UT Health San Antonio
Joe R. & Teresa Lozano Long School of Medicine

Department of Population Health Sciences
Clinical Research Informatics Division

STANDARD OPERATING PROCEDURE

SOP Number: CRI.SOP. DMLC-001	**Title: Data Management Plan Creation and Maintenance**		
Version No.: 0.0	**Effective Date: DRAFT**		**Page 1 of 16**
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: Nicolette Zuniga Rapp	**Date:**	4/3/2024
CISIL Approver 2:	DocuSigned by: Bert Berwitz	**Date:**	4/3/2024

1.0 Purpose

A Data Management Plan (DMP) provides comprehensive documentation of all operations performed on data, from collection for a study to the locked database. As such, the DMP contains essential documentation. Creation of the DMP helps achieve consensus on how data for a study will be collected, processed and stored. DMPs are maintained throughout the active data collection phase of a study and are updated to reflect current procedures as they change. As such DMP components are version-controlled and archived with study data at project close.

The purpose of this procedure is to outline the contents of and the process for creating and maintaining Data Management Plans (DMPs) as version-controlled study-specific documentation for data managed by the Clinical Research Informatics Division (CRI) at the University of Texas Health Science Center at San Antonio (UTHSA).

2.0 Scope

This procedure applies to all DMPs created by CRI at UTHSA. The CRI Data Management Lifecycle Policy (CRI.POL.003) specifies the studies where a DMP will be created and maintained. CRI.POL.003 outlines the conditions under which DMPs created or maintained by other organizations may be followed in lieu of a UTHSA DMP.

3.0 Responsibility

3.1 The CRI Directors will ensure that all CRI personnel who perform data management design and planning tasks are trained on and comply with this procedure.

3.2 The Clinical Research Informatics Specialist (CRIS) or qualified designee drafts and maintains the DMP.

3.3 The CRIS ensures that all individuals performing activities described in the DMP are trained on and comply with this procedure and the procedures outlined in the DMP prior to performing tasks outlined in the DMP.

3.4 It is the responsibility of all CRI faculty and staff to adhere to the approved DMP for a study.

4.0 References

4.1 ICH E 6, Good Clinical Practice E6(R2), March 2018

4.2 National Institutes of Health Draft Data Management and Sharing Plan Policy, November 2019 Office of The Director (OD), National Institutes of Health (2020). NOT-OD-21-013 - Final NIH policy for data management and sharing. HHS.

4.3 Office of The Director (OD), National Institutes of Health (2020). 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. HHS.

4.4 Office of The Director (OD), National Institutes of Health (2020). NOT-OD-21-014 - Supplemental information to the NIH policy for data management and sharing: elements of an NIH data management and sharing plan. HHS.

4.5 Lebedys, E. & Famatiga-Fay, C. & Bhatkar, P. & Johnson, D. & Viswanathan, G. & Zozus, M. N., (2021) "Data Management Plan", Journal of the Society for Clinical Data Management 1(4). doi: https://doi.org/10.47912/jscdm.116

4.6 Zozus MN, Chapter 4 Data Management Planning, The data book: collection and management of research data. (2017) Boca Raton FL, CRC Press Taylor & Francis Group.

5.0 Acronyms and Definitions

Term	Definition
SOP	Standard Operating Procedure
CRI	Clinical Research Informatics Division
CRIS	Clinical Research Informatics Specialist; Clinical Research Informaticist
DMP	Data Management Plan. The DMP is comprehensive documentation of data and its handling from definition, collection and processing to final archival or disposal. (Lebedys 2021)
DIR-CAPA	Deviation or Incident Report and Corrective and Preventative Action Plan Form specified in CRI.POL-001 CRI Quality Management System.
GCDMP	Good Clinical Data Management Practices
Note to File	Documentation of an event of consequence to data integrity, data quality or human safety intended to be maintained and archived with the DMP
Qualified Designee	An individual designated by an individual in the responsible role and directly overseen by the individual in the responsible role or equally qualified by training, education or experience according to the Training Matrix specified in CRI.POL-002 Human Resources Management Lifecycle (HRMLC) to perform a responsibility of the designating role.
QMS	Quality Management System. The CRI QMS is established by CRI.POL-001 CRI Quality Management System
SCDM	Society for Clinical Data Management
UTHSA	University of Texas Health Science Center at San Antonio

6.0 Procedure

6.1 Operating Principles

6.1.1 CRI maintains process documentation as work-product and in information system audit trails to the extent supported by our information systems. Thus, rather than a single document, the DMP is an index for and pointer to essential data-related documentation for a study.

