

NIH's New Scientific Data Sharing Policy and NIH website and UNMC Resources

Leon S. McGoogan Health Sciences Library
Sponsored Programs Administration





Agenda

The new NIH policy for data mgmt./sharing

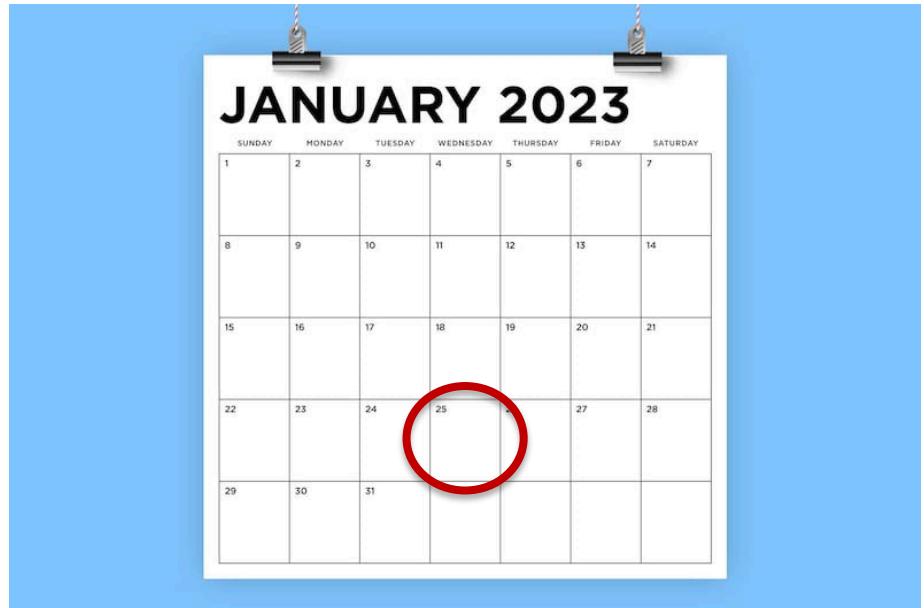
- When (will this go live)?
- What (changes to our grant applications)?
- How (will post-award be different)?
- Who (is providing us resources)?
- Where (can we find resources to help)?



There is a new NIH Data Management and Sharing Policy – going live (very) soon

The new NIH Data Management and Sharing Policy that goes into effect for applications due on or after **January 25, 2023**

All of our February and March applications fall under the new DMS policy.



The Brass Tacks Slide

View Burden Statement

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 09/30/2024

Introduction
1. Introduction to Application (for Resubmission and Revision applications)
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Research Plan Section
2. Specific Aims
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3. *Research Strategy
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4. Progress Report Publication List
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Other Research Plan Section
5. Vertebrate Animals
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11. Other Plan(s)
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Under the DMS Policy, NIH requires researchers to prospectively **plan for how scientific data will be preserved and shared** through submission of a Data Management and Sharing Plan (Plan). NIH expects researchers and institutions to implement data management and sharing practices as described in their application.



Upload here! Comment on any costs in Budget Justification

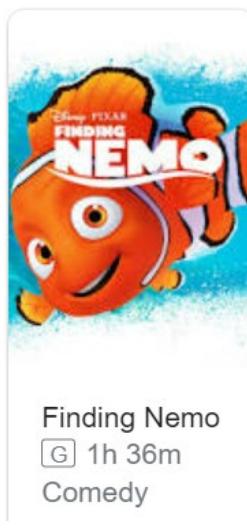


NIH Data Sharing Policy: A Brief History

The current policy is from 2003

There have been updates since then:

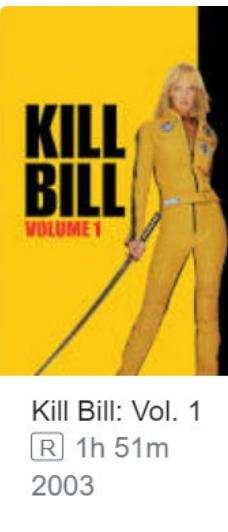
- 2008 GWAS Policy
- 2014 Genomic Data Sharing Policy
- 2015 Plan for Increasing Access to Scientific Publications and Digital Scientific Data
- 2016 Dissemination of NIH-Funded Clinical Trials



Finding Nemo
G 1h 36m
Comedy



Pirates of the
Caribbean: ...
PG-13 2h 2...
2003



Kill Bill: Vol. 1
R 1h 51m
2003



The new DMS Policy: uniting multiple notifications and requirements

The new policy incorporates the guidance from the past several years and pulls everything together into a single policy.

