**Data Management and Sharing Plan**

*Data Management and Sharing Plan (DMS Plan) template for* ***Studies on Animals***

*Remove grey and blue text prior to submission. Instructions are in grey italics. Example text is in blue.*

*Add an introductory statement of (1) the entity/ies providing data collection or management services for the study, such as the organization providing data management services if different from the PI’s lab, as well as any central or core labs generating data, and (2) the main information systems used to store and process data such as a lab information system, specialized lab software, commercial or locally developed.*

***Example text:*** Study data will be managed by the *[insert name of PI, research group or lab]*, Department of *[insert Department]*, Joe R. and Teresa Lozano Long School of Medicine at the University of Texas Health Science Center at San Antonio (UTHSA). The *[Insert the name of primary software used to manage and process data such as Graphpad, Prizm, Microsoft Excel]* database will be used to manage study data. The *[insert type of samples if tissue, including blood, samples will be converted to data*] samples will be processed in the PI’s lab.

***Example UTHSA Institutional Core Lab text:*** This project will generate data through the [*insert the appropriate core lab/s Flow Cytometry, Structural Biology, Mass Spectrometry, Bioanalytics and Single-Cell, Optical Imaging, and Biobanking]* UTHSA Institutional Core Laboratories.

**Element 6: Oversight of Data Management and Sharing**

*This section should cover all sources of data. Individual data elements or variables don’t need to be stated. We suggest using a table of data sources that covers all Scientific Data, e.g., data sources from which data that will support an analysis under one of the grant/contract aims are received. The NIH DMS Policy requires statement of data sources. At a minimum, data sources supporting pre-specified primary and secondary outcomes intended for publication, are expected to be shared unless sharing is not possible*. *Data Type: the general category/ies of data that are generated or acquired from the associated data source. For example the Data Type “digital images” would be generated from a Confocal microscopy and Atomic force microscopy. Data source is the method through which data are generated or from which data are acquired. Data from the same source should be lumped into one row, such as a different parameters from Mass Spectrometry would be covered in a row labeled Mass spectrometry. Data Volume should indicate the total order-of-magnitude estimate of data size from that source (for all experimental/observational units) and for how many experimental or observational units. Proposed Repository/ies should be chosen from among the discipline-specific repositories listed in* [NOT-OD-21-016](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-016.html). *If a discipline-specific repository does not exist, a repository should be selected from the general, i.e.,* [not-discipline-specific repositories](https://www.nlm.nih.gov/NIHbmic/generalist_repositories.html) *listed on the NIH page or one that otherwise meets the requirements for repositories such as persistent identifiers, web-searchable metadata, and adherence to the* [FAIR principles](https://www.go-fair.org/fair-principles/). *Use of data standards for each data type and source of data should be indicated in the right-most columns of the table (EX: exchange standards, DE: standard data elements, CT: Controlled Terminologies, DM: Common Data Models). The researcher and core labs will be the most likely to know if discipline-specific repositories or data standards exist. If none exist state N/A rather than deleting the table; if the NIH Program Official reviewing the plan knows of any that should be used, this will prompt them to say so during the Just In Time (JIT) period when the budget can more easily be adjusted to account for any additional cost incurred by implementing the standards or by a change in repository. The actual standards used are stated later in the DMS Plan.*

***Example text:*** in blue

|  |  |
| --- | --- |
| **Table 1**: Data Types (Element 1A) and Sources (Element 1B) | Data Standards  |
| Data Type/ Categories    | Data source  | Data Volume  | Proposed Repository\*(If sharing)  | EX  | DE  | CT  | DM  |
| Mouse Phenotype data | Paper source | < 1 MB, 20 mice  | NCI/Mouse Phenome Database (MPD) | N/A  | N/A  | N/A  | N/A  |
| CD56 Expression | Flowcytometry  | < 1 MB, 20 mice | NCI/Mouse Phenome Database (MPD) | N/A  | N/A  | N/A  | N/A  |
| CD56 /pyk2 levels | ELISA, ELISPOT,  | < 1 MB, 20 mice | NCI/Mouse Phenome Database (MPD) | N/A  | N/A  | N/A  | N/A  |
| Digital Images | Confocal microscopy and atomic force microscopy  | > 1 TB, 20 mice. | NCI/Mouse Phenome Database (MPD) | N/A  | N/A  | N/A  | N/A  |
| Genomic data  | Single cell core (CyTOF, RNA Sequencing) | > 1 TB, 20 mice | NCI/Mouse Phenome Database (MPD) | N/A  | N/A  | N/A  | N/A  |

Standards (EX: exchange std., DE: Data Element std. or common data element set, CT: Controlled Terminology, DM: Common Data Model)

\* Repositories that meet NIH requirements for repositories.

