Study Management
SM – 308.01

STANDARD OPERATING PROCEDURE FOR
Specimen Management

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I. INTRODUCTION AND PURPOSE

The proper collection and processing of specimens obtained from study subjects are important factors impacting the integrity of the data collected in a clinical trial. The specimens provide important information about the drug's action within the body and the subject's biologic and clinical response. To ensure accurate data, specimens must be collected in specified tubes, quantities and at the specified time points. Specimens must also be processed, possibly preserved and shipped appropriately. Additionally, research or ancillary staff must adhere to good laboratory practices when collecting, processing, and arranging for shipment of the specimens to the testing laboratory. This standard operating procedure (SOP) describes the steps Georgia CORE monitors at the sites to ensure the regulatory and clinical requirements involved in specimen collection and handling are fulfilled.

2. SCOPE

This SOP applies to the activities at sites monitored by Georgia CORE involved in collecting and handling specimens from subjects enrolled in clinical studies which are subject to investigational new drug (IND) regulations for drugs and biologics or those eligible for investigational new drug (IND) exemption during all phases of development.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.62	Investigator recordkeeping and record retention
May 1997	International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline
June 2010	IATA Transport of Biological Specimens

4. REFERENCES TO OTHER APPLICABLE SOPS

SS-203	Pre-Study Site Visit
SS-204	Site Initiation Visit
SM-304	Routine Monitoring Visits
SM-305	Closeout Visits
DM-501	Data Management

5. ATTACHMENTS

A. Specimen Shipping Log

6. RESPONSIBILITY

This SOP applies to those members of Georgia CORE involved in monitoring the sites' management of specimen collection and processing. This includes the following:

- President and CEO
- Georgia CORE staff and consultants
- Research coordinators conducting clinical trials

7. DEFINITIONS

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

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. General instructions
B. Collecting the specimens
C. Processing the specimens
D. Specimen storage
E. Preparing the specimens for shipping

9. PROCEDURES

A. General Instructions

• Research Staff/Consultant	Assess that all participating sites have the requisite capability for collecting, handling, storing and retaining specimens collected from subjects for the study. Ensure personnel responsible for specimen handling and processing are properly trained according to applicable regulation standards and guidelines, site specific requirements and the protocol. Review, with the Investigator and Subinvestigators, their responsibility for carrying out all study-related specimen collection procedures according to the clinical protocol and ensuring that specimen storage and retention requirements are fulfilled.

B. Collecting the specimens

• Research Staff/Consultant	Check with the site staff that they: • observed appropriate precautions based upon OSHA guidelines, infection control manual, and/or the institutional procedure manual for the handling of bodily fluids when they collect the appropriate specimens identified in the study protocol. • noted the date and time of the collection as well as any relevant information pertaining to the subject's status at the time of the procedure in the subject's medical record and/or on the case report form. • labeled the tubes or other containers with subject identifiers, date, time, and any other information required.

C. Processing the specimens

• Research Staff/Consultant	Check with the site staff that they are: • processing the specimen according to the specifics defined in the protocol (for example, centrifuge speed, duration, temperature requirements) • spinning, separating and transferring the specimen to the appropriate transport tube(s), as required • labeling the study-specific tubes or other containers with subject identifiers, date, time, and any other information required to prepare for storage or shipment

	• completing the laboratory requisition slip; including one copy with the specimens when shipped and retaining one copy filed with the other study-related subject records.

D. Specimen storage

• Research Staff/Consultant	Check with the site staff that they: • are monitoring the performance of the equipment used for specimen storage (e.g. refrigerator, freezer) and maintaining a monitoring record (e.g. a daily temperature chart) • have alternative storage capabilities available in case of emergency, e.g. power failure

E. Preparing the specimens for shipping

• Research Staff/Consultant	Check with the site staff that they have: • prepared and packaged the specimens according to the shipping instructions specified in the protocol and/or central laboratory procedure manual • In compliance with IATA biological specimen transport • completed the specimen shipping log (Attachment A) • retained a copy of the shipping receipt and filed it with the other study-related subject records.

10. HISTORY OF CHANGES

Version Number	Section Number	Modification	Approval Date
308.00	All	Original Version	
308.01	3, E	Added IATA biological specimen transport reference	09 March 2012
308.01	All	No changes necessary	01 June 2014
308.01	I, 9A	Updated introduction & general instruction descriptions	01 May 2017

Attachment A

Specimen Shipping Log

STUDY #	SUBJECT INITIALS	SPECIMEN COLLECTION DATE	SPECIMEN TYPE	VISIT #	NO. OF SPECIMENS SHIPPED	SHIPPED TO	SHIP DATE	STUDY STAFF INITIALS