(Also a new NIH website)

DMS = Data Management and Sharing

DMSP = Data Management and Sharing Plan

- The policy establishes the requirements for DMS Plans
- The policy emphasizes the importance of **good DM practices** and the expectation for maximizing the **appropriate sharing** of scientific data generated from NIH-funded studies.
- DMSPs are required for all **research** proposals to NIH.





Do we need to talk about why?

Sharing scientific data **accelerates biomedical research** discovery, in part, by enabling validation of research results, providing **accessibility** to high-value datasets, and promoting **data reuse** for future research studies.

As a steward of the nation's investment in biomedical research, NIH has long championed policies that make research available to the public to achieve these goals.



NIH has a long-standing commitment to making the research it funds available to the public.

NIH policies expect:

- The appropriate sharing of scientific data to be maximized
- Data from large scale genomic studies to be broadly and responsibly shared
- Research tools developed with NIH funding to be made accessible to other researchers
- Unique model organisms to be made available to the scientific community
- Clinical trials to be registered and summary results reported in ClinicalTrials.gov
- Peer reviewed manuscripts to be publicly available on PubMed Central

Related Posts



[Introducing NIH's New Scientific Data Sharing Website](#)



[Refreshing NIH's Genomic Data Sharing Policy](#)

Our goal is to lead a cultural shift that makes data sharing the norm.



The NIH has built a comprehensive website around the new DMS Policy

<https://sharing.nih.gov/>

The NIH has built a “kiosk” with the current NIH Data Management and Sharing Policy, the future Policy, FAQs, samples and examples, templates, etc.

Applications for Receipt Dates BEFORE Jan 25 2023

Applications for Receipt Dates ON/AFTER Jan 25 2023

Applications for Receipt Dates ON/AFTER Jan 25 2023

ON THIS PAGE:

- 🔗 Why Share Data
- 🔗 Expectations Under NIH's Data Management & Sharing Policy
- 🔗 Applicability & Effective Date
- 🔗 Compliance

More on this later!



DMS Policy details

The final DMS Policy does not create a uniform requirement to share **all** scientific data.

Though there is a requirement to submit a DMSP

Through the requirement to submit a Plan, researchers are prospectively planning for data sharing, which we anticipate will increasingly lead researchers to integrate data sharing into the routine conduct of research.

The final DMS Policy defines **Scientific Data**

"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.

Scientific Data **do not include** laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens."

How much and what kind of data are to be shared?

NIH's standard is enough sufficient to “[validate and replicate.](#)”

These data [are intended](#) to be used by others.

Not all Scientific Data are worthy of publication, thus there will be valuable SD outside of manuscripts.

Scientific Data are defined independent of publication, and the Policy covers data that are unpublished, null, or negative.





What actually/exactly needs to be in DMSPs?

The Policy leaves this up to the ICOs (Institute, Center, Office).

- The policy lets ICOs meet their scientific, policy, and programmatic goals in different ways; ways that enhance their respective science.

Consistency, anyone?

- They intend to promote consistency by sticking to their **key tenets**:
 - Plans submitted at the time of submission (they want you to be thinking about data sharing from the earliest moment possible).
 - NIH ICOs may include specific requirements in their Funding Opportunity Announcements (FOAs).
 - Watch for specific requirements or particular interoperability standards in FOAs!



Timing of Submission of DMSPs

The final DMS Policy requires submission of a Plan for extramural grants at the time of **application**.

- (NOT during JIT or at the time of award.)
- This can create budgeting difficulties, not to mention allowing for adequate time (if needed) for institutional – i.e. IT input – review and approval.

New DMS Policy goes into effect on **January 25, 2023** for grant applications, contract proposals, and OTAs executed on or after that date.





How are DSMPs to be assessed?

It is for NIH Program Staff (the ICs)

Peer reviewers may comment on the proposed budget for data management and sharing, although these comments **will not impact the overall score**

What about the costs?

- Well, they need to be “reasonable,” but...
“Over time, and through these reviews, we hope to learn more about what constitutes reasonable costs for various data management and sharing activities across the NIH portfolio of research.”





Elements of an NIH Data Management and Sharing Plan

The Draft Supplemental Information suggested a limit of two pages, which was thought to be insufficient to describe approaches for data management and sharing for larger projects, more complicated projects, or projects leveraging consortia. Some commenters requested templates.

