

**Data Management
DM – 401.01**

**STANDARD OPERATING PROCEDURE FOR
Data Management**

Approval: Lynn M. Durham, Ed.D.
President and CEO

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(Signature and Date)

Approval: Frederick M. Schnell, MD, FACP
Chief Medical Officer

04 Feb 2021

(Signature and Date)

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Reviewer: Jane Clark, PhD, RN, AOCN, OCN (2020)
Previous Reviewers: Joni Shortt, BSN, RN, CCRC (2017)
Alice Kerber, MN, APRN (2014)
Primary Author: Anita Clavier, BSN, MPH (2013)

1. INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) described the processes Georgia CORE staff and consultants use to monitor sites to ensure appropriate and accurate data collection, entry, and management.

2. SCOPE

This SOP applies to data management for all clinical studies subject to investigational new drug (IND) regulations for drugs and biologics or those eligible for investigational new drug (IND) exemption during all investigational phases or development.

3. APPLICABLE REGULATIONS AND GUIDELINES

The Code of Federal Regulations and the International Conference on Harmonization, Good Clinical Practice: Consolidated Guideline and selected program and guidance documents apply to this SOP (Appendix A).

4. REFERENCES TO OTHER APPLICABLE SOPs

GA-102	Sponsor Responsibilities and Delegation of Responsibilities
SS - 203	Pre-study Site Visit
SS - 204	Site Initiation Visit
SS - 301	Communications
SS - 303	Documentation and Records Retention
SS - 304	Routine Monitoring Visits
SM - 305	Closeout Visits
QA - 601	FDA or Pharmaceutical Sponsored Audits

5. ATTACHMENTS

- A. Source Documentation Requirements
- B. Data Clarification Form

6. RESPONSIBILITY

This SOP applies to those members of Georgia CORE research network involved in data collection, entry, and management. Members include the following:

- President and CEO
- Georgia CORE staff and consultants
- Site Investigator/Subinvestigators and research team members conducting clinical trials

7. DEFINITIONS

The following definitions apply to this SOP (Appendix B):

Audit trial
Case Report Forms (CRFs)
Confidentiality
Documentation
Essential Documentation
Quality Assurance (QA)
Source Data
Source Documents

8. PROCESS OVERVIEW

- A. Collection of research data
- B. Entry of data to case report forms (CRFs) including remote data entry
- C. Management of the data including procedures for quality control, data query resolution, and record retention and archiving

9. PROCEDURES

A. Collection of Research Data

Georgia CORE staff and consultants

Review the protocol to ensure that it describes in detail appropriate methods for collecting, evaluating, correcting, transcribing, and transmitting subject data. If not, obtain the information from the investigator initiating the study.

Train key Research Network site personnel at participating sites on how to collect, evaluate, correct, transcribe, and transmit the data onto the CRFs or other data collection forms.

Ensure that Research Network site staff are complying with source documentation requirements (Attachment A) during monitoring visits.

B. Entry of Data to Case Report Forms (CRFs) including Remote Data Entry

Georgia CORE staff and consultants

Ensure that Research Network site staff is:

- recording and transcribing all subject data that is consistent with source documentation, complete, and legible,
- completing all fields in the CRFs according to protocol and training specifications,
- correcting errors by striking through the error, dating and initialing the entry, and making the correction, ensuring the original entry is not obliterated. If necessary, enter an explanation in the margin.

If remote data entry is required, check with the Research Network site staff to:

- determine that they have the following information regarding remote data capture:
 - hardware and software necessary to comply with regulatory and protocol requirements concerning remote data entry,
 - names and contact information for support services associated with the system,
 - manual of instructions and operations,
 - certificates of training on the remote data capture system,
 - source documentation worksheets and/or CRF used, if applicable,

- data entry personnel requirements,
- security procedures,
- storage of data and requirements.
- ensure that only Research Network site staff trained on the system will enter data for the study using their unique and private Username and Password,
- ensure that training certifications for eCRFs are filed with the regulatory documents,
- determine if the Research Network site staff have specific subject instruction materials for use in the study if remote data capture device/equipment is to be provided to subjects and that the materials have been submitted to the IRB for review and approved, and
- ensure that data is entered promptly, according to study specifications from the source documentation.