Data collection and processing methods:

*In the data collection and processing methods section, for each data source in the table, state three things:*

1. *whether the data are generated by humans or electronically,*
	1. *for electronically generated and processed data how the instrumentation is calibrated, such as use of standard's or manufacturer-specified calibration procedures and how the testing processes are quality contolled like running against standards controls*
	2. *for data that are generated or processed by humans, how the processes involving humans are quality controlled, such as two raters with measured Inter-rater reliability.*
2. *any data processing that occurs after the data are generated or acquired by the researcher, and*
3. *the procedures that will be followed for human-based operations such as Standard Operating Procedures (SOPs), instrumentation Manuals, a laboratory procedure or protocol. SOPs, calibration of equipment and use of a second independent rater or independent review of a representative sample are common ways that this definition and control occurs* *for processes involving humans.*

*Systematically addressing these three things for each data source communicates that the researcher is in control of the data generation and processing and instills confidence that processes are in place to prevent errors, to detect and correct errors when they occur, and ultimately that the data will be capable of supporting conclusions.*

***Example text got one data source***: (1) Mouse phenotype data will be recorded on a paprt form and manually data entered into Microsoft Excel by lab members on the day of collection. Validations for missing data and out of range data will be added to the Excel spreadsheet to identify missing and out-of-range data. Data collection methods and processing are specified in our standard Lab MOP(Manual Of Procedures). Transformation of the data to the analysis datasets and to the sharing format required by the repository will be performed by the Biostatistician.

***Example UTHSA Institutional Core Lab text:*** The *[Core Lab name]* Institutional Core Laboratory will [*delete as appropriate: generate, store, curate, re-format]* and distribute the [*insert the type of data from Table 1 such as* Flow Cytometry, Structural Biology, Metabolomics, Lipidomics, Single-Cell, Optical Imaging, Biological sample inventory, *etc …]* data. The \_\_\_\_\_\_\_\_\_\_ data are generated from the \_\_\_\_\_\_\_\_\_\_\_\_ analyzer/equipment. The analyzer/equipment is calibrated by \_\_\_\_\_\_\_\_ [*insert statement such as running standards prior to analyzing samples for the study, or according to the manufacturer’s specifications.]* Raw data are processed by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. We anticipate \_\_\_\_\_ Mb/Gb/Tb of data will be produced (Table 1). *[Insert a statement about process control such as laboratory personnel in the core lab work according to a set of standard protocols/SOPs or Study-specific lab procedures will be created to assure consistency in data generation and processing.]* The core laboratory will store this data for a period of \_\_\_\_\_ weeks during active data collection. *If needed,* The data processing performed by staff of the core laboratory will consist of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. After this, all data will be transferred to storage devices under the responsibility of the PI.

Scientific Data to be Shared: Mouse phenotype data, lab data, final analytic datasets on which study publications are based and include pre-specified primary and secondary outcomes (Table 1).

Metadata and associated documentation to be shared:

*In the Metadata to be shared section, state any documentation that will be shared along with shared data. In general, documentation needed to interpret and use the shared data to replicate the analysis or to correctly reuse the data should be shared with the data. The list provided in the example is extensive and most often fewer associated documents need be shared.*

***Example text:*** A summary of the study/experimental/observational protocol summary/abstract, and final versions of the Mouse phenotype data collection form, the lab Manual of Operations (MOP), and Statistical Analysis Plan (SAP) will be shared unless limited by the repository.

**Element 3: Standards**

*In the Standards section, list the standards indicated in Table 1 that will be applied to the scientific data and associated metadata. If community or discipline-specific standards do not exist, that should be stated.*

***Example text:***

No community or discipline-specific standards exist for collecting mouse data. Although, Flowcytometry data output is in standard FCS file format, Confocal microscopy and Atomic force microscopy images are in TIFF file format, ELISPOT output is in CTX file format, MINSEQE (Minimum Information About a Next-generation Sequencing Experiment) used for single cell core data.

**Element 2: Related Tools, Software or Code**

*In the related tools, software or code section, list specialized tools, software, or code needed to access or manipulate shared scientific data. If no specialized software, code, or tools are needed, state this.*

***Example text:*** No specialized tools, software, or code are needed to access or manipulate shared scientific data.

**Element 4: Data Preservation, Access, and Associated Timelines**

*The data preservation, access, and associated timelines section should state when and how long the scientific data will be made available and through which repository.* *NIH has provided additional information to assist in selecting suitable repositories for scientific data resulting from funded research (NOT-OD-21-016). Local considerations for data sharing may apply such as:*

* *The UTHSA Library Records Retention Officer is available for consultation regarding the records retention policy and relevant resources at libraryrecordsmgtsvc@uthscsa.edu, or 210-450-8260.*
* *For very large data collections for which the investigator needs additional space local data storage prior to sharing or for retention locally, UTHSA IMS offers* [*local data storage options*](https://ims.uthscsa.edu/computer_networking/servers_storage.aspx)*.*
* *The Office of Technology Commercialization (OTC) is available to help with identification of and decisions about protection of Intellectual Property. If there is any chance that data should not be disclosed, contact* [*OTC*](https://otc.uthscsa.edu/)*.*

