continuous data is a person's height.

Both discrete and continuous quantitative data use measures of central tendency (mean, median, mode) and dispersion (Standard Deviation, standard error, Interquartile Range) to measure results. Which measurement a researcher chooses to use is based on the type of data on which a hypothesis is tested.

Qualitative Data

Qualitative data is defined as variable categories using verbal groupings rather than numbers. Many people tend to confuse qualitative research with qualitative data: qualitative research is the method of collecting data from first-hand observations, interviews, or questionnaires that researchers use to study society using unstructured or semi-structured techniques like those mentioned above. Data is qualitative when the variables in a data set are verbal rather than numerical.

Qualitative data is also called "categorical" data, or data that can be placed into organized categories.

There are two main types of qualitative or categorical data: nominal and ordinal.

> **Nominal data** variables have two or more categories that have "names" and no inherent order to them. For example, gender is a nominal category (female, nonbinary, male). When a variable only has two possible categories, it is called binary or dichotomous data. For example, asking if someone has a driver's license (yes/ no).
>
> **Ordinal data** can be places in categories with a clear order or hierarchy. For example, education level has a clear hierarchy ("high school," Bachelor's," "Master's," "PhD").

When analyzing qualitative data, a researcher will use frequency distribution in the form of a pie chart (nominal data), column, or bar chart (nominal or ordinal data).

Primary Data

Primary and secondary data have less to do with the variables used in data analyses and more to do with who generates the data that a researcher uses for analyses.

Primary data is data generated by the researcher for the primary use of the researcher. At a future time, this primary data may transform into secondary data when uploaded into a repository for use by others. Primary data is data used and collected in the moment and is used in current experiments. Because it is up to the researcher/ researcher's team to collect data, the process takes time and is very involved.

Primary data is largely available in its raw form; thus, it has not been processed or refined. But, because it has not been processed or refined, it is more accurate and reliable.

Secondary Data

Secondary data is usually defined as data that someone else has collected. This can come from large healthcare organizations, the government, or other large organizations. It can be used after the fact of collection. Thus, it is data that has already been used in earlier experiments.

Researchers can find such data in internal healthcare systems, data repositories, either specific to one's field of research or in a more generalist repository, or as part of a publication.

Choosing a Repository

What is a data repository?

A data repository is a type "of sustainable information infrastructure which produces long-term storage and access to research data" (re3data.org). A data repository provides long-term storage and searchability of data used in scientific research.

Why use a data repository?

The NIH mandates the writing of a data management and sharing plan as of January 25, 2023 for all grant applications. Beyond NIH's DMS Policy plan mandate, a data repository ensures accessibility and encourages reuse of data beyond the life of a grant or a single research project.

How to choose a data repository?

Choosing a data repository can depend on the research type, the grant type, or the data type. There are two main types of data repositories: "discipline-specific" and "generalist" repositories.

Discipline-specific repositories should be given primary consideration, since they will allow for optimal discovery and reuse. The NIH has compiled a list of scientific data repositories for making data available, which is organized by discipline. The NIH DMS Policy does not endorse

or require the use of a data repository affiliated with the NIH.

If no discipline-specific repository exists, it is appropriate to choose a generalist repository.

Discipline-Specific Repositories:

You can find a searchable table of NIH-supported, discipline-specific data repositories here:
https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/repositories-for-sharing-scientific-data

You can find a registry of research data repositories here:
https://www.re3data.org/

Generalist Repositories:

UNMC is recommending the use of several generalist repositories, including

- Dataverse
- Dryad
- figshare
- Zenodo

More generalist repositories may be recommended by UNMC later, or you can choose another one that suits your needs.

Writing Your Plan (DMPTool)

The NIH has provided a sample Data Management and Sharing Plan format page that you may use to assist in preparing the document. You can also see the format page with example responses here.

The NIH recommends that the Data Management and Sharing Plan document, which should be in a narrative format, is not more than two pages in length.

Your DMSP must include information pertaining to:

- Data Type
- Related Tools, Software, and/ or Code
- Data Preservation, Access, and Associated Timelines
- Access Distribution, or Reuse Considerations

- Oversight of Data Management and Sharing

You can find detailed definitions of each of these components on the NIH's Grant Guide or learn about these elements and see UNMC-specific examples here.

