Data Management & Sharing

Updates
## DMS Working Group

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Department/Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joseph Schmelz</td>
<td>Associate Vice President for Research</td>
<td>Radiology &amp; Research Imaging Institute</td>
</tr>
<tr>
<td>Mark Goldberg</td>
<td>Associate Vice President for Research</td>
<td>Radiology &amp; Research Imaging Institute</td>
</tr>
<tr>
<td>Kimberly Summers</td>
<td>Assistant Vice President for Research</td>
<td>Council of Principal Investigators/ Biochem &amp; Structural Biology/ Institutional Core Labs</td>
</tr>
<tr>
<td>Melanie Zuniga Rapp</td>
<td>Director, Research Admin &amp; Quality</td>
<td>School of Nursing</td>
</tr>
<tr>
<td>Wanda Quezada</td>
<td>Director, IRB</td>
<td>Council of Principal Investigators/ Greehey Cancer Research Inst</td>
</tr>
<tr>
<td>Meredith Zozus</td>
<td>Div. Chief &amp; Director of Clinical Research Informatics</td>
<td>Council of Principal Investigators/ Greehey Cancer Research Inst</td>
</tr>
<tr>
<td>Muayad Maallah</td>
<td>Clinical Research Informatics, Population Health</td>
<td>Director Research Operations, Dept of Medicine</td>
</tr>
<tr>
<td>Owen Ellard</td>
<td>Senior Director of Libraries</td>
<td>IMS/Web Initiatives</td>
</tr>
<tr>
<td>Christine Gaspard</td>
<td>Associate Director, Library</td>
<td>IMS/Web Initiatives</td>
</tr>
<tr>
<td>Andrea Schorr</td>
<td>Associate Director, Library</td>
<td>IMS</td>
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<tr>
<td>Chuntida Harinnitisuk</td>
<td>Director, Enterprise Systems &amp; Operations</td>
<td>IMS</td>
</tr>
<tr>
<td>Melissa Bazan</td>
<td>Research Compliance</td>
<td>Director, Institutional Core Labs</td>
</tr>
<tr>
<td>Angelife Pardo</td>
<td>Director, Privacy</td>
<td>OSP Manager, Grants &amp; Contracts</td>
</tr>
</tbody>
</table>
## Working Group Goals

1. Develop a comprehensive plan to increase faculty awareness
2. Define the types of support our faculty may need to:
   a. Develop a data management and sharing plan
   b. Select appropriate data standards and curation methods
   c. Select appropriate preservation, access and timelines
   d. Develop a budget to support data management and sharing
   e. Protect privacy of human subject research
   f. Data Security Measures
   g. Monitoring compliance with DMS Plan
3. Create a support service to navigate faculty to the appropriate resources and services
4. Develop outcome measures to assess effectiveness and customer satisfaction
Progress

• Regular communications from VPR, OSP and Library
• Department presentations Dr’s Zozus & Maallah
• Launched No-Cost DMS Plan Consultation Service
• Self-service templates posted Clinical Research Informatics website
• Participating in the Federal Demonstration Project (FDP) pilot of two versions of the NIH DMS template
• Joining Texas Digital Library – generalist repository
  • provide faculty with a no-cost solution to data sharing and centralize storage
• Single point of contact website under development
  • planned launch in April
• Adding Data Monitor to Pure/Scholars – tracking data sharing
NIH Policy for Data Management and Sharing

NOT-OD-21-013
Effective date: January 25, 2023

Presentation to the UTHSA IRB Research Forum: March 23, 2023

Meredith Zozus, PhD
Professor, Division Chief, and Director of Clinical Research Informatics
Joe R. and Teresa Lozano Long School of Medicine
University of Texas Health Science Center at San Antonio
Learning Objectives

• Be able to describe the rational for data sharing
• Explain the ways in which data management and sharing are related
• Describe some data management principles that support data sharing
• List things required by the NIH Data Management and Sharing Policy
• Identify available repositories
• Describe the contents of an NIH DMS Plan
• Know who to call to help with Data Management and Sharing questions
Optimist’s view:

Data have value when they are used.
Sharing ↑ Return On Investment

an alternate view
There’s been a lot of policy work leading up to this.

Two Sides of Data Sharing

Incoming

Data collection & Management
Data standardization
Data documentation & curation, i.e., metadata
  Metadata are information that define or describe the data, “data about data”
Data quality

Outgoing

FAIR Principles describing the expectations for shared data.