6.1.2 CRI DMPs rely on the policies and SOPs in the CRI QMS where standard procedures are appropriate and can be used for a study. As such,

6.1.2.1 CRI DMPs reference rather than re-state information in this higher-level QMS documentation.

6.1.2.2 Unless the Clinical Research Informaticist (CRIS) or designee elects otherwise, once an SOP or policy is relied upon or referenced by a study DMP, the study is grandfathered and may continue to operate on the initially referenced version of the SOP.

6.1.3 DMPs generally specify project-specific procedures describing how data are collected and processed in sufficient detail for all operations within the CRI scope of work and performed on study data to be reproduced.

6.1.4 Where study-level procedures are consistent across a group of studies such as those in a drug development program or conducted by a clinical research network, a DMP may cover more than one study.

6.1.5 All versions of DMP components used for a study will be maintained in the CRI Project Management System (PMS). This association with a study will be maintained throughout the records retention period applicable to the study.

6.2 Creating a New DMP:

6.2.1 The CRIS or qualified designee will ensure that a DMP is available for each new study for which CRI is providing professional services prior to the start of data system development or the start of data collection for the study.

6.2.1.1 Where contractually specified, a DMP drafted and maintained by another organization may be used with approval from a CRI Director.

6.2.1.2 In all other cases, except where documented by a waiver obtained from a CRI Director, a DMP will be developed and maintained for studies for which CRI is providing professional services such as taking responsibility for data acquisition, processing, storage or provision.

6.2.2 The CRIS or qualified designee will create the DMP covering the DMP Table of Contents (Attachment 2) items relevant to the informatics scope of work for the study.

6.2.2.1 The CRIS will use the current version of the DMP Table of Contents Form (Attachment 2) to indicate DMP sections not relevant to the CRI scope of work for the study. The documentation corresponding to these sections will not be expected as part of the DMP.

6.2.2.2 Documentation for DMP sections may be described in detail within the DMP sections listed on the DMP table of contents (Attachment 2) or by reference to the storage location of equivalent documentation (whether study specific or organizational guidelines).

6.2.2.3 The CRIS will use the current DMP Table of Contents Form to indicate DMP sections for which procedural documentation from other sources will be used or for which documentation is stored in locations other than the DMP itself.

6.2.2.4 All such documents comprising the DMP are subject to version control and the appropriate version number shall be included on the DMP Table of Contents.

6.2.3 The CRIS or qualified designee will circulate drafts of DMP components requiring documentation of approval by signature to those from whom approval is required. Broader circulation within and input from the study team informs processes and is encouraged.

6.2.4 The CRIS or qualified designee will make updates and modifications to the DMP in accordance with the review comments, as appropriate.

The review is an iterative process and will continue until DMP components requiring approval are approved.

6.3 DMP Approval:

6.3.1 The CRIS or qualified designee will send the final version of DMP components requiring approval to a CRI Director, the study Principal Investigator (or equivalent clinical leadership) and the study Statistician for final review and approval.

6.3.2 Multiple DMP components are considered essential documents for a study according to ICH E6(R2) and will be maintained as a version-controlled document as specified herein. All approved versions will be preserved by saving a read-only copy on the project record in the CRI Project Management System (PMS).

6.3.3 The CRIS or qualified designee is responsible for the review and revision of all DMPs as outlined in Section 6.7 *DMP Review & Revisions*.

6.4 DMP Implementation:

6.4.1 The CRIS or qualified designee will distribute all new versions of the DMP (DMP components) to personnel performing tasks specified and controlled by the DMP.

6.4.2 The CRIS will ensure that personnel impacted by procedural changes in the DMP understand the changes.

6.4.2.1 Depending on the extent of the changes, this may be accomplished through documented training, explanation in team meetings or team members verbally acknowledging the changes.

6.4.2.2 Where existing process controls are insufficient to detect lack of adherence to the changes, the CRIS is encouraged to personally check fidelity by work review and documenting such in a note to file.

6.5 DMP Deviations:

6.5.1 All unplanned deviations from procedures outlined in the DMP shall be documented on the Deviation or Incident Report and Corrective and Preventative Action Plan Form (DIR-CAPA). The DIR-CAPA form and process is specified in CRI.POL-001 CRI Quality Management System.

