Office of Research Support & Regulatory Management

UTSouthwestern Medical Center

Supercharge Your Compliance Infrastructure: Strategies for Data Management and Sharing (DMS) Policy Support

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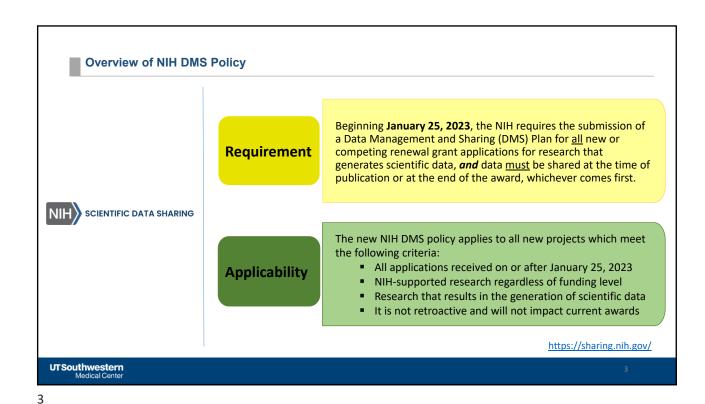
June 13, 2023

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Outline

- Overview of NIH DMS Policy Requirements
- Learning Objectives
- Questions

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Learning Objectives

1. Identify administrative infrastructure components that support the NIH Data Management and Sharing Policy

2. Learn how to effectively communicate new policy requirements to researchers

3. Discuss the latest developments with the NIH Data Management and Sharing Policy

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Importance of Administrative Infrastructure

- Spread the word far and wide
- Ensure all researchers understand what is going on
- Manage multiple channels of distribution, communication, and recording of new developments
- · Collate feedback and comments made on the submitted DMS Plans at JIT
- Identify potential avenues for compliance monitoring

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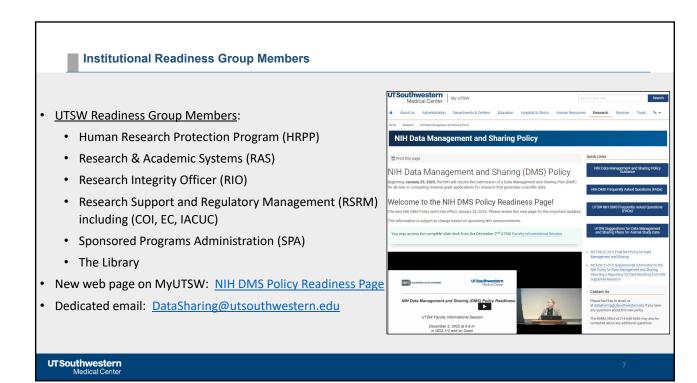
Purpose of the Administrative Institutional Readiness Group

Institutional Readiness Group

Ensure readiness for the new NIH Data Management and Sharing (DMS) Policy, and communicate ongoing changes.

- Coordinate activities across business units
- Craft template language for investigators to use in data management and sharing (DMS) plans
- Ensure communication within the UTSW research community

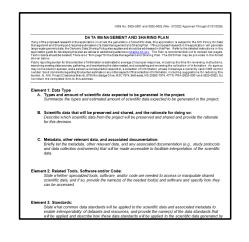
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Highlights of Dedicated Web Page

• NIH web site providing general information on the Policy and Data Sharing: https://sharing.nih.gov

- NIH developed an <u>optional DMS Plan format</u> that aligns with the recommended six elements of a DMS Plan:
 - 1. Data Type
 - 2. Related Tools, Software and/or Code
 - 3. Standards
 - 4. Data Preservation, Access, and Associated Timelines
 - 5. Access, Distribution, or Reuse Considerations
 - 6. Oversight of Data Management and Sharing
- In mid-January, NIH provided examples of data management plans or data sharing expectations for the new "optional" DMS Plan template that follows their policy.
 - Just because you follow their examples, does not guarantee acceptance of the DMS Plans.



