Data Management
DM – 401.00

STANDARD OPERATING PROCEDURE FOR
Data Management

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I. INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) describes the processes Georgia CORE monitors at sites to ensure the appropriate collection of clinical research data, transcription of the data to case report forms (CRFs), and the management of the data.

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 of development.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 11	Electronic records; Electronic signatures
21 CFR 312.50	General responsibilities of sponsors
21 CFR 312.56	Review of ongoing investigations
21 CFR 312.60	General responsibilities of investigators
21 CFR 312.62	Investigator recordkeeping and record retention
21 CFR 312.64	Investigator reports
21 CFR 312.68	Inspection of investigator's records and reports
21 CFR 312.70	Disqualification of a clinical investigator
FDA Information Sheets, October 1995	Recordkeeping in Clinical Investigations
October 2009	Guidance for Industry Investigator Responsibilities---Protecting the Rights, Safety, and Welfare of Study Subjects
May 1997	International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline
March 1, 2014	NCI Guidelines for Auditing Clinical Trials for the NCI National Clinical Trials Network (NCTN) Program, NCI Community Clinical Oncology Program (NCORP) and Research Bases

4. REFERENCES TO OTHER APPLICABLE SOPs

GA-102	Sponsor Responsibilities and Delegation of Responsibilities
	Pre-Study Site Visit
SS-203	Site Initiation Visit
SS-204	
SM-301	Communication
SM-303	Documentation and Records Retention
SM-304	Routine Monitoring Visits
SM-305	Closeout Visits
QA-601	Audits by Third Parties

5. ATTACHMENTS

A. Source Documentation Requirements
B. Data Clarification Form

6. RESPONSIBILITY

This SOP applies to those members of Georgia CORE involved in data collection, transcription to CRFs, and the management of the data. This includes the following:

- President and CEO
- Georgia CORE staff and consultants
- Site Coordinators conducting clinical trials

7. DEFINITIONS

The following definitions from the International Conference on Harmonization, Good Clinical Practice: Consolidated Guideline, apply to this SOP.

Audit Trail: Documentation that allows reconstruction of the course of events.

Case Report Form (CRF): A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject.

Confidentiality: Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

Documentation: All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

Essential Documents: Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

Quality Assurance (QA): All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with GCP and the applicable regulatory requirement(s).

Source Data: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

Source Documents: Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).

8. PROCESS OVERVIEW

A. Collection of research data
B. Transcription of the data to case report forms (CRFs), including remote data entry
C. Management of the data, including procedures for:
- Quality control
- Data query resolution
- Record retention and archiving

9. PROCEDURES

A. Collection of research data

• Research Staff/Consultant	Review the protocol to ensure that it describes in detail, appropriate methods for collecting, evaluating, changing and transmitting subject data. If not present in the protocol, obtain the information from the Investigator initiating the study. Instruct key study personnel at the sites on how to collect, transcribe, correct, and transmit the data onto the CRF or other data collection forms and logs. Train key study site staff on proper correction of incorrect data entries. Check with the site staff that they are following source documentation requirements (Attachment A). Examine clinical study data collected and held at the sites, in relation to the source documents, during monitoring visits.

B. Transcription of the data to case report forms (CRFs), including remote data entry

• Research Staff/Consultant	Check that the site staff is: • recording all documentation clearly and legibly. • transcribing data onto the CRF in a timely manner from the source documentation • completing all fields in the CRFs according to protocol and training specifications • correcting errors by striking through the error, dating and initialing it, and making the correction, ensuring the original entry is not obliterated and, if necessary, an explanation is noted in the right margin.
• Research Staff/Consultant	If remote data entry is required, check with the site staff to: • determine that they have the following information regarding remote data capture: o Hardware and software necessary to fulfill protocol requirements concerning remote data capture o Names and contact information for support services associated with the system o Manual of instructions/operations o Certificates of training on the remote data capture system o Source data worksheets and/or CRF used (if applicable) o Data entry personnel requirements o Security procedures o Storage of data and requirements • ensure that only research 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 site staff have specific subject instruction materials for use in the research if remote data capture device /equipment is to be provided to subjects and that the materials are submitted to the IRB for review and approval • ensure that data is entered by computer according to study specifications promptly from the source documentation

C. Management of the data

• Research Staff/Consultant	Assess CRF completion status at each monitoring visit that is conducted during the course of the study, and at the closeout visit when the study is completed or otherwise suspended or terminated. Collect any discrepancies noted at the monitoring visit on the monitor's copy of the Data Clarification Form (DCF) (Attachment

	B), for each subject monitored, to ensure an audit trail of clarifications and corrections. Ensure that the site staff collects 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 site staff that the first sets of completed CRFs are reviewed for completeness and accuracy by another member of the research team or by another designated individual.
• Research Staff/Consultant	Point out errors on the CRF to the site personnel who should correct the CRFs using the procedures described above prior to the completion of the monitoring visit. If CRFs are transmitted from the site to the Designee between monitoring visits and upon review errors are discovered, contact the site and request that the CRF be corrected as required, resubmitted, and retain a record of the request for correction. If it is noted that data management procedures are not being followed by the site staff, document this, discuss and/or implement corrective actions (e.g. retraining) with the site staff, including the Investigator or Subinvestigator, and report all findings to the President. If sites do not comply with data management procedures on an ongoing basis, document the pattern of non-compliance and provide a copy of the documentation to the President. In cases of ongoing non-compliance, institute site termination procedures when authorized to do so by the President.
• Research Staff/Consultant	At the conclusion of the study, review with the site staff: • that data is to be retained according to regulatory and Georgia CORE 's requirements (see Attachment A SOP SM-303.00 Documentation and Records Retention) • to obtain Georgia CORE's written approval prior to destroying any study-related data.

10. HISTORY OF CHANGES

Version Number	Section Number	Modification	Approval Date
401.00	All	Original Version	
401.00	All	No change was necessary	09 March 2012
401.00	All	No change was necessary	01 June 2014
401.00	3, 6, 9B, Attachment A	Removal of old resource, Addition of new resource, clarification changes	01 Jan 2017

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 subject's diagnosis and status prior to treatment, including documentation of medical history, particularly that relevant for the disease or condition being treated.

5. Record names of study drugs and dosing times, calculations of dose

6. Maintain signed orders for study drugs

7. Document the dates and the results evaluations 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 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 adverse event (AE) should include AE name, date started, date ended, causality, grade per current (protocol specified) Common Terminology Criteria for Adverse Events (CTCAE) and specify whether it was a serious adverse event.

9. Record subject's condition during and/or after treatment.

10. Document final disposition of the subject and subject status at time of study termination.

Attachment B

SAMPLE DATA CLARIFICATION FORM

Study Number/Title: _____

_____

Investigator: _____ Site Personnel and title: _____

Monitor: _____ Visit Date: _____

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

_____ _____ _____

Monitor's Name (Print) Signature Date

_____ _____ _____

Investigative Site Staff Name (Print) Signature Date