

**Study Management**  
**SM – 308.02**

**STANDARD OPERATING PROCEDURE FOR**  
**Specimen Management**

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

**04 Feb 2021**

(Signature and Date)

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

**04 Feb 2021**

(Signature and Date)

**Issue Date:** 01 June 2017  
**Effective Date:** 01 September 2020  
**Expiration Date:** 01 September 2022  
**Document Review Date:** 30 June 2020  
**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**

Georgia CORE is responsible for ensuring that biological specimens obtained from study subjects are collected, processed, preserved, and transported in compliance with guidelines provided by the protocol, laboratory procedures, and IATA regulations. The specimens provide important information about the action of the study agent within the body and the biologic and clinical responses of the study subject. Georgia CORE staff and consultants are responsible for monitoring Research Network sites to ensure compliance with the regulatory and clinical requirements of specimen management.

**2. SCOPE**

This standard operating procedure (SOP) describes the steps to be followed by Georgia CORE staff and consultants when monitoring Research Network sites involved in

collecting, processing, preserving, and transporting biological specimens from subjects enrolled in clinical studies which are subject to investigational new drug (IND) regulations for drugs and biologic or those eligible for investigational new drug (IND) exemption during all phases of 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**

SS - 203	Pre-study Site Visit (PSV)
SS - 204	Site Initiation Visit
SM- 304	Closeout Visits
SM- 305	Routine Monitoring Visits
DM- 501	Safeguarding Protected Health Information

### **5. ATTACHMENTS**

A. Specimen Shipping Log

### **6. RESPONSIBILITY**

This SOP applies to Georgia CORE leadership, staff, and consultants responsible for or involved in monitoring the collection, processing, preserving, and transport of biological specimens at Research Network sites. Including are the following:

- President and CEO
- Georgia CORE staff and consultants

### **7. DEFINITIONS**

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

Source data

Source documentation

### **8. PROCESS OVERVIEW**

- A. General instruction
- B. Collecting the specimens
- C. Processing the specimens
- D. Storing the specimens
- E. Preparing the specimens for transport

### **9. PROCEDURES**

#### **A. General Instructions**

Georgia Center for Oncology Research and Education

Georgia CORE staff and consultants

Assess that all participating Research Network sites have the requisite capability to collect, process, store, and prepare specimens for transport.

Ensure that Research Network staff responsible for specimen management are properly trained according to applicable regulatory standards and guidelines, site-specific requirements, and study protocol.

Review the responsibilities for compliance with all study-related specimen management procedures according to the clinical protocol with Research Network site Investigator/Subinvestigator(s) to ensure that specimen management requirements are met.

**B. Collecting the Specimens**

Georgia CORE staff and consultants

Confirm with Research Network site staff that they:

- Observed appropriate precautions based on OSHA guidelines, infection control manuals, and/or institutional procedures manual for the handling of biological specimens specified in the study protocol,
- Noted the date and time the specimen was collected and relevant information pertaining to the status of the subject at the time of the specimen collection in the medical record and on the case report form for the subject,
- Labeled the specimen collection containers with the subject identifiers, date, time, and any other protocol-specific information required.

**C. Processing the Specimens**

Georgia CORE staff and consultants

Confirm with Research Network site staff that they are:

- Processing the study specimen according to the specific protocol-defined requirements, i.e., centrifuge speed, duration, temperature requirements),
- Preparing the specimen appropriately to be transferred to the appropriate transport or storage container.
- Labeling the study-specific specimen containers with subject identifiers, date, time, and any other

protocol-specific, storage, or transport required information,

- Completing specimen laboratory requisition slip and including one copy with the specimen when transported and retaining a copy that is filed with other study-related subject records

#### **D. Storing the Specimens**

Georgia CORE staff and consultants

- Confirm with Research Network site staff that they:
- Are monitoring the performance of the equipment used for specimen storage (i.e., temperature of refrigerator, freezer) and maintaining a monitoring record (i.e., a daily temperature chart),
  - Have an alert system in place to monitor the performance of the specimen storage equipment in case of an emergency (i.e., power failure),
  - Have an alternative storage capability available in case of emergency (e.g., power failure).

#### **E. Preparing the Specimens for Transport**

Georgia CORE staff and consultants

- Confirm with Research Network site staff that they:
- Prepare and package the specimens according the shipping instructions specified in the protocol, study laboratory procedure manual, and in compliance with the current IATA Dangerous Goods Regulations for biological specimen transport.
  - Complete the Specimen Shipping Log (Attachment A)
  - Have retained a copy of the shipping receipt and filed it with other study-related subject records.

### **10. History of Changes**

<b>Version Number</b>	<b>Section Number</b>	<b>Modifications</b>	<b>Approval Date</b>
308.00	All	Original Version	
308.01	3, E	Added IATA Biological Specimen Transport reference	09 March 2012
308.01	All	No change was necessary	01 July 2014

308.01	I, 9A	Updated introduction and General Instructions descriptions	01 May 2017
308.02	All	Edited for clarity and accuracy, updated references and links to websites	30 June 2020