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Resources: Institutional Account with DMPTool.org



Creating a DMS Plan in DMPTool.org

- DMPTool is a free, open-source, online application that helps researchers create data management plans
- NIH works with DMPTool.org to disseminate their DMS Plan template and requirements
- DMPTool is easy to use, a webinar about its use was made available on the UTSW NIH DMS Policy web page

UTSW created an institutional account with **DMPTool.org!**

- Single Sign-On (SSO)
- Template language for UTSW PIs to use in their DMS plans was added to DMPTool.org

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Selecting an Acceptable Data Repository

NIH Preference on Repositories:

- In general, NIH does not endorse or require sharing data in any particular repository, although some initiatives and funding opportunities will have individual requirements. **Overall, NIH encourages** researchers to select the repository that is most appropriate for their data type and discipline.
- NIH strongly encourages the use of *established NIH-supported repositories* to the extent possible for preserving and sharing scientific data.
 - o NIH-supported repository information can be found at sharing.nih.gov

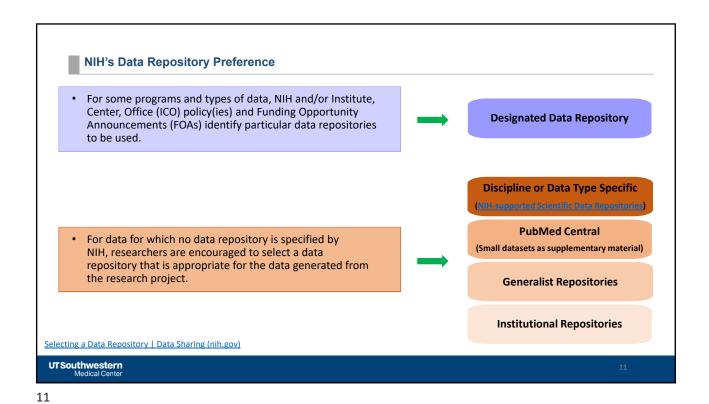
Can't find a repository that suits your data?

• When investigators cannot locate a repository for their discipline or the type of data they generate, a *generalist repository* or *institutional repository* can be used to share data.

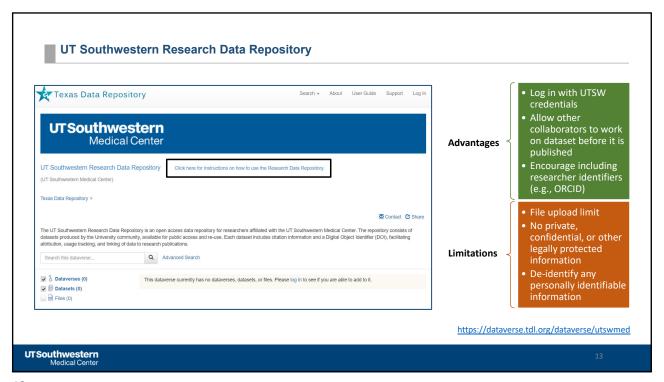
Selecting a Data Repository | Data Sharing (nih.gov)

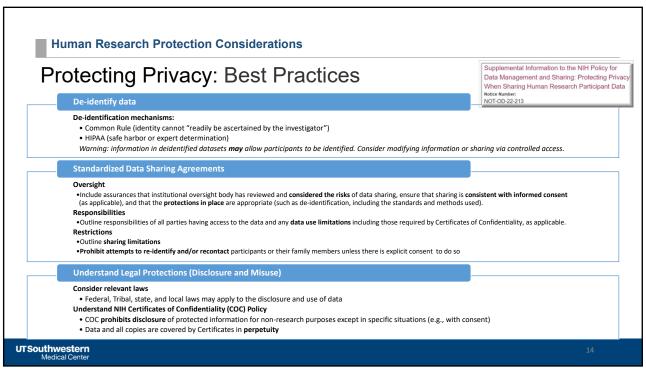
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Properties: UT Southwestern Research Data Repository UTSW joined the Texas Data Repository Dataverse and developed the UT Southwestern Research Data Repository. This institutional repository gives UTSW investigators an open-access generalist repository option that meets NIH's data sharing expectations. The repository consists of datasets generated by the University community, available for public access and reuse. Each dataset includes citation information and a Digital Object Identifier (DOI), facilitating attribution, usage tracking, and liking data to research publications. https://dataverse.tdl.org/dataverse/utswmed