To draft your plan, UNMC requires that you use DMPTool, an online Data Management Plan builder that uses the 2023 NIH template to quickly guide you through the process. UNMC's Sponsored Programs Administration office expects investigators to use this tool to develop their DMS Plans.

DMPTool Frequently Asked Questions

We will continue to gather answers to new questions and update this page. For general questions about data sharing, go to the Frequently Asked Questions section below.

How do I ensure that the summary text provided by DMPTool to guide me through the writing process does not appear on my downloaded data management and sharing plan?

> When you are about the download your data management and sharing plan, under download settings, the “question text” box is automatically selected. Unselect that box. That de-selection ensures that the summary text provided by DMPTool is not downloaded with your plan. See the Using DMPTool section below for further customization of your data management and sharing plan.

Can I get feedback on my data management and sharing plan before turning it in with my application?

> Yes. Use the Request Feedback option in DMPTool. You can also email researchdata@unmc.edu directly. Please allow a 48-business hour turnaround time for a full review.

I have PIs from other universities as well as my own university who are a part of my grant. Can they access the draft data management and sharing plan on DMPTool?

> Yes. After “Project Details,” there is a “Collaborators” tab. Click on that tab. You will see two titles: “Project Contributors” and “DMP Collaborators.” You will need to add the Principal Investigators to BOTH Project Contributors AND DMP Collaborators. After adding PIs to “DMP Collaborators,” you can “Invite collaborators” via email and give them permission to comment on the data management and sharing plan. They will receive an email from DMPTool notifying them that they’ve been added to your data management and sharing plan.

Can I add references, hyperlinks, or URLs to my data management and sharing plan?

No. NIH policy explicitly prohibits the use of hyperlinks in any grant application materials, and the new data management and sharing plain is no exception. The NIH may withdraw your application from consideration if you include hyperlinks.

Please see the NIH's policy on hyperlinks here:
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-174.html

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Using DMPTool

To draft the DMS Plan for your NIH applications, UNMC requires that you use DMPTool (log in with UNMC credentials), an online Data Management Plan builder, where you can use NIH 2023 template to guide you through the process. See the information below on how to access and begin using this tool, as well as how to download your DMS Plan from DMPTool once it is ready.

Why use DMPTool to write your data management and sharing plan?

- DMPTool (https://dmptool.org/) allows for deeper engagement and reflection on your collected data:
  - The Tool has built-in, customized commentary from the NIH, DMPTool, and UNMC
  - Commentary is built by NIH's Office of Data Science, the California Digital Library, and UNMC data professionals.
- You can "Request Feedback" with a push of a button
  - The "Request Feedback" tab allows UNMC's data professionals to review the plan and make comments for improving the Plan.
- Using DMPTool helps UNMC make decisions about investing in further data management and curation of our research data
  - UNMC will be better informed and situated to find gaps in researcher knowledge, types of data used on campus, and build momentum for a more fully fleshed-out data management infrastructure.
- A group of researchers and librarians from across the country are in the process of evaluating the grant-writing burden and are using resources like DMPTool in the hopes of lightening the burden on research requirements in the future.

How to Access the DMPTool

Follow along with the video recording or use these step-by-step instructions on how to access the DMPTool and start a plan:

1. Go to DMPTool's website at: https://dmptool.org/
2. On the right-hand side of the screen, there is a **Sign in/Sign up** section
3. Enter your UNMC email address for access
4. Press **Continue**
5. The screen will automatically recognize your email address and ask if you want to sign in through the UNMC system
6. Press **Okay**
7. Enter your UNMC credentials
8. Once signed in, you will see **My Dashboard**, which displays the data management plans that you have written using DMPTool
9. To create a new plan, click **Create Plan** in the lower left-hand side of the screen
10. Enter the title of you research project
11. If not automatically entered, select **University of Nebraska Medical Center (unmc.edu)** as your primary research organization
12. Begin to type **NIH** into **Select the primary funding organization**
13. Click on **National Institutes of Health (nih.gov)**
14. You will then be prompted to choose a template
15. Choose **NIH-GEN DMSP (2023)** from the drop-down menu.
16. Click **Create plan**

How to Download your DMS Plan from DMPTool

Follow along with the video recording or use these step-by-step instructions on how to download your data management and sharing plan:

1. Click on the **Download** tab at the far-right header.
2. You will see options for **Format**, **Download Settings**, and **PDF Formatting**.
3. DMPTool Automatically defaults to PDF Download; however, you can also download as a Word Doc, A Text File, a JSON file, or a CSV by choosing the file format option in the Format drop-down menu.
4. If you choose the default **PDF Format**:
    1. Focus on the four options for **download settings**.
    2. There are two automatically checked options, **"section headings"** and **"question text"**:
    3. **Un-check the "question text" option**.
        - When you un-check the **"question text"** option, you will not get the extra DMPTool summaries for each element. This helps to keep your

DMPTool to the appropriate length without the directions, examples, or summaries from DMPTool.

4. Choose the appropriate font type (sans-serif), size of the font (11-point), and margins according to the NIH guidelines.
5. Click the **Download Plan** button at the bottom of the page.

5. If you choose **docx format** (downloaded as a Word document):
    1. You will only have the four **download settings**
    2. There are two automatically checked options, **“section headings”** and **“question text”**:
    3. **Un-check the “question text” option**.
        - When you un-check the **“question text”** option, you will not get the extra DMPTool summaries for each element. This helps to keep your DMPTool to the appropriate length without the directions, examples, or summaries from DMPTool.
    4. Click **Download Plan** at the bottom of the page. Your document will download as a Word document, where you can make further changes to the font type, font size, margins, and further add or revise the document.
    5. When you are ready for upload, save your Word document as a PDF for upload with your application using the “Save As” under File in Word.

DMS Plan Elements

The NIH is requiring this information in a narrative form, which can be easily created via the UNMC-required DMPTool (https://dmptool.org/).

Here is the expected information as part of the six elements for the two-page DMSP to be uploaded as with the application submission (see the Submitting Your DMS Plan section below).

Element 1: Data Type

A. Types and amount of scientific data expected to be generated in the project:

From the NIH:
Summarize the types and estimated amount of scientific data expected to be generated in the project.

For example:
“This project will produce sequencing, transcriptomic, and epigenetic data generated from 10x snRNAseq. Data will be collected from 100 patients, generating approximately 350 datasets. Estimated size of data is about 10,000 gigabytes (Gb). Data file types include: comma separated values (CSVs), fastq sequencing files, and R code (R).”

B. Scientific data that will be preserved and shared, and the rationale for doing so:

From the NIH:
Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.

For example:
“Raw sequencing files, validated data, processed data collected from raw sequencing files, and the code used to process files will be preserved and shared. Research participants and family member identities will be de-identified using masking techniques. Only de-identified individual data will be made available.”

C. Metadata, other relevant data, and associated documentation:

From the NIH:
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.

For example:
“README files, code, clinical metadata in the form of persistent unique identifiers, biospecimen metadata such as specimen IDs, and assay metadata such as valid barcode reads will be shared to help interpret the data.”

Element 2: Related Tools, Software and/or Code

From the NIH:
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.

For example:
“Raw sequencing files in fastq format will be made available and may need specialized

programs to be manipulated. Metadata and processed sequencing data is available in comma separated format (.csv files) and do not need specialized tools to access or manipulate."

Element 3: Standards

From the NIH:
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.

For example:
"FAIR Data sharing protocols will be applied, so that data is Findable, Accessible, Interoperable, and Re-usable. Sequencing data will be structures and described using the following standards: 1) Description of the biological system, samples, and variables studied, 2) Sequence read data of each assay, 3) Final processed data for the set of assays, 4) General information about the experiment and sample-data relationships, and 5) Metadata appropriate to the datasets so that they can be linked."

Element 4: Data Preservation, Access, and Associated Timelines

A. Repository where scientific data and metadata will be archived:

From the NIH:
Provide the name of the repository(ies) where scientific data and metadata arising from the project will be archived; see Selecting a Data Repository).

For example:
"All sharable datasets will be deposited int eh National Institute on Aging Genetics of Alzheimer's Disease Data Storage (NIAGADS) repository"

B. How scientific data will be findable and identifiable:

From the NIH:
Describe how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools.

For example:
“The NIAGADS repository proves metadata, persistent identifiers (DOIs), and long-term access.”

C. When and how long the scientific data will be made available:

From the NIH:
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.