6.5.2 Incident reports with project impact shall be maintained with the DMP in the section for project- or program-specific DIR-CAPA forms.

6.6 Retention of Documentation:

6.6.1 DMP components are version-controlled and are maintained throughout the life of a project and archived with project data.

6.6.2 The retention period applicable to the covered project or projects is documented on the DMP table of contents.

6.7 DMP Review & Revision:

6.7.1 The DMP shall always reflect current project processes and procedures.

6.7.2 All substantive revisions, i.e., changes to processes, to DMP components requiring review and approval will be circulated for approval according to the DMP approval process (see Section 6.3).

6.7.3 The DMP component signatories must review and approve all substantive versions of DMP components.

6.7.4 Minor revisions to DMP components, i.e., grammatical changes that do not alter data acquisition, storage, processing, or release, can be addressed outside of the formal approval process, as these will not require signed approval. Such non-substantive updates shall be documented as such on the updated version.

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: DMP Workflow Diagram

Attachment 2: DMP Table of Contents Template and Explanation of DMP Contents

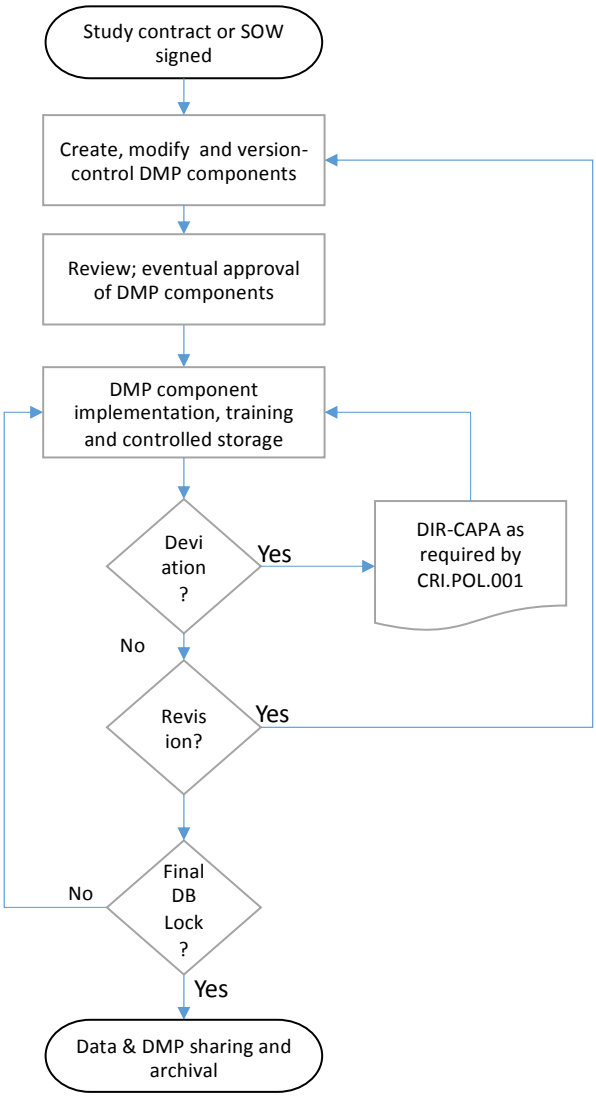
Attachment 3: Guidelines for Determining Data Quality Assessment and Control for Data Sources

Attachment 4: Data Management Plan Component Approval Form

10.0 Revision History

Version No.	Revision Date	Description of Revision
0.0	10/29/2021	This is a draft procedure for trial use.

Attachment 1: DMP Creation and Maintenance Process



Attachment 2: DMP Table of Contents Form (CRI.SOP.DMLC-001.FRM-001)

