SM-405– Specimen Collection and Management

1. **PURPOSE:**
   To describe the methods used for specimen collection, handling, and shipping for studies conducted at UTRGV.

2. **SCOPE:**
   This SOP applies to the Principal Investigator (PI) and designated research personnel who perform specimen collection and management at UTRGV.

   This SOP does not apply to biospecimens within the UTRGV Biospecimen Bank.

3. **RESPONSIBLE INDIVIDUALS:**
   The PI is responsible for ensuring that qualified study staff have received and maintained current biosafety training at UTRGV prior to handling biological specimens.

4. **RELATED TERMS AND DEFINITIONS:**

   Bloodborne Pathogens (BBP)
   International Air Transport Association (IATA)
   Occupational Health and Safety Administration (OSHA)
   Subject Identifier (ID)
   Universal Precautions

   Please reference the Standard Operating Procedures Glossary of Terms for complete definitions of terms in this SOP.

5. **POLICY STATEMENT:**
   This SOP applies to all personnel who collect or handle research specimens.

6. **PROCEDURES:**

   6.1 Qualified study staff who are International Air Transport Association (IATA) certified and Bloodborne Pathogens (BBP) trained will follow detailed instructions for handling specimens outlined in the study protocol and/or laboratory manual if provided.

6.2 Study specific laboratory manuals, including all updated/revised versions, will be placed in study specific regulatory binder or maintained in the eRegulatory platform.

6.3 Study staff who handle specimens should be documented in the delegation log and filed in the regulatory binder for each study.

6.4 Study personnel will perform the following tasks for collection of biological specimens:

- Before specimen collection, the subject should be well informed regarding the purpose of the procedure and should have understood and signed the Informed Consent Form (ICF), as described in SOP SM-402.
- Ensure that equipment meets the requirements of the protocol, and that the equipment has been properly maintained and calibrated.
- Ensure the safety and well-being of subjects during the collection of specimens and exercise universal precautions.
- Label each specimen laboratory requisition completely as soon as possible to avoid errors. The protocol number, subject ID, date, and time of specimen collection and specimen type should be included, according to the specifications in the protocol.
- Document all specimens collected for clinical research in the source document and Case Report Form (CRF).

6.5 Study personnel will perform the following while processing biological specimens:

- Adhere to detailed instructions in the protocol or laboratory manual
- Set the right conditions for processing the sample (i.e., centrifuge speed, duration, and temperature requirements).
- Spin, separate and transfer the specimen to the appropriate transport tube(s).
- Label the study-specific test tubes or other containers with subject identifiers, date, time, specimen type and any other information required to prepare for storage or shipment.
- If storage of specimens is required per protocol, store in appropriate temperature monitored freezer.
- 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.

6.6 Study personnel will ensure the following during storage of biological specimens:

- Ensure that biological specimens are stored in a secure and suitable environment that conforms to the requirements of the protocol.
- Establish and maintain limited access for authorized personnel to protect subject confidentiality.
- Document the storage time for biological specimens as defined in the protocol.
- Maintain daily temperature logs.
- In the event of a power or equipment failure, the sponsor must be notified immediately.
- If specimens require transfer to another UTRGV facility, the designee will ensure the viability of the specimens by using shipping materials specified in the protocol (i.e., dry ice)

6.7 Study personnel will ensure the following when shipping biological specimens:

- Comply with applicable laws and standards of transport when specimens are shipped.
- Adhere to the detailed safety and shipping requirements described in the protocol and/or specific laboratory manual provided by the Sponsor/designated central laboratory.
- Document this process and maintain with essential study documents.

REFERENCES:

- 29 CFR Part 1910.1030, Occupational Exposure to Bloodborne Pathogens
- IATA Dangerous Goods Regulations, 48th Edition, 2007 and IATA Dangerous Goods Regulations
- UTRGV SM-402
- UTRGV QA-604
- UTRGV QA-605

FORMS OR ATTACHMENTS:

None