For example:
“The data will be made available as soon as possible or at the start of the publication process, whichever comes first.”

Element 5: Access, Distribution, or Reuse Considerations

A. Factors affecting subsequent access, distribution, or reuse of scientific data:

From the NIH:
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.

For example:
“Following all federal, Tribal and state laws, all data from donors that do not allow for sharing will be excluded from shared datasets. Most participants allow for sharing for study of neurodegenerative diseases, with some allowing for sharing only for academic research use. Those allowing for partial sharing will be shared with NIAGADS with the conditions specified in the consent documentation.”

B. Whether access to scientific data will be controlled:

From the NIH:
State whether access to the scientific data will be controlled (i.e., made available by a data

repository only after approval).

For example:
“All data will be shared in the controlled access data repository, NIAGADS. The access to this repository is limited to qualified investigators with a legitimate research interest, and is approved by an independent committee of researchers (the Data Use Committee) designated by NIAGADS.”

C. Protections for privacy, rights, and confidentiality of human research participants:

From the NIH:
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).

For example:
“IRB documentation and informed consent documents will include language describing plans for data management and sharing data, describing the motivation for sharing, and explaining that personal identifying information will be removed. To protect participant and family member privacy and confidentiality, shared data will be de-identified according to all federal and state guidelines and following the safe-harbor method. Only the minimum of PHI will be collected for the purposes of the study, and all team members are HIPAA trained.”

Element 6: Oversight of Data Management and Sharing

From the NIH:
Describe how compliance with this Plan will be monitored and managed, frequency of oversight, and by whom at your institution (e.g., titles, roles).

For example:
“The following individual, XXXX, will ultimately 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, and will report on data sharing and compliance in the annual project progress reports. This person is the Principal Investigator of the project, an Associate Professor of XXXX at UNMC. His email is xxxxx@unmc.edu. This other person is Research Project Coordinator in Dr. XXXX's lab, will also maintain the Data Management and Sharing Plan, and coordinate permissions with data repositories."

Example DMS Plans

Using the UNMC-approved DMPTool to generate DMS Plans, we provide examples below of different versions of DMS plans to fit various needs based on discipline and research type. More example plans may be added over time.

Example plans created by DMPTool

- Qualitative Data
- Genomics Data
- Basic Science Data
- Clinical Trial Data

Example plans in NIH format (provided by Babu Guda)

- Example 1 - Collecting genomic/phenotypic/clinical data from human subjects
- Example 2 - Collecting clinical and MRI/fMRI data from human subjects
- Example 3 - Collecting gene expression data from human or non-human subjects

Example plans from NIH

The NIH has created example DMS plans for different contexts, including:

- Clinical and/or MRI data from human research participants
- Genomic data from human research participants
- Genomic data from a non-human source
- Secondary data analysis
- Human genomic data
- Technology development
- Human clinical and genomics data
- Non-human (zebrafish) data

Since these may be updated frequently, we recommend that you visit their website to see the latest plans that have been provided.

Budgeting for DMS

Each application for research funding should include a budget for data management and sharing. This budget should be included as part of your overall budget for the project on either:

- the ***R & R Detailed Budget Form*** under “F. Other Direct Costs” or
- the ***PHS 398 Modular Budget Form*** under “Additional Narrative Justification.”

Please see the NIH’s Budgeting for Data Management and Sharing webpage here https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing/budgeting-for-data-management-sharing#after for links to the forms, information on allowable costs, and how the budget will be assessed.

UNMC Budget Worksheet

The following budget worksheet has been created for UNMC researchers to estimate data management and sharing costs. This worksheet shows how to estimate a budget, showing each broad category of the data management and sharing lifecycle, how many hours to project for each activity based on the size of the grant request, and the justification for inclusion into a budget.

Because not all researchers will need to budget for every item on this list, a cost calculator is forthcoming. This cost calculator will help researchers customize a data management and sharing budget for individual project proposals.

Please note that **all activity hours are estimates**; we underscore that a researcher’s individual project may require more or fewer hours over the lifespan of the project. Also note that a research project may or may not contain data management for every item on this list. For instance, not every project will need image management, in which case a researcher not using image data would be expected to omit that item from that project’s overall budget.