Human Research Protection Considerations

Choosing a Repository: Points to Consider

Supplemental Information to the NIH Policy for Data Management and Sharing: Protecting Privac When Sharing Human Research Participant Data Notice Number: NOT-OD-22-213

Controlled Access

Data requesters must verify their identity and the appropriateness of their proposed research use to access data (*Gold Standard)

- 1. There are explicit limitations on subsequent use (laws, regulations, policies, informed consent, and/or data use agreements)
- The data are sensitive
- Potentially stigmatizing traits, illegal behaviors, or other information that could cause harm or be used for discriminatory purposes.
- If data are sensitive, it may be possible to de-identify the data in ways that would allow appropriate sharing.
- 3. The data can't be fully de-identified
- · Some de-identified datasets contain enough information that may allow reidentification of participants
- 4. There are unknown risks to participant privacy if released without controls.
- Unanticipated approaches or technologies that become known

Open Access

Available to data requesters without additional restriction

- 1. Scientific data are de-identified AND institutional review has determined that they pose very low risk when shared and used.
- 2.Participants explicitly consent to share data openly without restrictions

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Enterprise Box Account

UTSW is pursuing the creation of an Enterprise Box Account, which would provide researchers with an institutional repository option:

- · Controlled access
- · No limit on storage
- · Single Sign-On



https://www.box.com/

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Communications Campaign

Prior to January 25th

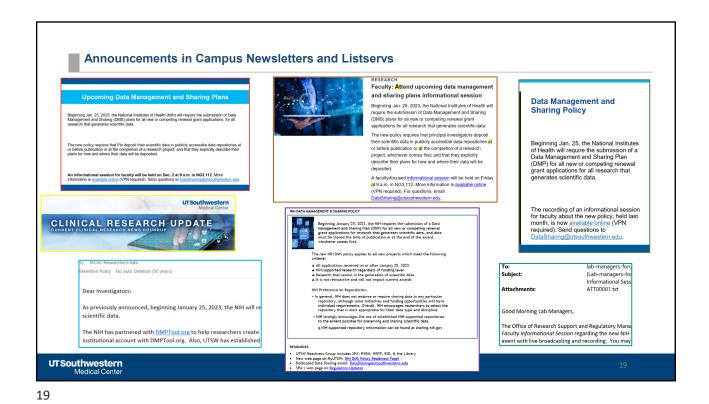
- Two All Faculty Emails
- Invite to Informational Session
- Prior to Implementation
- Faculty Informational Session
- Today@UTSW Newsletter
- Announcements in Academic Connections
- SPA Research RoundUp Meeting
- Lab Managers Forum Listserv
- IACUC Listserv
- HRPP Research Matters Meeting
- Provosts & Business Affairs Meeting
- · Administrators Meeting
- Clinical Research Update
- HRPP Updates Meeting