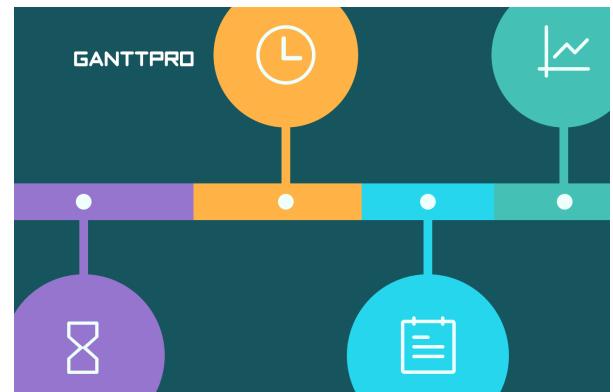
In the final supplemental information, we have noted the elements to be addressed in [two pages or less](#), indicating that these descriptions need not be long narratives. In addition, short Plans are anticipated to limit researcher burden.

When should data be shared?

The final [DMS Policy](#) states that “[s]hared 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 award/support period, whichever comes first.”

Publication triggers release of the data that underlie that publication (which many publishers require, anyway).

Data that do not form the basis of a publication produced during the award period should be shared by the end of the award period.





Where to include DMSPs in applications?

[View Burden Statement](#) **PHS 398 Research Plan** OMB Number: 0925-0001
Expiration Date: 09/30/2024

Introduction	
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Appendix	
13. Appendix	Add Attachments Delete Attachments View Attachments

Forms H has a new
“Other Plans” upload
option.

This option is available in
all of the updated SF424
formsets:

- PHS 398 Research Plan Form
- PHS 398 Career Development Award Supplemental Form
- PHS 398 Research Training Program Plan
- PHS Fellowship Supplemental Form



Data Repositories



Where should the Scientific Data be shared?

The final [DMS Policy](#) strongly encourages the use of [established repositories](#) to the extent possible. This reflects NIH's preference that scientific data be shared and preserved through repositories, rather than kept only by the researcher or institution and provided on request.

Bonus: The NIH has additional guidance to help researchers select an appropriate repository, in [NOT-OD-21-016: Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research](#)



NOT-OD-21-016

Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research

This supplemental information is intended to **help researchers choose data repositories** suitable for the preservation and sharing of data resulting from NIH-funded research. NIH promotes the use of established data repositories because deposit in a quality data repository generally improves the FAIRness (**Findable, Accessible, Interoperable, and Re-usable**) of the data.

While NIH supports many data repositories, it will not necessarily provide data repositories to preserve and share all data resulting from the research it funds. The broader repository ecosystem for biomedical data includes data repositories supported by other organizations, both public and private.

The guidance lists over 20 different variables to consider when selecting a data repository!



What makes a data repository “good?”

Selecting a Data Repository

1. For some programs and types of data, NIH and/or Institute, Center, Office (ICO) policy(ies) and Funding Opportunity Announcements (FOAs) identify particular data repositories (or sets of repositories) to be used to preserve and share data. For data generated from research subject to such policies or funded under such FOAs, researchers should use the designated data repository(ies).
2. For data generated from research for which no data repository is specified by NIH or the NIH ICO (as described above), researchers are encouraged to select a data repository that is appropriate for the data generated from the research project and is in accordance with the desired characteristics, taking into consideration the following guidance:
 - A. Primary consideration should be given to data repositories that are discipline or data-type specific to support effective data discovery and reuse. NIH makes a list of such data repositories available (see https://www.nlm.nih.gov/NIHbmic/domain_specific_repositories.html).
 - B. If no appropriate discipline or data-type specific repository is available, researchers should consider a variety of other potentially suitable data sharing options:
 - i. Small datasets (up to 2 GB in size) may be included as supplementary material to accompany articles submitted to PubMed Central (see <https://www.ncbi.nlm.nih.gov/pmc/about/guidelines/#suppm>).
 - ii. Data repositories, including generalist repositories (see https://www.nlm.nih.gov/NIHbmic/generalist_repositories.html) or institutional repositories, that make data available to the larger research community, institutions, or the broader public.
 - iii. Large datasets may benefit from cloud-based data repositories for data access, preservation, and sharing.



Desirable Characteristics for All Data Repositories

A. Unique Persistent Identifiers: Assigns datasets a citable, unique persistent identifier (PID), such as a digital object identifier (DOI) or accession number, to support data discovery, reporting (e.g., of research progress), and research assessment (e.g., identifying the outputs of federally funded research). The unique PID points to a persistent landing page that remains accessible even if the dataset is de-accessioned or no longer available.