C. Management of the Data Including Procedures for Quality Control, Data Query Resolution, and Record Retention and Archiving

Georgia CORE staff
consultants

Quality Control

Assess CRF completion status at selected monitoring visits conducted during the course of the study and at the closeout visit when the study is completed or otherwise suspended or terminated.

Document any discrepancies noted at the monitoring visit on the Data Clarification Form (DCF) (Attachment B) for each subject monitored to ensure an audit trail for clarifications and corrections.

Ensure that the Research Network site staff collect any discrepancies noted during the monitoring visit on their own Data Clarification Form and that they keep the Data Clarification Form with copies of the corresponding CRF in the appropriate study and participant files.

Compare both versions of the completed Data Clarification Forms to verify they are identical.

If not monitoring immediately after the first sets of CRFs are completed, check with the Research Network site staff that the first sets of completed CRFs are reviewed for completeness and accuracy by another member of the Research Network site staff or by another designated individual.

Georgia CORE staff and consultants

Data Query Resolution

Discuss errors on the CRF to the Research Network site staff who should correct the CRFs using the procedures described above prior to the completion of the monitoring visit.

If CRFs are electronically retrievable from the Research Network sites between monitoring visits, errors are discovered, contact the Research Network site staff, and a request that the CRF be corrected as required and resubmitted. A copy of the record of the request for correction is to be retained at the Research Network site (Attachment B).

Document that data management procedures are not being followed by the Research Network site staff, discuss with the Research Network site Investigator/Subinvestigator, and develop and implement a corrective action plan (e.g., retraining). Report all findings to the Georgia CORE President and CEO.

In case of non-compliance with data management procedures on an ongoing basis, document the pattern of non-compliance, including corrective actions implemented, and provide a copy of the documentation to the Georgia CORE President and CEO.

In cases of continuing non-compliance, institute Research Network site termination procedures when authorized by the Georgia CORE President and CEO.

Georgia CORE staff and consultants

Record Retention and Archiving

At conclusion of the study, Research Network site staff:

- review data to be retained according to regulatory and Georgia CORE procedure requirements (See Attachment A SOP SM-303.01 Documentation and Records Retention),

- obtain written approval from Georgia CORE prior to destroying any study-related data,

D. History of Changes

Version Number	Section Number	Modifications	Approval Date
401.00	All	Original Version	
401.00	All	No change necessary	09 March 2012
401.00	All	No change necessary	01 June 2014
401.00	3, 6, 9B, Attachment A	Remove old resource, add new recourse, clarification changes	01 January 2017
401.01	All	Edits for clarification	30 June 2020

ATTACHMENT A: Source Documentation Requirements

For each study, source documentation to support case report form data should include the following:

1. Date of entry into the study, protocol number, and subject number.
2. Note that written informed consent was obtained; consent form dated and signed by subject (or subject's representative).
3. Record current medications and medications discontinued 30 days prior to study start and 30 days (or longer, as specified by the protocol). Information includes medication name, dosage, route of administration, frequency, start date, and end date.
4. Record diagnosis and status of the subject prior to treatment, including documentation of medical history, particularly that relevant for the disease or condition being treated as required by the protocol.
5. Record names of study drugs ~~and~~, dosing times, and calculations of dose.
6. Maintain signed orders for study drugs
7. Document the dates and the ~~results~~ evaluation of results and procedures required by the study; note any deviations from the protocol and provide an explanation.
8. Record any reported complaints or adverse events that occurred ~~during~~ during the treatment period and for a period specified by the sponsor following the last dose of study drug. Record any treatment administered and/or recommended. Information of any adverse event (AE) should include AE name, date started, date ended, causality, grade per current (protocol specified) Common Terminology Criteria for Adverse Events (CTCAE -Version specified by the protocol) and specify whether it was a serious adverse event. Document that any serious adverse events are reported to the appropriate regulatory agencies and the IRB.
9. Record condition of the subject during and/or after treatment.
10. Document final disposition of the subject and subject status at time of study termination.

**ATTACHMENT B:
Data Clarification Form**

Study Number/Title: _____

Investigator: _____ Site staff and title: _____

Monitor: _____ Visit Date: _____

Pt. #	Initials	CRF Page	Query/Clarifications	Resolved Initials/ Date	Verified Initials/ Date

Monitor's Name (Print) Signature Date

Research Network Site Staff Name (Print) Signature Date