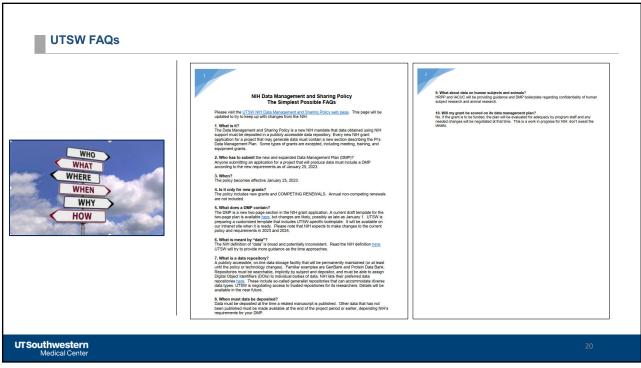
After January 25th

- Faculty Senate Meeting
- Institutional Compliance Research and Academics Virtual Office Hours
- IM Department Informational Session
- Executive Compliance Committee Meeting

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Impact on Animal Research Subjects Data

- No specific guidance on what type of data must be shared, other than data that is "necessary to validate or replicate research findings."
- To assist animal researchers, we created suggestions on how to meet NIH's data sharing expectations while maintaining confidentiality regarding animal research data.
- If data is obtained from images or recordings, the best consideration is to share the quantified data rather than the images and recordings.



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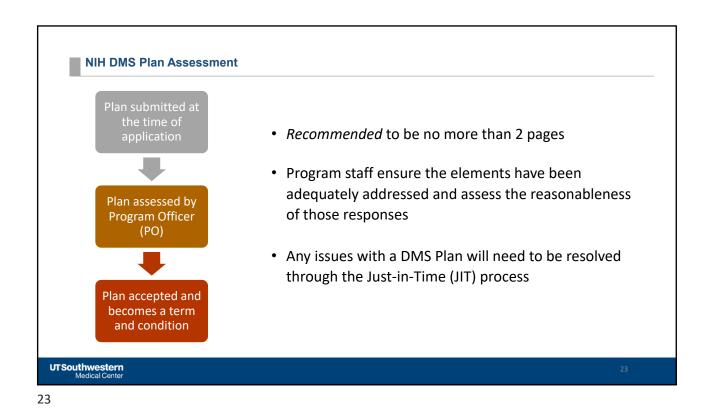
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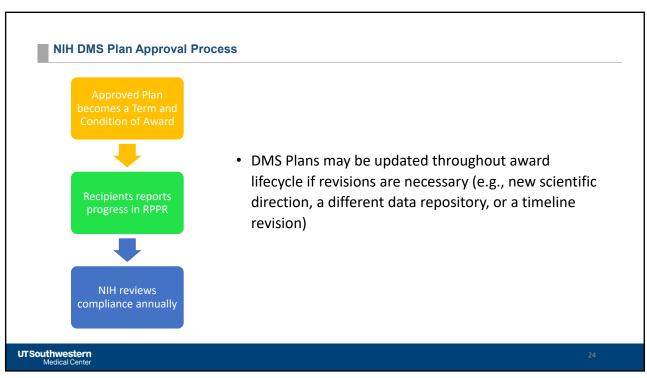
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NIH Enforcement



- Non-compliance could result in NIH adding terms and conditions to the award
- Prime institution is responsible for the performance and monitoring activities of the subrecipients and ensuring the DMS Plan is provided and followed
- Failure to comply may result in enforcement action and affect future funding decisions
- NIH will clarify enforcement mechanisms
 - o No enforcement actions are expected in calendar year 2023

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Compliance Monitoring for Institutions



- NIH has yet to provide succinct guidance regarding oversight and monitoring by an institution
 - o No structure exists
 - o No suggested institutional corrective actions from NIH
 - o No reporting mechanism for institutions
 - RPPR?
- Do institutions need to identify potential avenues for compliance monitoring?

