

Standard Operating Procedures for Clinical Research at USF Health Morsani CRC



SPECIMEN COLLECTION AND MANAGEMENT

SOP#: 308

Effective Date: 06/01/2016

Version: 1.0

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PURPOSE: The purpose of this Standard Operating Procedure (SOP) is to describe the methods used for specimen collection, handling, and shipping for studies conducted at the CRC.

SCOPE: This SOP applies to the PI and designated research personnel who perform specimen collection and management at the CRC.

RESPONSIBILITY: The Principal Investigator is responsible for ensuring that qualified study staff have received and maintained current biosafety training at USF prior to handling biological specimens.

DEFINITIONS:

Bloodborne Pathogens (BBP): Pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV).

International Air Transport Association (IATA): IATA Dangerous Goods Regulations (DGR) provides procedures so articles and substances with hazardous properties can be safely transported.

Laboratory Requisition: Form that serves as order and source documentation of laboratory tests.

Occupational Health and Safety Administration (OSHA): A government agency within the Department of Labor responsible for ensuring a safe and healthy work environment.

Subject Identifier (ID): A unique study specific number or code attributed to a specific study participant of a particular study designated by the PI/ sponsor and usually devoid of HIPAA identifiers.

Universal Precautions: Infection control measures used to reduce the risk of transmission of bloodborne pathogens through exposure to blood or bodily fluids. These preventative measures treat all blood and bodily fluids as infected or disease carrying. Measures include:

- Use of single-use disposable injection or percutaneous equipment, or sterilized, if single-use equipment is not available
- Discarding sharps, such as needles, scalpels, etc. without recapping, in rigid, liquid-proof containers that is sealed and destroyed prior to being completely full
- Washing hands with soap and water before and after procedures
- Use of barriers such as gloves, gowns, goggles, or face mask to prevent contact with blood or body fluids
- Disinfecting instruments and contaminated equipments and work space

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1. Qualified study staff who are IATA certified and BBP trained will follow detailed instructions for handling specimens outlined in the study protocol and/or lab manual if provided.
2. Study specific lab manuals, including all updated/revised versions, will be printed and placed in study specific regulatory binder or maintained in electronic form (PDF) for site access. Written acknowledgement of version changes will be noted in study files if manuals will be accessed electronically.
3. Study staff who handle specimens should be documented in the delegation log and filed in the regulatory binder for each study.
4. Study personnel will perform the following tasks for collection of biological specimens:
 - 4.1. 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#402 *Informed Consent Process*.
 - 4.2. Ensure that equipment meets the requirements of the protocol and that the equipment has been properly maintained and calibrated.
 - 4.3. Ensure the safety and well being of subjects during the collection of specimens and exercise universal precautions.
 - 4.4. Label each specimen lab requisition completely as soon as possible to avoid errors. The protocol number, subject ID, date and time of specimen collection should be included, according to the specifications in the protocol.
 - 4.5. Document all specimens collected for the clinical trial in the source document and case report form (CRF).
5. Study personnel will perform the following while processing biological specimens:
 - 4.1 Adhere to detailed instructions in the protocol or laboratory manual
 - 4.2 Set the right conditions for processing the sample (ie: centrifuge speed, duration, and temperature requirements).
 - 4.3 Spin, separate and transfer the specimen to the appropriate transport tube(s), as instructed.
 - 4.4 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.
 - 4.5 Complete the laboratory requisition slip. Include one copy with the specimens when shipped.

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4.6 Retain one copy and file with the other study-related subject records.

6. Study personnel will assure the following during storage of biological specimens:

PROCEDURE (cont.):

- 6.1. Ensure that biological specimens are stored in a secure and suitable environment that conforms to the requirements of the protocol.
 - 6.2. Establish and maintain limited access for authorized personnel to protect subject confidentiality.
 - 6.3. Document the storage time for biological specimens as defined in the protocol.
 - 6.4. Maintain daily temperature logs during normal USF business hours.
 - 6.5. In the event of a power or equipment failure, the sponsor must be notified immediately.
 - 6.6. If specimens require transfer to another USF facility, the designee will ensure the viability of the specimens by using shipping materials specified by in the protocol (ie: dry ice)
7. Study personnel will ensure the following when shipping biological specimens:
- 7.1. Comply with applicable laws and standards of transport when specimens are shipped to central laboratory.
 - 7.2. Adhere to the detailed safety and shipping requirements described in the protocol and/or specific laboratory manual provided by the Sponsor/designated central laboratory.
 - 7.3. Document this process and maintain with essential study documents.

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29 CFR Part 1910.1030, *Occupational Exposure to Bloodborne Pathogens*
IATA Dangerous Goods Regulations, 48th Edition, 2007 and IATA Dangerous Goods Regulations 49th Edition (English)
Effective 1 January 2008
<http://www.research.usf.edu/dric/biosafety/>

RELATED POLICIES:

USF HRPP Policy and Procedure Manual
SOP#102: Training Clinical Research Staff
SOP #103: Responsibilities of the Research Team

APPENDICES:

None

REVISION HISTORY: Keep a running history of all revision dates.

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