DMP Section	Version Date	Location
Protocol or Protocol Summary		☐ N/A ☐ DMP **OR** Directory/URL:
Human Subjects Protection information sheet		☐ N/A ☐ DMP **OR** Directory/URL:
CRI Personnel Log or Study Personnel Log		☐ N/A ☐ DMP **OR** Directory/URL:
CRI Scope of Work (deliverables, milestones and timelines) and budget		☐ N/A ☐ DMP **OR** Directory/URL:
Original DMP created to comply with NOT-OD-21-013 and accepted with an NIH award and NIH DMP updates		☐ N/A ☐ DMP **OR** Directory/URL:
Communication plan (required reporting and event escalation path)		☐ N/A ☐ DMP **OR** Directory/URL:
Data sources i) Context / Data Flow Diagram (DFD) ii) Work Flow Diagram (WFD)		☐ N/A ☐ DMP **OR** Directory/URL:
Data collection forms / Case Report Forms (CRF)*		☐ N/A ☐ DMP **OR** Directory/URL:
Annotated CRF for study logical data model/s **		☐ N/A ☐ DMP **OR** Directory/URL:
Data Element Definition*		☐ N/A ☐ DMP **OR** Directory/URL:
Data quality checking rules (edit checks)*		
List and documentation of data systems used for data collection, processing or storage^		☐ N/A ☐ DMP **OR** Directory/URL:
Instrumentation calibration & maintenance^		☐ N/A ☐ DMP **OR** Directory/URL:
Data acquisition procedures^ Site Data Sources form (CRI.SOP.DMLC-004.FRM-001) Study Data Integration Form (CRI.SOP.DMLC-003.FRM-001)		☐ N/A ☐ DMP **OR** Directory/URL:
Data processing procedures**, ^ Study Data Collection and Processing Plan Form (CRI.SOP.DMLC-004.FRM-002)		☐ N/A ☐ DMP **OR** Directory/URL:
Data-assisted or alerted trial operations ^		☐ N/A ☐ DMP **OR** Directory/URL:
Data quality control procedures*		☐ N/A ☐ DMP **OR** Directory/URL:
Database Lock Checklist* and forms^ Database Freeze and Lock Form (CRI.SOP.DMLC-006.FRM-001)		☐ N/A ☐ DMP **OR** Directory/URL:
Data sharing plan* Data Release Form (CRI.SOP.DMLC-007.FRM-001)		☐ N/A ☐ DMP **OR** Directory/URL:
Data archival and disposal plan* Data Archival or Sharing Form (CRI.SOP.DMLC-008.FRM-001)		☐ N/A ☐ DMP **OR** Directory/URL:
Applicable data retention period		☐ N/A or years from or Data will be retained until: (date):
Privacy and confidentiality*		☐ N/A ☐ DMP **OR** Directory/URL:
Project- or Program-specific DIR-CAPA forms^		☐ N/A ☐ DMP **OR** Directory/URL:

*Requires project or program PI and Statistician approval. **Statistician-only approval.
^Generates process documentation in addition to any approval signatures.

All DMP documentation is subject to version control and the date of the current version included in the DMP.

Guidelines for DMP Section Content

Additional detail may be found in the GCDMP Data Management Plan Chapter.

a) **Protocol Summary**: This section shall include a paragraph summary of current protocol or serve as an index to where the study protocol and all amendments are stored at UTHSA.

b) **Human Subjects Protection information sheet**: This form is required under the CRI Umbrella IRB protocol when CRI is performing research activities on studies where the UTHSA IRB is not the IRB of record for a study and not relying on the IRB of record for a study.

c) **Scope of Work and Budget**: The actual SOW and budget for CRI are stored on the project record in the Project Management System (PMS). This section should include the PMS project name and other identifiers sufficient to locate the study scope of work and budget. The current and historical versions of the study capacity plan maintained by the CRIS should also be stored in the PMS and indexed here.

d) **Original NIH DMP Accepted With An NIH Award**: As of January 25, 2023, all applications for NIH funding require a two-page Data Management Plan (NOT-OD-21-013 – Final NIH Policy for Data Management and Sharing). The version of the DMP submitted with the application should be stored in this section unless updated in response to summary statements or a Just In-Time (JIT) request, or as a condition of award. The original DMP from the time of award is the record of the original plans for data management and sharing. If drafted by CRI, the application DMP will state that the DMP for the proposed research will be maintained according to CRI.POL.003 and the CRI DMP SOP. All updated versions of the NIH DMP shall be stored in the DMP. The DMP components for the study should be consistent with the NIH DMP or implemented with an NIH DMP revision pending and offered to the NIH Project Official responsible for reviewing the NIH DMP when such reviews take place. NIH program official reviews of NIH DMPs may not occur until the annual progress report for the NIH award.