Findable $\rightarrow$ metadata
Accessible
Interoperable $\rightarrow$ data standardization
Reusable $\rightarrow$ documentation and quality
Wide variety in the topics required in Data Management and Sharing Plans.

Topics associated with upstream data collection and processing received the lowest coverage compared to topics pertaining to sharing.
The “Goes Ins” Determine the “Goes Outs”

**Incoming**
- Data collection & Management
- Data standardization
- Data documentation & curation, i.e., metadata
  - Metadata are information that define or describe the data, “data about data”
- Data quality

**Outgoing**
- FAIR Principles describing the expectations for shared data.
  - Findable → metadata
  - Accessible
  - Interoperable → data standardization
  - Reusable → documentation and quality
Active phase
(data accumulating and changing)

Inactive phase
(no new data, no changes)

Planning phase

Start of data collection

Stop of data collection
## A Data Management Plan (DMP):
- documents all operations performed on all data.
- a plan
- a manual
- a record
- a living document
- a controlled document
- contains essential documents
- should be shared with data

### Start of data collection  |  Active phase (data accumulating & changing)  |  Stop of data collection (no new data, no changes)
---|---|---
**Planning phase**
- Project personnel, the duration of their association with the project, their roles, responsibilities, data access, training, other qualifications, and identifiers.
- Description of all data sources
- Data and workflow diagrams
- Definition of data elements
- Planned active phase data model
- Planned inactive phase data model
- Procedures for or pointers to all operations performed on data:
  - Observation and measurement
  - Data recording
  - Data processing
  - Data integration
  - Data quality control definitions & acceptance criteria
- Description of software and devices used for data including:
  - Calibration plans
  - Configuration specifications for the project
  - Validation or testing plans
  - Scheduled maintenance
  - Plan for handling unscheduled maintenance
  - Change control plans
  - Security plan
  - Data back-up and schedule
- Privacy and confidentiality plan

**Active phase**
- Personnel role and signature log
- Training and other qualification records
- Current description of all data sources
- Record of changes in data sources
- Current data and workflow diagrams
- Record of changes to data and workflow diagrams
- Current version of data elements
- Active phase data model
- Record of all revisions to data elements
- Active phase data model
- Record of revisions to procedures
- Observation and measurement artifacts
- Data recording artifacts
- Data processing artifacts
- Data integration artifacts
- Data quality control artifacts
- Issue reports and resolutions
- Pointers to system manuals
- Artifacts demonstrating that procedures were followed
- Summary of back-up and security incl. incident reports

**Inactive phase**
- Personnel role and signature log
- Training and other qualification records
- Record of changes in data sources
- Record of changes to data and workflow diagrams
- Active phase data model
- Record of all revisions to data elements
- Inactive phase data model
- Record of all revisions to data elements
- Artifacts from carrying out procedures
- Issue reports and resolutions
- System manuals
- Record of calibration, validation, maintenance and change control
- Summary of back-up and security incl. incident reports

- CDA/DUA, Informed consent or authorization tracking
- Association of CDA, DUA, ICF or authorization to data
- Project management plan (deliverables, timeline, and tracking & reporting plan, resource estimates)
- Record of completion dates
- Record of completion dates
- Data retention, archival, and disposal plan
- Data sharing plan
- Data retention, archival, and disposal plan
- Data sharing plan
A few good data handling pointers

1. Clear plan of what data will answer the scientific question.
2. Provide complete descriptive information for each data element (e.g., units, labels and definitions, audit trails, data handling rules).
3. Specify and assure the use of consistent measurement techniques.
4. Train data collectors and ensure proper qualifications.
5. Record data at the time it is measured or observed.
7. Use the most capable and streamlined data collection and handling process possible.
8. Expect things to go wrong, check data for discrepancies at the earliest possible time.
9. Maintain written policies and procedures for each data collection and management process – sufficient to reconstruct results.
10. Control the research and data collection process → Entropy affects us all.
12. Ensure data and metadata reside with the organization, not in individuals heads or hard drives!
The “Goes Outs”

Data collection & Management
Data standardization
Data documentation & curation, i.e., metadata
Metadata are information that define or describe the data, “data about data”
Data quality

FAIR Principles describing the expectations for shared data.

Findable → metadata
Accessible
Interoperable → data standardization
Reusable → documentation and quality
Data sharing is for secondary use.

Secondary use → using data for purposes other than those for which they were originally collected.

puts NEW pressure and higher expectations on our data management practices.

