SM-405 STANDARD OPERATING PROCEDURE FOR SPECIMEN COLLECTION AND HANDLING

1. INTRODUCTION AND PURPOSE

The proper collection and processing of specimens obtained from study subjects are part 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 at the specified time points, processed, possibly preserved, and then 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 for fulfilling the regulatory and clinical requirements involved in specimen collection and handling.

2. SCOPE

This SOP applies to the activities involved in collecting and handling specimens from subjects enrolled in clinical studies conducted at this investigative site subject to investigational new drug (IND) regulations for drugs and biologics during all phases of development.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.62	Investigator recordkeeping and record retention

4. REFERENCES TO OTHER APPLICABLE SOP'S

SM-403	Subject Management While on Study
DM-501	Data Management

5. ATTACHMENTS

N/A

6. RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in ensuring appropriate specimen collection and handling at this research site. This includes the following:

- Principal investigator
- Sub-investigator
- Research coordinator

7. DEFINITIONS

The following definitions from the International Conference on Harmonisation, 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. Collecting the specimens
B. Processing the specimens
C. Preparing the specimens for shipping to the testing laboratory

9. PROCEDURES

A. COLLECTING THE SPECIMENS

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Research coordinator	Observing appropriate precautions based upon OSHA guidelines, infection control manual, and/or the institutional procedure manual for the handling of bodily fluids, collect the appropriate specimens identified in the study protocol. In the subject's medical record and/or on the case report form, note 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. Label the test tubes or other containers with subject identifiers, date, time, and any other information required.

B. PROCESSING THE SPECIMENS

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Research coordinator	Process the specimen according to the specifics defined in the protocol (for example, centrifuge speed, duration, temperature requirements). Spin, separate and transfer the specimen to the appropriate transport tube(s), as required.

	Label the study-specific test tubes or other containers with subject identifiers, date, time, and any other information required to prepare for storage or shipment. Complete the laboratory requisition slip. Include one copy with the specimens when shipped. Retain one copy and file with the other study-related subject records.

C. PREPARING THE SPECIMENS FOR SHIPPING TO THE TESTING LABORATORY

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Research coordinator	Prepare and package the specimens according to the shipping instructions specified in the protocol and/or central laboratory procedure manual. Retain a copy of the shipping receipt and file with the other study-related subject records.