B. Long-Term Sustainability: Has a plan for long-term management of data, including maintaining integrity, authenticity, and availability of datasets; building on a stable technical infrastructure and funding plans; and having contingency plans to ensure data are available and maintained during and after unforeseen events.

C. Metadata: Ensures datasets are accompanied by metadata to enable discovery, reuse, and citation of datasets, using schema that are appropriate to, and ideally widely used across, the community(ies) the repository serves. Domain-specific repositories would generally have more detailed metadata than generalist repositories.

D. Curation and Quality Assurance: Provides, or has a mechanism for others to provide, expert curation and quality assurance to improve the accuracy and integrity of datasets and metadata.

E. Free and Easy Access: Provides broad, equitable, and maximally open access to datasets and their metadata free of charge in a timely manner after submission, consistent with legal and ethical limits required to maintain privacy and confidentiality, Tribal sovereignty, and protection of other sensitive data.

F. Broad and Measured Reuse: Makes datasets and their metadata available with broadest possible terms of reuse; and provides the ability to measure attribution, citation, and reuse of data (i.e., through assignment of adequate metadata and unique PIDs).

G. Clear Use Guidance: Provides accompanying documentation describing terms of dataset access and use (e.g., particular licenses, need for approval by a data use committee).

H. Security and Integrity: Has documented measures in place to meet generally accepted criteria for preventing unauthorized access to, modification of, or release of data, with levels of security that are appropriate to the sensitivity of data.

I. Confidentiality: Has documented capabilities for ensuring that administrative, technical, and physical safeguards are employed to comply with applicable confidentiality, risk management, and continuous monitoring requirements for sensitive data.

J. Common Format: Allows datasets and metadata downloaded, accessed, or exported from the repository to be in widely used, preferably non-proprietary, formats consistent with those used in the community(ies) the repository serves.

K. Provenance: Has mechanisms in place to record the origin, chain of custody, and any modifications to submitted datasets and metadata.

L. Retention Policy: Provides documentation on policies for data retention within the repository.

NIH promotes FAIRness in data management and sharing



FAIR Principles

GO FAIR is committed to making data and services **findable, accessible, interoperable and reusable (FAIR)**.



Findable: Metadata and data should be easy to find for both humans and computers.



Accessible: The exact conditions under which the data is accessible should be provided in such a way that humans and machines can understand them.



Interoperable: The (meta)data should be based on standardized vocabularies, ontologies, thesauri, etc. so that it integrates with existing applications or workflows.



Reusable: Metadata and data should be well-described so that they can be replicated and/or combined in different research settings.



How long are the data to be shared?

From the NIH GPS:

Length of Time to Maintain Data

Per Section 8.4.2 of the NIH Grants Policy Statement, grantee institutions are required to keep the data for **3 years** following closeout of a grant or contract agreement. Contracts may specify different time periods. Please note that the grantee institution may have additional policies and procedures regarding the custody, distribution, and required retention period for data produced under research awards.



NIH's new data sharing website

A key goal of the site is to serve as a [central portal](#), providing information on both NIH-wide and NIH Institute and Center-specific sharing policies and data repositories in a way that is easily sortable and searchable.

It includes

- Relevant policies; NIH-wide and IC-specific
- Step-by-step guides
- Infographics
- Tools and resources
- Sample sharing plans
- Guidance for budgeting for data sharing

Data repositories!





The site links to NIH IC registries

NIH-supported Scientific Data Repositories*

Institute or Center	Repository Name	Repository Description	Access to Data	Open Data Access
All	Keyword Filter			
Common Fund	Metabolomics Workbench (MetWB)	The Metabolomics Program's Data Repository and Coordinating Center (DRCC), housed at the San Diego Supercomputer Center (SDSC), University of California, San Diego, has developed the Metabolomics Workbench. MetWB will serve as a national and international repository for metabolomics data and metadata and will provide analysis tools and access to metabolite standards, protocols, tutorials, training, and more.	How to access MetWB data	Yes
NCATS	National COVID Cohort Collaborative (N3C)	The NCATS National COVID Cohort Collaborative (N3C) Data Enclave contains harmonized clinical, laboratory and diagnostic data derived from the EHRs of more than 12 million people who were tested for COVID-19 or had related symptoms.	How to access N3C data	Yes
NIDDK	NIDDK Information Network (DKnet)	The NIDDK Information Network serves the needs of basic and clinical investigators by providing seamless access to large pools of data relevant to the mission of NIDDK. The goal of DKnet is to develop a community-based network for integration across disciplines to include the larger DK universe of diseases, investigators, and potential users.	How to access DKnet data	Yes

Showing 1 to 50 of 104 rows 50 ▲ rows per page

Search all NIH data repositories, or by individual IC, or by keyword.