At some point, this became a whole different sport ...
The Guiding Principles

Findable:
F1. (meta)data are assigned a globally unique and persistent identifier
F2. data are described with rich metadata (defined by R1 below)
F3. metadata clearly and explicitly include the identifier of the data it describes
F4. (meta)data are registered or indexed in a searchable resource

Accessible:
A1. (meta)data are retrievable by their identifier using a standardized communications protocol
A1.1 the protocol is open, free, and universally implementable
A1.2 the protocol allows for an authentication and authorization procedure, where necessary
A2. metadata are accessible, even when the data are no longer available

Interoperable:
I1. (meta)data use a formal, accessible, shared, and broadly applicable language for knowledge representation.
I2. (meta)data use vocabularies that follow FAIR principles
I3. (meta)data include qualified references to other (meta)data

Reusable:
R1. meta(data) are richly described with a plurality of accurate and relevant attributes
R1.1. (meta)data are released with a clear and accessible data usage license
R1.2. (meta)data are associated with detailed provenance
R1.3. (meta)data meet domain-relevant community standards

1 – 10 – 100 Rule

FAIR is expensive to achieve “after the fact”
A Lot of FAIR is Handled by the Repository

Domain Specific Repositories

Generalist Repositories
Generalist Repository Ecosystem Initiative (GREI)

**Vision:** to develop collaborative approaches for data management and sharing through inclusion of the generalist repositories in the NIH data ecosystem. ... ultimately to better enable search and discovery of NIH-funded data in the generalist repositories.

**Mission:**
- to establish a common set of cohesive and consistent capabilities, services, metrics, and social infrastructure across various generalist repositories.
- to raise general awareness and help researchers to adopt FAIR principles to better share and reuse data.

7 generalist repositories comprise GREI

What Do Investigators and Research Teams Need to Do Differently to Share Data?

• “user manual” type documentation
• Traceability helps
• Document “metadata” about the study and shared data
• Select a repository that meets NIH requirements
• Consider discipline-specific and general data standards
• Plan for data sharing up-front
• Most Importantly → Sharing language should be in the consent!
NIH DMS Policy Requires

1. Two page Data Management and Sharing Plan (DMS Plan or DMSP)

2. Data Management and Sharing Budget

3. Data Management and Sharing Budget Justification
DMS Plan Not Scored; Not Seen By Reviewers

“On the proposed budget for data management and sharing, peer reviewers may provide comments on the reasonableness of the budget, but these comments will not impact the score. Peer reviewers will only use the information found in the budget justification to determine whether the requested DMS costs are reasonable and will not be provided with the separate DMS Plan attachment (see NOT-OD-22-189).”

An NIH ICO official reviews the plan.
DMSP Elements (NOT-OD-21-014)

• Type/s of data to be shared
  • Type of scientific data used in the research (data source), for each:
    • modality (images, -omics data, survey data, clinical data, etc.)
    • size estimate
    • degree of processing
    • identified (protected health information) or not
    • level of aggregation
    • whether shared, if so:
      • the intended repository
      • list of metadata, other relevant data, and documents shared with the data

• Statement whether specialized tools are needed to access or manipulate shared scientific data. If so, name, how to obtain, and whether it will likely remain available for the duration of sharing.

• Standards applied to the data
• Data preservation and access timelines
• Access, distribution and reuse considerations
• Oversight of Data Management and Sharing
Plan

1

Data Expected to be Collected and Used in the Study

The table should cover all Scientific Data, e.g., analytic datasets including pre-specified primary and secondary outcomes, are expected to be shared unless sharing is not possible.

Sharing of data will not occur at the Clinical Research Center (CRC) Division, Department of Population Health Sciences, Joe N. and Teresa Lozano Long School of Medicine at the University of Texas Health Science Center at San Antonio (UTHSC) serving as the study Data Coordinating Center. The REDCap information system (described in the Equipment section of the application) will be used to manage study data.