e) **Documentation of Personnel and Role on the study**: Documentation of personnel and role serves as an index of CRI personnel taking actions on study data. This documentation will assist an auditor in connecting the identity of an individual with operations performed on data such as data changes documented in system audit trails and DIR-CAPA forms. The UTHSA IRB Study Personnel form may be referred to in this section. All personnel with access to study data or study participants should be listed on the IRB personnel form. If a separate study log is needed for additional detail, it should be included or referenced in this section.

f) **Project communication plan Communication plan (and event escalation path)**: This section shall include or index:
   i) A list of required reporting undertaken or supported by CRI such as study metrics and status reports and the location where study reports are provided to the research team (and others if applicable) and where copies of distributed reports are stored.

ii) Statement of the escalation path by which study risk and problems are reported if other than that outlined in the DIR-CAPA process in the CRI QMS Policy (CRI.POL.001)

g) **Data sources**:

i) Data Flow Diagram (DFD): All study data sources shall appear on a high-level Data Flow Diagram (DFD) that shows all data crossing the boundary of the CRI QMS. This high-level DFD is also referred to as a context diagram and should fit on one page.

ii) Work Flow Diagram (WFD): A similarly high-level work flow diagram should accompany the DFD and show the sequence of steps in data acquisition and processing starting with data origination and terminating at the clean-file for a patient.

Chapter 11 of The Data Book, Designing and Documenting Data flow and Workflow, covers the symbol sets and conventions that should be used for the DFD and WFD.

h) **Data collection forms / CRFs**: This section shall contain or index all implemented versions the CRFs or eCRF and Form Completion Instructions (also called CRF Completion Guidelines, CCGs). Information systems such as REDCap and IDEAS that track all form changes are the preferred source of this information for studies using eCRFs. If paper CRFs or CCGs are also generated by CRI they shall be included or indexed in this section.

i) **Annotated CRF/s for logical data model/s used for the study**: This section shall contain or index the logical data models in which study data are stored or delivered. There may be more than one. The purpose of an annotated form is to explicitly show where each data value collected on the form is stored in the database or where each data value collected on the form is found in delivered data. Table, data element and valid value level information should be included. Information systems such as REDCap and IDEAS store and track changes to the data dictionary and are the preferred source of this information for studies using them. Where study data are provided in a data model other than the study database, an annotated form should be included for each logical data model used.

j) **Data Element Definition**: Data element definition including the data element name, prompt, definition, data type, and valid values shall be included or indexed in this section. Where standard data elements are used, a data element ID that provides a one-to-one link to this information will suffice. Information systems such as REDCap and IDEAS store and track changes to data element definition and are the preferred source of this information for studies using them.

k) **Data quality checking rules (query rules, data validation checks, edit checks)**: Query rule definitions and changes to rules shall be included or indexed in this section. Information systems such as REDCap and IDEAS store and track data quality checking rules and changes to them and are the preferred source of this information for studies using such systems.

l) **List of data systems used and versions**: For each system used to collect, process or otherwise manage study data the following information shall be included or indexed in this section:
   i) System name and all versions used for the study
   ii) Location of validation or testing documentation and release
   iii) List of system interfaces
   iv) System Access and Privileges Matrix for system roles used in the system for the study
   v) System security processes followed for data at rest and in transit
   vi) Back-up and recovery processes followed
   vii) Organization managing the servers or otherwise hosting the data system

m) **Instrumentation, Calibration & Maintenance**: This section shall include or index manuals for instrumentation provided by UTHSA and used to acquire data for the study. If other than specified in the manual, calibration procedures shall be included or indexed in this section.

n) **Data Acquisition**: This section shall include or index study-specific procedures followed for data origination and collection. These are generally documented in the Manual of Procedures distributed to sites in the study.

o) **Data processing**: This section shall include or index study-specific procedures followed for data processing. All operations performed on data not otherwise documented shall be included or indexed here.

p) **Data-assisted or alerted trial operations**: This section shall include an index the rule specifications (and changes to specifications) for rule-based automation and decision support such as workflow, signal detection, or alerts implemented within CRI maintained information systems used for the study. Information systems such as REDCap and IDEAS store and track workflow and alert rules and changes to them and are the preferred source of this information for studies using such systems.

q) **Data Quality Control (DQC)**: This section shall describe of index description of all error-rate-based Data Quality Control used for the study and the acceptance criteria for each. Specification of other relevant dimensions of Data Quality measured, description of the measurement method, and the acceptance criteria used should also be included in this section. The results of DQC or their storage location shall be documented in this section. The report, other statement of findings and Corrective And Preventative Action (CAPA) responses from all independent audits of the study shall be included in this section.

