UT Health San Antonio
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Department of Population Health Sciences
Clinical Research Informatics Division

STANDARD OPERATING PROCEDURE

SOP Number: CRI.SOP.DMLC-008	**Title: Data Archival and Public Data Sharing**	
Version No.: 0.0	**Effective Date: DRAFT**	**Page 1 of 5**
Supersedes Version: N/A **Dated:** N/A	REQUIRED APPROVALS BELOW	
CRI Director:	DocuSigned by: Meredith Zozus	**Date:** 3/13/2024
CISIL Approver 1:	DocuSigned by: Melanie Ezuniga Kapp	**Date:** 4/3/2024
CISIL Approver 2:	DocuSigned by: Lacy Gerwitz	**Date:** 4/3/2024

1.0 Purpose

The purpose of this procedure is to outline the processes for archival and sharing of data for clinical studies managed by Clinical Research Informatics (CRI). Effective archival and sharing facilitates reuse of data by others, often individuals not involved in the original study. It is rarely sufficient to archive or share just the data. Two common reasons for reuse of data from a study are to answer questions about the research and to answer new research questions. Archiving and sharing data necessitates inclusion of additional documentation defining and describing the data in support of reuse.

2.0 Scope

This procedure applies to study data archival and sharing performed by CRI.

This procedure applies to all CRI faculty, staff, and contract informatics employees performing data surveillance and reporting tasks.

3.0 Responsibility

3.1 The CRI Directors will ensure that all personnel who perform study data archival and sharing tasks are trained on and comply with this procedure.

3.2 The Clinical Research Informatics Specialist (CRIS) shall identify required archival and sharing of study data, and oversee archival of CRI study data and relevant documentation and where applicable sharing activities.

3.3 CRI faculty and staff who perform study data archival and sharing tasks shall adhere to this approved SOP.

4.0 References

4.1 SOP.DMLC-001 *Data Management Planning*

4.2 SOP.DMLC-003 *Data Collection and Processing*

5.0 Definitions

Data Archival: the process of moving data and associated documentation that is no longer actively used to separate storage for long-term retention.

Traceability: A characteristic of data values indicating that all operations performed on them from origination to analysis can be chronologically viewed. Traceability allows reconstruction of analysis data sets from the data source and vice versa.

6.0 Procedures

6.1 The CRIS documents in the Data Management Plan (DMP) data archival and sharing plans for a study in accordance with the specific needs of the study. These are often outlined within the study protocol, data management and sharing plan required by the funder, and other supporting documents.

6.2 The CRIS works with the study Principle Investigator (PI) and Statistician to determine the necessary archival and sharing requirements.

6.3 The CRIS determines the documentation to be archived or shared with data, matching the enumerated items to the planned reuse and available resources as well as applicable regulations, sponsor or funder requirements, or repository requirements. Items archived or shared with data range from the entire trial master file to a minimal list of documentation necessary to understand the data origination, processing, content, and format. The suggested minimal list includes the following:

- 6.3.1.1 a data dictionary or copy of the data collection form annotated with data elements, controlled terminology and data structure in which the data are archived or shared
- 6.3.1.2 the definition of each data element on the data collection form
- 6.3.1.3 the research protocol describing the study that produced the data, and
- 6.3.1.4 the study data

6.3.2 In general, shared data should be accompanied by documentation sufficient for someone not involved with the original study to understand and use the data.

6.3.3 When data processing such as de-identification, re-formatting or transposition to a common data model is planned

- 6.3.3.1 data processing will be carried out according to CRI.SOP.DMLC-004 Data Collection and Processing.
- 6.3.3.2 data processing activities will be enumerated and comprehensively described to maintain traceability between the data source and the shared or archived data for all data values.

6.3.4 The timing and logistics associated with the data archival or sharing will be fully described in the Data Management Plan according to CRI.SOP.DMLC-001.

6.3.5 The Trial PI and Statistician will review and approve the archived or shared data and associated documentation prior to archival or sharing.

7.0 SOP Deviations

Deviations from this and all SOPs are handled according to CRI.POL.001 *Clinical Research Informatics Quality Management System (QMS)*.

8.0 Review & Revisions

Review and revisions of this and all SOPs are handled according to CRI.POL.001 *Clinical Research Informatics Quality Management System (QMS)*.

9.0 Attachments

Attachment 1 Data Archival or Sharing Approval Form

10.0 Revision History (Since Last Version)

The revision history will be documented using the table shown below:

Section	Revision Date	Description of Revision

Attachment 1: Data Archival or Sharing Approval Form

This form is used to document approval of data and associated documentation for archival or sharing and location of archived or shared data. *To change archive disposal dates, the original form in the Data Management Plan must be amended with a single line through original dates and new dates provided.*

Study Name: _____

Digital Object Identifiers (DOI's) for Shared Data: or ☐ Not Applicable

☐ Costs for electronic data archive have been covered by: _____

End date of data sharing period: ___ ___ / ___ ___ ___ / ___ ___
dd mon yy

Location of Electronic Data Archive: or ☐ Not Applicable

☐ Costs for electronic data archive have been covered by: _____

Automatic disposal date for electronically archived data: ___ ___ / ___ ___ ___ / ___ ___
dd mon yy

Location of Paper Data Archive: or ☐ Not Applicable

☐ Costs for paper data archive have been covered by:_____

Automatic disposal date for paper archived data: ___ ___ / ___ ___ ___ / ___ ___
dd mon yy

CRIS: _____

Signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___
dd mon yy

Approvals:

Study Statistician: _____

Signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___
dd mon yy

Study PI: _____

Signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___
dd mon yy

Signatures indicate review and approval of data and associated documentation to be archived or shared.