<table>
<thead>
<tr>
<th>Concept/Site Data</th>
<th>Data Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical (CHF) data</td>
<td>EX DE CT DM</td>
</tr>
<tr>
<td>Patient-reported data</td>
<td>EX DE CT DM</td>
</tr>
<tr>
<td>Laboratory data</td>
<td>EX DE CT DM</td>
</tr>
</tbody>
</table>

**Data Collection and Processing**

- **Data collection and processing** will include manual data entry of CHF data, data-based cleaning of source data, and data quality checks. Near real-time integration of data with REDCap, medical coding of adverse events and drugs, and transformation of the data to the analyses datasets and to the sharing format required by the repository.
- Data will be managed according to the study Data Management Plan (DMP), Data Management Plan Creation and Monitoring (DMPCR) and the REDCap User Guide. It is expected that REDCap will capture all aspects of this DMP and ensure traceability of all operations performed on data from collection through archiving. The Clinical Research Information (CORS) leads study data management according to, and maintains the study DMP. Briefly, a REDCap study database will be created to accommodate a screening log, e-consent, randomization, CHF, and control data, and patient-completed questionnaires. Randomized questionnaires will be completed on patient-owned computers, tablets or smartphones with study devices, for patients with a personal device.
- CHF data will be entered into REDCap by clinical trial in two separate files. CHF data will be imported into REDCap and integrated workflows. Population measures for data cleaning, i.e., to identify missing and aberrant data and events will run on project, de-identifiers, and errors as far as possible, to assure that expected data and samples are received and that filing of associations identified are provided to the study DMP. Discrepancies identified are provided to the study DMP for resolution and are tracked.
- Risk based monitoring will be specified in the Monitor Plan section of the DMP and include remote Site Initiation Visits (SIVs) Closeout Visits (CIVs). Central statistical monitoring, and remote SIVs are performed for the first 2 years on all sites. Process control measures may encompass such visit monitoring. In person monitoring visits with on-site Data Verification (SDV) will be performed when reviewed through statistical monitoring or study risk indicators. Process control will be applied in the state of data collection calculated from SDV findings to maintain an error rate with the upper bound of 5% (90% confidence) below 5%. (SDV) is performed at the site level for each patient and all expected data are received and no open discrepancies. (Data are locked for the study after all expected data are received, all discrepancies are resolved, and the database lock checked and approved. (CHF, SDM C-005, Database Lock, CHF, SDM D-009, Data lock Documentation.)

**Data sharing**

- All changes to data after the first recording in REDCap are tracked in an immutable system audit trail for traceability (9).
- Study management data are captured in REDCap during routine study operations and undergo de-identification and include: de-identified site screening, enrollment, protocol deviations, unanticipated problem reporting, risk-based monitoring indicators, and data status with manual captured through system automation. Enrollment data and status overall and by site are available daily and reported weekly for trial tracking and management by study leadership. Ongoing data in the CRC, the Research Data Coordinators monitors data collections via the monitoring and works with sites to proactively address them.

**Scientific Data to be Shared**

- Include patient level, final analytic datasets on which study publications are based and include pre-specified primary and secondary outcomes (table). Methodologies to be shared will include the REDCap audit trail for all shared data, and final versions of the study protocol, eCHF and data dictionary, Site Manual of Operations (SMO), Data Management Plan (DMP), and Statistical Analysis Plan (SAP) unless limited by the repository. UTHSC-approved sharing agreements enforce the MOP. DMP and SAP are publicly available online from the data coordinating center.

**Standards**

- List the standards to be applied to the scientific data and associated metadata.
- Lab, CRF, and patient reported data will be shared in the Clinical Data Interchange Standards (CDISC) Study Data Tabulation Model (SDTM) and include WHOOCH, MedRA, and CDRvlan exchange files. The clinical lab tests listed using the CDISC validated questionnaire. The HA GUID is used for the study participant identifier.

**Related Tools, Software or Code**

- Specialized tools, software, or code needed to access or manipulate shared scientific data.

**Data Preservation, Access, and Associated Timelines**

When and how long the scientific data will be made available. The UTHSC Library Records Retention Office will consult with the data creators/curators to determine the records retention policy and relevant sources at the data creator/curator (e.g., institutional, or at 210-453-5820). UTHSC has provided the following instruction to assist in selecting appropriate repositories for data resulting from funded research (NOT-OD-21-016).

**Data Level of Support**

- Repository Metadata Standard
- Repository Data Sharing
- Data Records Retention Period

**Access, Distribution, or Reuse Considerations**

- Any access/evaluation of the data will be determined by the investigator and will be consistent with the study DMP and any agreements for secondary use.

**Access to Unpublished Data**

- All research participants have consented for subsequent access and use of this scientific data. Access to shared data will be controlled according to the repository policy which requires a request and merit review and will be available to researchers and educators.

**Oversight of Data Management and Sharing**

Describe how compliance with this Plan will be monitored and measured, frequency of oversight, and how at whom the oversight will be performed.