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Survey of Institutional Compliance Monitoring Plans

Institution	FY 22 NIH Funding	Current Plan	Responsibility Institutional Entity (If Provided)
Large University with a Medical School	\$650-700M	Periodic audits of DMS Plans, no current structure for the audit plan	Same group as IACUC/IRB
Large University with a Medical School	\$200-250M	PI or other investigative personnel must be identified on DMS Plan to take responsibility for compliance and oversight	N/A
Academic Medical Center	\$250-300M	PI responsible	N/A
Academic Medical Center	\$150-200M	No guidance	N/A
Academic Medical Center	\$150-200M	No guidance	N/A
Large University with a Medical School	\$50-100M	Post-Approval Monitoring or PI	Human Research – IRB Animal Research – IACUC Other Research – PI
Medium University with a Medical School	\$50-100M	Deferred any oversight/compliance questions to the Library	Library
Medium University with no Medical School	\$10M	PI is ultimately responsible but will implement a risk-based audit approach	Sponsored Projects
Large University with a Medical School	\$<10M	No institutional guidance	Individual academic departments
Large University with a Medical School	\$<10M	PI responsible	N/A
<u> </u>			

Many institutions indicate that they are in a "holding pattern" and not implementing any compliance monitoring without further NIH guidance

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Monitoring Components for an Institutional Process

- · What is being shared
 - o Appropriate data from the relevant studies identified in DMS Plan
- When is it being shared
 - Shared on or before publication



- o Non-published data shared before award close-out
- o Other time points in the DMS Plan Not encouraged
- 90-120 days after project period ends

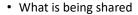
UTSW Policy:

- Justifications for not sharing data followed
- · How is data shared
 - $_{\circ}\,$ Repositories identified in DMS Plan
- Appropriate reporting of data sharing progress in RPPRs

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Monitoring Components for the HRPP





Consistent

with informed

o Appropriate data from the relevant studies identified in DMS Plan

o Appropriate data from the relevant studies in

When is it being shared

Shared on or before publication





o Other timepoints in the DMS Plan?

- · Justifications for not sharing data followed
- · How is data shared
 - o Repositories identified in DMS Plan
- Appropriate reporting of data sharing progress in RPPRs

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Potential Institutional Monitoring Options (in order of effort/burden)

- 1. No monitoring by the institution, PI completely responsible
- 2. Ad hoc monitoring at close-out or at other triggers (e.g. first manuscript publication)
- 3. Ad hoc monitoring during award period and review at all close-outs
- 4. Reviews at RPPR (annual)
- 5. Reviews at RPPR (annual) and close-out
- 6. Reviews at RPPR, manuscript review, and close-out
- 7. Reviews at RPPR, timepoints in the DMS Plan, manuscript publication, triggers, & close-out Additional options:
 - IRB reviews as part of QA
 - · IACUC reviews with PAM

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Our Challenges

- Access to DMS Plans and RPPRs in eResearch
- · Changes expected to NIH policy guidance in 2024 and beyond
- Resources with appropriate expertise and increased workload (e.g. HRPP)
- · Need for a closed repository for human research data
 - Institutional agreements may be needed for external closed repositories
- · No institutional policy on data sharing
 - · Many institutions implemented a policy on data sharing at prior to the NIH policy
- · Administrative burden for PIs
 - The more involved the monitoring by the institution, the more PI time will be needed
- · Changes to DMS Plans during the award
- Will not receive feedback on first DMS Plans submitted for several months (Feb 5 submissions)

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2023 & 2024

- Unresolved Items:
 - $\circ\quad \mbox{Still}$ no guidance on how long data has to be shared
 - $\circ\quad$ Data sharing depends on repository and retention schedule
 - o Timeline for cleaning and transformation of data
 - o Length of plan is restrictive
 - o Look at Intellectual Property (IP) protection before sharing data, rather than before publishing
 - o Lack of guidance for oversight and compliance including budget compliance
 - o Not been able to track comments for JIT
 - NIH has yet to provide additional budgeting/costing guidance
- NIH is gathering data and feedback through a Pilot Project of selected institutions in calendar year 2023
 - o Goals of Pilot Project:
 - Test structured templates and tools for DMS Plan submission
 - Establish cost policies and identify types of cost required
- Institutional Readiness Group needed to communicate new developments as we navigate through this new requirement

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