Download the Budget Worksheet (PDF)

Submitting Your DMS Plan

Starting January 25, 2023 and thereafter, the NIH requires applicants to use the FORMS-H application package, which is a new, updated application package that incorporates the new DMS Policy requirements.

This new FORMS-H application package should be used for:

- Applications submitted for due dates on or after January 25, 2023
- All application types (New, Resubmission, Renewal, Revision)
- Applications submitted early for intended due dates on or after January 25, 2023

The major changes to the FORMS-H application show two new additions for submitting the plan and budget items, as described in the following sections:

DMS Plan (narrative created with DMPTool)

After creating your DMP Plan narrative using the DMPTool, you will attach it under the "Other Plans" section of the appropriate PHS 398, which may be different depending on the type of application:

- **For most applications**: this should be attached under “11. Other Plans” in the PHS 398 Research Plan
- **For career development award applications**: this should be attached under "17. Other Plans" in the PHS 398 Career Development Award Supplemental Form sections

For more details, see the highlighted sections in the annotated forms for the Research Plan or Career Development Award Supp Form.

DMS Budget (costs & justification)

You will use the R&R Budget Form to add budget items pertaining to the Data Management and Sharing Plan in two places:

- **Costs** - add a "Data Managment and Sharing Costs" line item within section “F. Other Direct Costs”
- **Justification** - add a "Data Managment and Sharing Justification" section to your full budget justification document and upload within the usual section, “L. Budget Justification”

See the highlighted sections in the annotated form for the R&R Budget Form.

DMS Budget Guide

UNMC is working to develop a budgeting guide along with a "menu" of DMS costs that can be used by investigators and administrators as you develop your DMS budget. This website will be updated with this content once it is developed.

Note: Failure to include a budget for DMS costs may result in your project not having sufficient funds to meet the guidelines laid out in the NIH's DMS Policy and/or your specific management and sharing needs as described in your DMS Plan. It is better to budget for something (and potentially have the NIH cut things back) rather than not budget at all.

Webinars & Resources

While the NIH rolls out their new DMS Policy, additional information is being provided via webinars (hosted by UNMC and the NIH) and through the variety of other resources included below.

Past UNMC-Specific Webinars

UNMC held several webinars leading up to the policy start date in January 2023, and continued to hold additional webinars to provide updates on guidance. Click on the title of each webinar to view the recorded video.

NIH DMSP Update and Budget Guidance (May 2023)

Choosing a Repository for Scientific Data (January 2023)

Writing a Data Management & Sharing Plan with DMPTool (January 2023)

Open Forum: The NIH Data Management and Sharing Policy Explained (January 2023)

NIH DMS Policy Overview & Workshop (December 2022)

NIH Data Management and Sharing Introduction (August 2022)

Past NIH-Hosted Webinars

At this time, the NIH has hosted two webinars covering the new DMS Policy. Recordings of these are included below, but additional information including slide decks can be found on their DMS Learning page.

Understanding the New NIH Data Management and Sharing (DMS) Policy
This NIH webinar was held in August 2022.

Diving Deeper into the new NIH Data Management and Sharing Policy
This NIH webinar was held in September 2022.

Other Resources

UNMC-Focused Resources for DMS

- **This SPA DMS page and its FAQ section below** - Includes UNMC-focused answers based on NIH guidance
- **McGoogan Health Sciences Library** - Includes support and consultation on Data Management Plans
- **DMPTool** - UNMC-required platform that provides customized templates to construct DMS Plans
- **Research IT Office** - Their Research Data Management pages provide general tips and tools for all types of data management, not necessarily specific to the new NIH DMS Policy.

External Guides and Recommendations

- AAU/APLU Guide to Accelerate Public Access to Research Data
- COGR/ARL NIH Data Management and Sharing Readiness Guide
- Wilkinson et al. The FAIR Guiding Principles for scientific data management and stewardship

Applicable NIH Policies (Effective Jan 25, 2023)

- NIH-OD-21-013 – Final NIH Policy for Data Management and Sharing
- NOT-OD-21-014 – Supplement: Elements of an NIH Data Management and Sharing Plan
- NOT-OD-21-015 – Supplement: Allowable Costs for Data Management and Sharing
- NOT-OD-21-016 – Supplement: Selecting a Repository for Data Resulting from NIH-Supported Research
- NOT-OD-22-131 – Request for Public Comments on DRAFT Supplemental Information to the NIH Policy for Data Management and Sharing: Protecting Privacy When Sharing Human Research Participant Data
- NOT-OD-22-189 – Implementation Details for the NIH Data Management and Sharing Policy
- NOT-OD-22-195 – New NIH "FORMS-H" Grant Application Forms and Instructions