**Data Management**

Data will be managed under the UTHSC CHQ Quality Management System (QMS). The CHQ QMS is described in the Facilities and Resources Section of the application and is performed by the UTHSC Patient Data Governance Committee and UTHSC Compliance. The CHQ QMS encompasses management of the personnel (CHQ-P00), data (CHQ-P005), and technology (CHQ-P004) applied by the UTHSC Data Management Plan (CHQ-P005) developed under the CHQ (https://sites.uthscsa.edu/chq/). Information and Management design and operations are led by the study CHQ and the CHQ QMS will provide web-based synchronous training on the use of the REDCap system for patient screening, consent, randomization, patient-completed questionnaires, and manual entry of study data, as well as procedures for reviewing missing and deleted data in REDCap. Data and Informatics related to the study is managed in an institutional project management and task tracking system fully specified by the Data Management Plan (CHQ-P005-001). Information and management procedures are reconciled with ROBIE and the Good Clinical Data Practices (GCP).
Example UTHSA DMS Plan Template

available at [https://lsom.uthscsa.edu/phs/resources/](https://lsom.uthscsa.edu/phs/resources/)

Grey italics: Instructions
Blue font: Example text

Green text: Specifics for Genomic Data (separate genomic sharing plans are no longer required)

Black headers designate topics required by the NIH DMS Policy
We are in a Pilot !!

available at https://lsom.uthscsa.edu/phs/resources/

Click yes to use the templates and participate in the pilot.

Participating in the pilot entails:
1. considering use of one of the two NIH templates
2. completing a survey or brief interview with a UTHSA Clinical Research Informaticist following submission of your grant to provide feedback on the NIH templates.
DMS Budget

Costs associated with data sharing:
• Are allowable
• Include costs of sharing itself as well as data management, curation, and preparation for sharing.
• Must be incurred during the performance period, even paying for data preservation or sharing beyond the award period.
• Should be broken out separately in the budget
• Should have separate budget justification text
# DMS Budget Calculator

The role:

**NOTE: If you select a role to add more than four rows you will need to resize/resize the print options under the data files (good for data dictionary).**

**NOTE 2:** This sheet uses "unit cost" methods. The Investigator indicates the (1) Role, (2) Number of Units, (3) Minutes per Unit, (4) and training time required, and (5) any non-labor costs for the activity on the row (columns B through E and G). Columns J through M are calculated as are the bold total hours per data management and sharing activity total that appear in the green shaded cell for the category in column F. **The template has some example information filled in. Change any entries not applicable to your research.**

**NOTE 3:** This sheet calculates number of hours for data management and sharing costs undertaken solely because data will be shared and for the purpose of drafting the required budget justification paragraph that breaks these cost out into the NIH-outlined Data Management and Sharing activity categories (appearing in the grey shaded rows below). Data collection and management activities to support the research itself should already be accounted for in the main project budget not here. These hours may be added to the personnel costs in the main budget. For questions or help, email informatics@uthscsa.edu or contact OSP.

## Roles and Costs

<table>
<thead>
<tr>
<th>Role</th>
<th>Hours</th>
<th>Base Pay</th>
<th>Hourly Rate</th>
<th>Fringe %</th>
<th>Hourly Rate + Fringe</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI</td>
<td>5</td>
<td>212,100</td>
<td>101.97</td>
<td>26%</td>
<td>128.48</td>
<td>642.42</td>
</tr>
<tr>
<td>Sub-I or postdoctoral researcher</td>
<td>30</td>
<td>52,600</td>
<td>12.59</td>
<td>26%</td>
<td>101.64</td>
<td>1,024.18</td>
</tr>
<tr>
<td>Research Coordinator</td>
<td>65</td>
<td>36,500</td>
<td>17.55</td>
<td>35%</td>
<td>23.69</td>
<td>1,539.84</td>
</tr>
<tr>
<td>Data Manager</td>
<td>18.5</td>
<td>97,800</td>
<td>47.02</td>
<td>35%</td>
<td>63.48</td>
<td>1,174.31</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>118.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>4,380.75</strong></td>
</tr>
</tbody>
</table>