Links to access



Budgeting

Let's talk money!

The NIH wants this and they are willing to pay for it.

- *This = the research community valuing high-quality data management and sharing practices.*

What about after the grant ends?

- *“...the final Supplemental Information clarifies that fees for long-term data preservation and sharing are allowable, but funds for these activities must be spent during the performance period, even for scientific data and metadata preserved and shared beyond the award period. NIH funds cannot legally be spent after the award period.”*

Personnel costs related to data management and sharing are allowable.





How much should we budget for DMSPs?

It depends...

- Where the data are going to be housed
- How expensive it is for you to manage, archive, and share your scientific data
- Many (NIH IC) data repositories are free

Reminder:

While the [DMS Plan](#) will be a new upload into “[Other Plans](#),” Any costs related to DMSPs will need to be described in the [Budget Justification](#).

So, which repository are PIs supposed to pick?

The Federal government will not say which repositories are acceptable vs. unacceptable.

Instead, they will enforce the requirement that PIs commit to selecting a data repository, and the NIH has provided a [comprehensive guidance document](#) that explains the characteristics of suitable repositories. (next slide)

In addition, individual FOAs may stipulate the use of certain data repositories.

In this way, the NIH is trying to navigate tricky issues: supporting PI choice and IC autonomy, encouraging research communities to develop their own standards and resources.

*it's
up
to
you*



Resources (and support!) from McGoogan

General Information:

Research Guide for Data Management: <https://unmc.libguides.com/rdm>

Website on VCR SPA page:

<https://www.unmc.edu/spa/policies/nihdmsp/index.html>

Resources (and support!) from McGoogan



Upcoming webinars:

Writing a Data Management and Sharing Plan with DMPTool:

January 10 from 12-1pm

January 18 from 12-1pm

Selecting a Data Repository for Scientific Data:

January 24 from 12-1pm



More Support from McGoogan

Research Data Services Librarian:

Lisa Chinn, PhD, MLIS
lchinn@unmc.edu

Your researchers can set up an appointment, email to ask questions, or request further guidance:

researchdata@unmc.edu

Book a Data Services appointment:

<https://go.unmc.edu/veb3>



We are wrapping up

Before we move on, are there any questions about DMSPs?

We encourage everyone to take a look at the NIH DMSP website.

<https://sharing.nih.gov/>

A screenshot of the NIH Data Management and Sharing Policy website. The page has a dark blue background with a network of glowing purple and pink nodes and lines. At the top right, the URL "https://sharing.nih.gov/" is displayed. Below it, the main title "Expediting the Translation of Research Results to Improve Human Health." is centered. Underneath the title, there's a section titled "LATEST NEWS & EVENTS" with the sub-headline "Gearing Up for 2023: Implementing the NIH Data Management and Sharing Policy". A "View More" button is located below this text. The overall design is modern and professional, emphasizing connectivity and research.



Reminders

Effective date is
Jan 25, 2023

Currently funded projects
and applications
submitted prior to that
date fall under the [current](#)
NIH Data Mgmt & Sharing
Policy

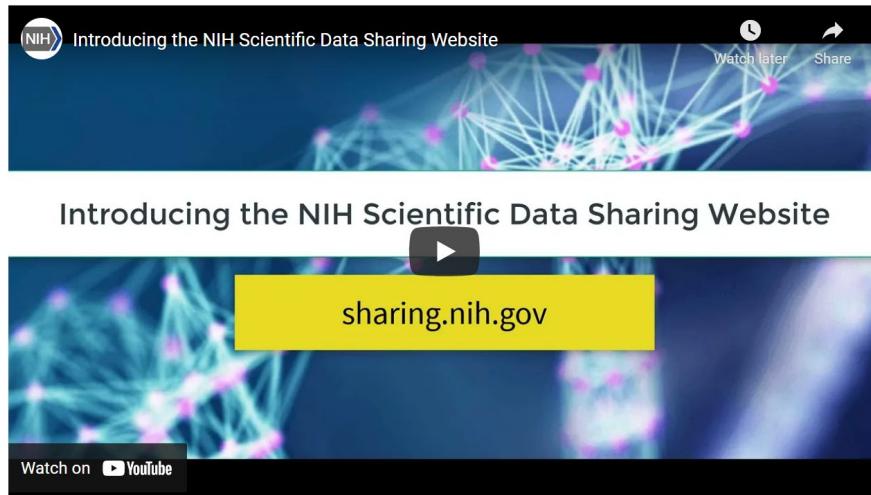
ATTENTION! ×

New Data Management & Sharing Policy Effective
January 25, 2023!