*In general, this information should be stated for each data source for which data will be shared. A table may be the most efficient and systematic way to present this information. Columns in the table include the following. Level of de-identification (if any human data are involved): Removal of the HIPAA identifiers and any information that could indirectly identify an individual. In general, de-identified information would be shared unless specific authorization has been obtained from research participants. It is best practice to state even de-identified data sharing in the Informed consent form for a study.If only animal data are used, the cell should be populated with “N/A animal data”. Repository persistent identifier is the type of permanent identifier that the repository assigns to shared data. The repository metadata standard is the standard that is used by the repository to describe the study that generated the data and the shared dataset; the PI is often the best person to complete this information and will need to provide this study-level descriptive information to the repository along with deposition of data to be shared. Data sharing start is the time at which you anticipate data sharing occurring. Note that sharing upon publication is expected unless there is justification for not doing so;in which case, the justification should be stated below the table.. Data sharing duration is the time period for which data will be shared. The records retention period is optional and was added to indicate the local retention duration.*

***Example text:*** in blue *in Table 2*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Data  | Level of de-identification  | Repository persistent unique ID  | Repository Metadata Standard | Data Sharing Start | Data Sharing Duration | Records Retention Period |
| Mouse Phenotype data | N/A animal data | Project DOI | DCAT | Publication\* | 10 years | AV |
| CD56 Expression | N/A animal data | Project DOI | DCAT | Publication\* | 10 years | AV |
| CD56 /pyk2 levels | N/A animal data | Project DOI | DCAT | Publication\* | 10 years | AV |
| Digital Images | N/A animal data | Project DOI | DCAT | Publication\* | 10 years | AV |
| Genomic data  | N/A animal data | Project DOI | DCAT | Publication\* | 10 years | AV |

\* Data will be shared at the time of an associated publication or end of the performance period, whichever comes first. AV: retention period as long as Administratively Valuable according to UTHSA record retention schedule.

***Example text:*** The scientific data generated from this study will be shared in the NCI/MPD Central Repository (https://phenome.jax.org/about/contributedata). We anticipate four publications from the proposed work. Analysis datasets for each publication will be shared through the NCI/MPD repository and indexed by a project-level repository generated DOI. Row-level shared data are linked by a unique study ID. Data for this study will be retained in the PI’s lab following the award period. Data are classified “as long as administratively valuable” by our institutional Records Retention Schedule described in UTHSA [HOP 2.2.1](https://uthealthsa.sharepoint.com/RAC/Documents/HOP/Chapter02/2.2.1.pdf). We anticipate internal retention for ten years following the award period.

**Element 5: Access, Distribution, or Reuse Considerations**

The access, distribution or reuse considerations section should s*pecify any of the following factors that impact sharing.*

1. *Factors affecting subsequent access, distribution, or reuse of scientific data*
2. *Whether access to scientific data will be controlled*
3. *Protections for privacy, rights, and confidentiality of human research participants*

***Example text:*** Access to shared data will be controlled according to the repository policy which requires a request and merit review and will be available according to repository processes.

**Element 6: Oversight of Data Management and Sharing**

The oversight of data management and sharing section states how compliance with this DMS Plan will be monitored and managed, frequency of oversight, and by whom at out institution as required by the NIH DMS Policy. The institutional oversight text below has been provided by the UTHSA VPR’s Office and OSP. Aside from inserting the PI’s name and statement of any Quality Management System in place in the lab/research group/research setting, we strongly recommend no changes. Description of the QMS under which the data will be collected and managed instills confidence in readers that the data will be capable of supporting research conclusions.

***Text Provided by UTHSA VPR’s Office and Office of Sponsored Programs:***

The PI for the project *[Investigator Name]* at the University of Texas Health San Antonio (UTHSA) will be responsible for the day-to-day oversight of data management activities and data sharing. The PI will conduct regular meetings with key study personnel to ensure quality of data entry and the timeliness of data collection, analysis, storage, and sharing. Program services are available to assist investigators in the creating and internal monitoring of NIH compliant data management plans. The Vice President for Research Office and Office of Sponsored Programs at UTHSA have created a data management and sharing plan compliance program as part of the process for submitting the annual NIH progress report. In addition, the Offices will conduct an audit at the time of publication to identify award specific data DOIs and include that information in the annual report. If needed, the Offices will work with the PI to evaluate and update the DMS as the project progresses.

*The PAGE LIMIT was initially stated by NIH as 2 pages. We understand that the limit has been extended, but a recommendation of 2 pages is still stated on the NIH site.*

[*https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing/writing-a-data-management-and-sharing-plan*](https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing/writing-a-data-management-and-sharing-plan)