## Data Management and Sharing Tasks

<table>
<thead>
<tr>
<th>Role</th>
<th>Number of Units</th>
<th>Minutes per Unit</th>
<th>Training Time (hours)</th>
<th>Non-labor Costs</th>
<th>Assumptions or notes for budget justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Ctr</td>
<td>4</td>
<td>180</td>
<td>12</td>
<td></td>
<td>Assume drafting a data dictionary and a protocol summary for planned projects. Two analyses (planned publications) two files per analysis (1) analysis dataset, (2) Protocol Summary, (3) Data dictionary describing shared data files. Minutes per unit includes time to read the data, generate checks, and write the data dictionary for the data dictionary. No notes for data dictionary.</td>
</tr>
<tr>
<td>Research Ctr</td>
<td>6</td>
<td>30</td>
<td>3</td>
<td></td>
<td>Minutes per unit includes time to read the data, generate checks, and write the data dictionary for the data dictionary. No notes for data dictionary.</td>
</tr>
<tr>
<td>Data Manag</td>
<td>1</td>
<td>600</td>
<td>10</td>
<td></td>
<td>Minutes per unit includes time to read the data, generate checks, and write the data dictionary for the data dictionary. No notes for data dictionary.</td>
</tr>
</tbody>
</table>

## Activity category TOTAL hours:

<table>
<thead>
<tr>
<th>Role</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Management</td>
<td>118.5</td>
</tr>
<tr>
<td>Data Sharing</td>
<td>27</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>4,380.75</strong></td>
</tr>
</tbody>
</table>
Budget Justification Template

Estimated costs for DMS is $------

Estimated effort associated with data management and sharing totals includes the [Insert roles that match those discussed in funding application AND budget such as: PI, Research Associate, Post-Doctoral Associate, and Research Assistant]. This effort (included for each of these roles in the project budget DMSP Other direct line of the budget) falls in the following DMS categories.  

Curating data for sharing: no activities under this DMS budget category are requested in this budget; the data from the analysis datasets will be shared in the analyzed format with no alteration to the shared data solely for the purposes of data sharing.  

Developing supporting documentation: The postdoctoral associate will draft supporting documentation including text descriptions of shared data and the studies from which they were generated. The largest share of the budget request in this category is driven by drafting a protocol summary, a data dictionary, and an errata for data sharing; this documentation requires knowledgeable individuals to draft data element definitions (data dictionary) for the shared analysis datasets, creating a summary of the protocol describing aspects of the study directly pertaining to shared data, and detailing known errata in the data. The remaining time devoted is for renaming and creating pdf versions of seven additional documents to be shared with the data.  

Re-formatting data and data files according to accepted community standards: No effort is budgeted for formatting data files according to community standards. The standards used support the study analysis will already be applied prior to sharing.  

De-identifying data: Shared data are from mice; no de-identification needed.  

Local Data Management considerations: There are no special local considerations.  

Preparing metadata files: The postdoctoral associate will create the metadata files required for deposition of the data from the three aims in the Texas Data Repository.  

Preserving and sharing data through established repositories: Data preservation and sharing tasks include actual deposition of data in the repository including uploading of all shared files, confirming the upload and communication with the repository to resolve questions. These tasks will be done by the postdoctoral associate. No data repository charges are requested.
Resources

- **OSP checks applications** for a DMP, DMS Budget, and Justification
  → Investigator is responsible for generating a DMP that conforms to the NIH DMS Policy

- NIH Data Management and Sharing website


- **Self-service DMSP templates** ([informatics@uthscsa.edu](mailto:informatics@uthscsa.edu))
  - Prospective clinical study
  - Clinical study relying solely on existing data
  - Prospective Animal study
  - Basic-science or other lab-based study (not involving human tissue)
  - Basic-science or other lab-based study (involving human tissue)

- Clinical Research Informatics Specialists (CRISSs) available to assist Investigators with:
  - 2-page DMSP including data sharing Repository selection
  - DMS Budget (estimate for preparing and submitting data)
  - DMS Budget Justification

- Storage space for large datasets: IMS has options!
Clinical Research Informatics (CRI) services

For all things Data + Clinical Research
- Warehouse queries
- Self-service / TriNetX access
- Recruitment lists
- REDCap access and databases
- Research Registry builds
- Data Marts
- Clinical study database builds
- Advanced information systems for clinical studies (IDEAS platform)
- Clinical study Data Coordinating Centers
- Advanced Informatics collaboration / grant aims

Service Request form ➔ [https://lsom.uthscsa.edu/phs/resources/](https://lsom.uthscsa.edu/phs/resources/)
email ➔ informatics@uthscsa.edu
Discussion?

I read your documentation; it looks like these data will meet my needs. Thank you so much!

Everything you need to use the data is right here.

I've been trying to catch you for months!

Wait! There may be data in there that I need!

It's probably there. You figure it out. 15 minutes then I'm outta here!!

VS