Federal Agency Policy References and Reports

- NIH Data Sharing Policy
- NIH Data Management and Sharing Activities Related to Public Access and Open Science

- Informed Consent for Research with Data and Biospecimens
- Selecting a Repository for Data Resulting from NIH-Supported Research
- 2021 OSTP Public Access Congressional Report

If you are aware of other DMS resources that may be helpful to UNMC researchers, please reach out to researchdata@unmc.edu to share.

Frequently Asked Questions

General questions and answers about the new DMS Policy that may not be covered on other pages, as well as questions pertaining to UNMC-specific elements and procedures are included below. We will continue to gather answers to new questions and update this page. Review the section above titled Writing Your Plan (DMPTool) for specific questions about DMPTool.

Many additional questions specific to the NIH policy have been compiled and disseminated by the NIH and can be found on their DMSP FAQ page.

Where can I get help at UNMC for the NIH Data Management and Sharing Policy?

Several groups on campus will play a role in assuring UNMC and its researchers are ready to meet these new policy changes. Please direct any questions you have to researchdata@unmc.edu.

Alternatively, set up a consultation with UNMC's Data Services Librarian using the bookings page through the McGoogan Health Sciences Library.

Who is checking my data management and sharing plan?

The UNMC Sponsored Programs Office will check for presence of a plan within your application. They will not review your plan's quality or confirm that all plan parts are present for your type of research. For a thorough review of your plan, please contact researchdata@umnc.edu.

Am I expected to share all data generated during my research?

No. Under the DMS Policy, researchers are expected to maximize the appropriate sharing of scientific data, which is defined as data commonly accepted in the scientific community as being of sufficient quality to validate and replicate the research findings.

How does the DMS Policy fit in with other NIH data sharing policies and requirements (e.g., individual NIH Institute/Center or Office (ICO) funding

polices, the NIH Genomic Data Sharing (GDS) Policy, the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information)?

The DMS Policy establishes the foundation for NIH's data management and sharing expectations, which NIH ICOs and programs may build upon to meet their programmatic needs (e.g., designated repositories, specific data collection standards). Current NIH policies specific to certain types of research (e.g., clinical trials, research generating large-scale genomic data) continue to apply and complement the goals of the new DMS Policy.

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? Are the derived data generated considered scientific data and expected to be shared?

The DMS Policy applies to research that results in the generation of scientific data.? Scientific data can result from secondary research, but researchers are not expected to share the existing, shared primary data used to conduct the secondary research. Researchers are, however, expected to maximize appropriate sharing of any new, derived data generated as a result of their research.

Does the DMS Policy apply to social and behavioral scientific research? Can qualitative data be "scientific data"?

Yes, NIH-supported social and behavioral scientific research that results in the generation of scientific data are subject to the DMS Policy. Qualitative data may constitute scientific data if it meets the definition in the DMS Policy.

What steps does the DMS Policy take to ensure institutions and researchers protect research participants?

Award recipients must comply with any applicable laws, regulations, statutes, guidance, or institutional policies related to research with human participants and that protect participants' privacy.

Does the DMS Policy expect that research informed consent obtained from research participants must allow for broad sharing and the future use of data (either with or without identifiable private information)?

No. Informed consent for participation in research remains the cornerstone of trust between researchers and research participants and thus the DMS Policy does not dictate how this process is achieved. Rather, researchers' intention for scientific data management and sharing, as proactively described in Plans, is strongly encouraged to be part of the informed consent process. The DMS Policy does not expect that informed consent given by participants will be obtained in any particular way.

How will noncompliance with the NIH DMS Policy be handled?

NIH will monitor compliance with Plans over the course of the funding period during regular reporting intervals (e.g., at the time of annual Research Performance Progress Reports (RPPRs)). Noncompliance with Plans may result in the NIH ICO adding special Terms and Conditions of Award or terminating the award. If award recipients are not compliant with Plans at the end of the award, noncompliance may be factored into future funding decisions.