r) **Database Lock Checklist**: This section shall include or index all versions of the Database Lock Checklist and associated documentation including database lock and unlock approval forms.

s) **Data Sharing Plan**: This section shall include or index all versions of the data sharing plan. For federally funded studies, the data sharing plan included in the grant application shall be obtained from the study PI and serve as the initial record in this section. Requirements for data sharing plans may be found in

NOT-OD-21-014 - Supplemental information to the NIH policy for data management and sharing: elements of an NIH data management and sharing plan.

t) **Data Archival and disposal plan**: This section shall include or index all versions of the data archival plan. In general, a data archiving plan lists items to be archived, formatting requirements for data archival, responsibilities and plan for disposal of data, and the how sites will receive a copy of their data. The data retention period applicable to the study shall be documented on the DMP table of contents.

u) **Privacy and Confidentiality**: Other sections in the DMP will contain information about privacy and confidentiality. This section shall provide a comprehensive outline of the privacy and confidentiality requirements applicable to the study and include or index the plans for assuring compliance. Any de-identification required during active data collection, processing, retention or sharing should be described in this section, as should procedures for handling PHI inadvertently disclosed by sites or other organizations involved in study conduct to CRI in transferred data or on source documents.

v) **Project- or Program-specific DIR-CAPA forms**: This section shall include or index DIR-CAPA forms pertaining to the study or program covered by the DMP as outlined in CRI.POL.001. Notes to file documenting incidents not rising to the level of a DIR-CAPA may also be included or indexed in this section.

These items may be described in detail within the DMP or by reference to other documents (whether study specific or organizational/company guidelines). All such documents must be subject to version control and the appropriate version number included with the reference in the DMP.

Attachment 3: Guidelines for Determining Data Quality Assessment and Control for Data Sources

The data lifecycle can span decades and in many cases is partitioned across multiple organizations. It is common for some data for a study to originate or to be processed outside the controls of the CRI QMS. Examples of data originating outside the controls of the CRI QMS include data collected from medical records at clinical investigational sites, and Electronic Health Record (EHR) data obtained from institutional data warehouses. Examples of data processed outside the controls of the CRI QMS include data processed at external labs or central reading centers. Data origination and processing outside the controls of the QMS limit data quality assessment or error correction. Discrepancy detection and resolution are optimally performed as controls at data origination. Discrepancies detected downstream, such as when data later enter the CRI QMS are more expensive to correct or may not be correctable. Data processed outside CRI require data transfer and integration or system interfaces to enable data use during a study for things such as alerts, workflow automation, and reporting.

Any combination of data origination and processing within or outside the CRI QMS (quadrants in the Figure) may occur for a study managed by CRI. Studies often require multiple sources of data. Different data sources may fall in different quadrants. The quadrant for a data source determines the extent of data quality control possible, i.e., whether it is possible to manage the error rate to a desired acceptance criterion. Thus, classification of data sources according to collection and processing options, determines implications for data quality control and ultimately the data quality achievable by CRI.

Data Origination \ Data Processing	Within QMS	Outside QMS
Within QMS	Full DQC and AC are available.	Data origination DQC available. Outgoing AC available.
Outside QMS	Obtaining incoming error rate recommended. Data processing DQC available. Data processing AC available.	Data quality assessment or incoming error rate recommended. DQC not available. AC not available.

Figure: Options for Data Quality Control (DQC) and certification that data meet Acceptance Criteria (AC) for data originating and processed within and outside the CRI QMS. For data originating outside the CRI QMS (bottom row in the figure), origination DQC is not available and an origination AC cannot be applied. It may not be possible for CRI to measure the origination error rate. For data processed outside the CRI QMS (right column in the figure) processing DQC is not available and a processing AC cannot be applied. It may not be possible for CRI to measure the data processing error rate. Data originating and processed outside the CRI QMS are treated as secondary use data; CRI has no control over data origination, collection or processing. All other combinations offer opportunities for origination or processing DQC, for building in an accuracy assessment, and for measurement of origination or processing error rate. Data originating and processed within the CRI QMS allow documentation of the dataset error rate.