[VIEW CURRENT POLICY INFORMATION](#) [LEARN ABOUT NEW POLICY](#)

Do not show me this message again.

More resources



A 3-minute video providing an overview of the NIH DMSP website

<https://youtu.be/d2AdQZRjOHA>

<https://sharing.nih.gov/>



References and Resources

- [2003 Policy](#)
- [2023 Policy](#)
- [Elements of an NIH DMSP](#)
- [Allowable Costs for DM & Sharing \(i.e., there are reimbursable costs\)](#)
- [Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research \(very helpful guidance\)](#)
- [Introduction to the NIH Data Management and Sharing Plan \(YouTube\)](#)
- [Update on the Implementation of New NIH Data Management and Sharing Policy \(YouTube\)](#)

The screenshot shows a video player interface for a NIH Virtual Seminar. The title of the video is "Update on Implementation of the New NIH Data Management and Sharing Policy". Below the title, it says "NIH Virtual Seminar November 4, 2021". The video features three speakers: Tauton Paine, MA; Cindy Danielson, PhD; and Julia Slutman, PhD. Their names and titles are listed along with their email addresses: sciencepolicy@mail.nih.gov. The video player includes standard controls like play, pause, and volume, and a progress bar showing 0:03 / 42:12. A small video thumbnail in the top right corner shows a woman smiling. The NIH logo is in the bottom right corner of the video frame.

Update on Implementation of the New NIH Data Management and Sharing Policy



Thanks for your time and attention

Questions

Comments

Concerns

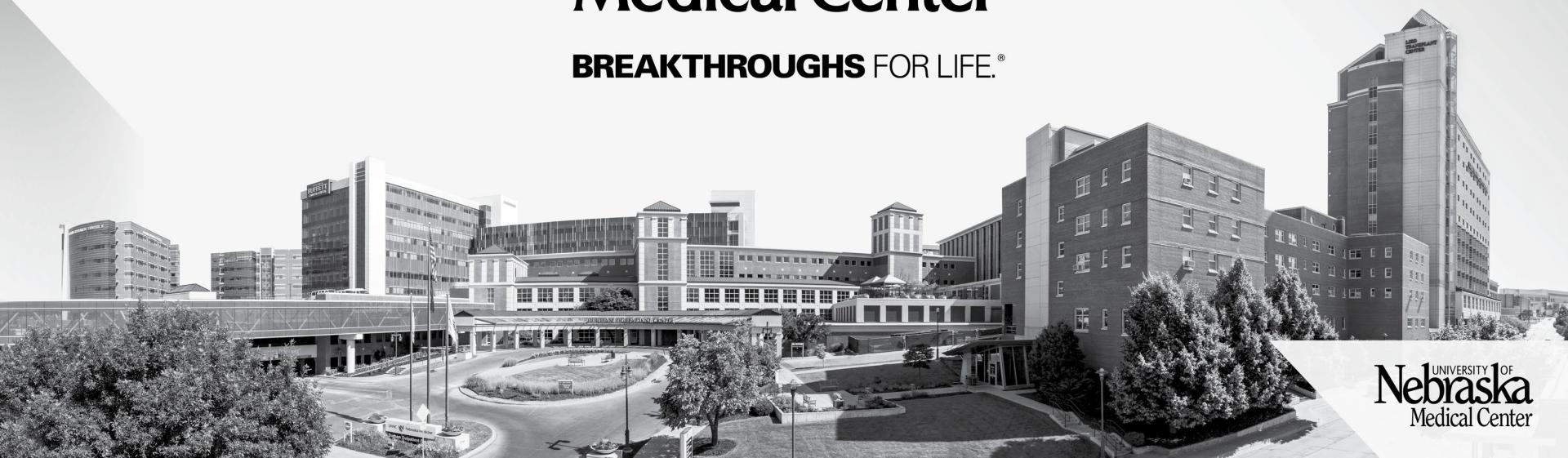
Discussion





University of Nebraska Medical CenterSM

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