What is a data or metadata standard?

The National Center for Data Services describes metadata as “information that describes, explains, locates, classifies, contextualizes, or documents an information resource.” In the context of data management, metadata allows you to track the provenance, or original source of a dataset, and help you to track which version of the data you are analyzing. Describing data in a machine-readable format allows you to search for data in a repository.

How will data management plans be assessed?

The evaluation of DMS Plans will be conducted by the agency, with input from the Contracting Officer’s Representative (COR) and other NIH subject matter experts as part of the proposal evaluation process.

Are projects establishing repositories or creating data infrastructure subject to the DMS Policy (i.e., establishing a data coordinating center with no research question proposed)?

No. Projects that?only?develop or support infrastructure resources (e.g., repository or knowledgebase establishment) and do not generate findings or scientific data are not subject to the DMS Policy. However, NIH recommends that the infrastructure developed with NIH resources comport with the desired characteristics for repositories (see “Selecting a Repository for Data Resulting from NIH-Supported Research”).

How should we handle situations where there are proprietary considerations about confidential data or intellectual property?

The NIH covered this briefly as part of a webinar, which can be found during this section of their recording. For more information specific to your situation, we would recommend you reach out to researchdata@unmc.edu.

How granular does the stored data have to be? Most of the time data are reduced from original capture to make it more manageable. Should it be original data or reduced data?

You should be storing all data, both raw and processed. The data management and sharing plan will ask where you plan to store data 1) during the lifetime of the project and 2) after the grant has ended. You will need to have a plan for storage during and beyond

the life of the project. Thus, storing is only the first component. Secondly, you'll need to think about preservation of the data. Where will this data live after the project is over? This is where data repositories—and finding and appropriate data repository in the grant application phase—is of the utmost importance. Thirdly, you'll be asked about your data sharing plan. Do you plan to share the raw and processed data, or just the processed data? It is up to you to ask what "manageable" means for your project. That being said, the policy is about making your data replicable and reusable by other researchers, so if the data that you usually share is reduced data, then can another researcher re-use that data and replicate the results adequately? If not, then you may need to think about sharing the raw and reduced data. If so, then you are sharing the data adequately.

How are we addressing patent implications? My reading of the policy is that when the grant ends, data needs to be available.

If there are patent implications for an invention, we recommend reaching out to UNeMed at the point at which you are writing your data management and sharing policy. In terms of general intellectual property, PIs own rights in data resulting from sponsored projects.? Sponsored projects are not works for hire, and thus the sponsor does not own the data.

Data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health.? Sponsors generally endorses the sharing of final research data.? One exception is personal health information.

Have agencies other than the NIH also mandated data management/sharing plans, and will these work via the same DMP tool we now have?

Yes. Almost every grant-funding agency—both federal and private—in the country is either in the process of developing a data management and sharing policy or has one in place. All grant-funding agencies have templates uploaded in to DMPTool. Simply choose the appropriate funding agency when creating a DMPTool data management and sharing policy and use the subsequent template.

How long should data be shared beyond the term of the NIH-funded grant? Can this be budgeted into the cost of Data Management and Sharing?

Data should be shared for at least 3-5 years after the award period. However, most repositories share data in perpetuity. Data repositories do not charge for ongoing storage of your data. Once the data is uploaded to the repository, a repository will not ask for further monetary assistance. Should you find a data repository that is asking for more funding after upload of data, please reach out to researchdata@unmc.edu.

Do K99/R00 grants require a plan?

No. At this time, the NIH is not requiring training grants to include a data management and sharing plan, because the DMSP is only required for the collection of scientific data.

However, the NIH has made it clear that this exception may change in the near future.

Are there repositories for qualitative (narrative transcripts) data?

Absolutely. There are discipline-specific repositories (found on re3data.org) and generalist repositories (listed in the above section titled Choosing a Repository). You can also reach out to researchdata@unmc.edu for a consultation on qualitative data repositories.

Contact Information

Several groups on campus will play a role in assuring UNMC and its researchers are ready to meet these new policy changes. Please direct any questions you have to researchdata@unmc.edu.

Consultations

Set up a consultation with UNMC's Data Services Librarian using the bookings page through the McGoogan Health Sciences Library.