Data originating outside the controls of the CRI QMS. Examples include, data collected in national surveys and captured during routine care. Unless planned into the initial data collection, data originating outside the CRI QMS often, lack an independent source of information that could be used in assessing the quality of the data. This precludes measuring accuracy and correcting errors detected in pre-existing data at the time of secondary

use. Thus, CRI does not "clean" or otherwise attempt to correct pre-existing data. Incoming data can be screened and discrepancies can be reported back to the data provider who may be able to make corrections, maintain traceability of the changes, and resend the data.

Data originating within the controls of the CRI QMS. An independent source of information can be designed into data-generating procedures. The independent source of information can be used to detect and correct errors at data origination. An error rate can be provided.

Data processed or managed outside the controls of the CRI QMS. In the absence of an independent source of information, the accuracy of data generally cannot be measured. In this scenario, limited opportunities exist for correcting data errors at the time of secondary data use. In the absence of an independent source of information, CRI cannot "clean" or otherwise attempt to correct pre-existing data. Incoming data can be screened and discrepancies can be reported back to the data provider who may be able to make corrections, maintain traceability of the changes, and resend the data.

Data processed or managed within the controls of the CRI QMS. Data processing errors can be detected as differences from initial data. The data processing error rate can be measured and controlled.

Data originating and processed or managed within the controls of the CRI QMS. An independent source of information can be designed into data-generating measurement or assessment procedures and used to detect and correct errors at the time of data origination. Data processing errors can be detected, and the data processing error rate can be measured and controlled. An absolute error rate can be provided across the data lifecycle.

In all cases, it is our policy (CRI.POL.003) to explicitly classify and describe to the investigator the limitations of data that originate or are processed outside the controls of the CRI QMS.

In the case of **data originating or processed outside the controls of the CRI QMS**, the following options for measuring data quality include:

A. pursue data quality assessment outside CRI

B. where data quality measurement is possible, include quality assessment of data originating or processed outside CRI in the CRI scope of work, or

C. refrain from data quality assessment.

The latter may be the optimal choice in the case of data posing little or no risk to the intended analysis or decision-making.

In the case of **data originating within the controls of the CRI QMS**, data quality measurement and control options include:

A. Collection of contemporaneous and independent data, or collection of corroborating independent data for use in

    a. detecting and correcting errors,

    b. adding process control to achieve a desired acceptance criteria

    c. refraining from contemporaneous detection and correction or control of errors.

B. Application of contemporaneous data error checks at the time of data origination that compare data to known values, ranges, or expected results of established logical relationships where possible to ensure

the consistency of data by detecting instances in inconsistency at data origination so that errors can be corrected (Error rate measurement is not possible for option B.)

C. Application of data error checks after data origination that compare data to known values, ranges, or expected results of established logical relationships where possible to detect and report discrepancies (In some cases, discrepancies can be investigated and those determined to be errors can be corrected.)

Data quality measurement and control add effort and cost to the project. They may or may not be necessary depending on the measurement or observation processes through which data are generated. Option A is the only option for which data quality meeting an acceptance criterion can be guaranteed.

Data processed by CRI are processed within the controls of the CRI QMS, the data processing error rate can be measured and controlled such that the investigator can expected the processing error rate to fall within the data processing acceptance criteria in the project scope of work.

a. adding control to detect and correct data processing errors

b. adding process control to achieve a desired acceptance criterion

c. refraining from detection or control of data processing errors.

10.1

Where the CRI Scope of Work includes quality assessment activities for external data. The data quality assurance or assessment activities and their limitations are documented in the Scope of Work.

Where the CRI Scope of Work includes quality assessment, if repeated data quality assessment using the same method and on the random sample the size agreed in the Scope of Work do not fall within the originally agreed acceptance criteria, where possible, the data will be remediated by CRI at no cost to the investigator until the specified measures meet the acceptance criteria agreed in the Scope of Work or another mutually agreeable resolution is reached.

In all cases, known or encountered problems with the data will be reported to the Investigator at the time of the request and as they are encountered.

The level of quality needed and the data collection and processing methods selected are Investigator decisions.

The fitness of the data for project use and claims made based on analysis of the data are Investigator decisions.

Attachment 4: Data Management Plan Component Approval Form (CRI.SOP.DMLC-001.FRM-002)

This form is used to document required approvals on Data Management Plan Components.

DMP Component:

Approvals:

PI: _____ or ☐ N/A for DMP component

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

Study Statistician: _____ or ☐ N/A for DMP component

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

CRI Director: _____ or ☐ N/A for DMP component

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

Signatures indicate review and approval of the DMP Component.