1. OBJECTIVE

To ensure that the Principal Investigator (PI) and all research team members assisting in the conduct of clinical research are informed about their obligations and responsibilities as they pertain to Good Clinical Practices (GCP), the investigational plan, applicable regulations, guidance, and institutional policies. This Standard Operating Procedure (SOP) applies to the written procedures followed by all members of a clinical research team involved in the conduct of human subjects' research at LSU Health New Orleans, including the Health Sciences Center (HSC), the Stanley S. Scott Cancer Center (SSSCC) and the Healthcare Network (HN), hereafter called the investigational site. These detailed instructions promote compliance in conducting clinical research.

SOP 2.11 describes the process for the proper collection, handling, and management of biospecimens for clinical research.

2. RESPONSIBILITY

The HSC, SSSCC and HN Clinical Trials Offices develop, implement, and maintain SOPs. The need to write a new or revise an existing SOP is based upon changes to federal regulations, guidelines, institutional policies, or procedures. These documents will be provided to departments and research teams conducting human subjects' research. Departments or research teams may develop additional research SOPs or a Research Procedure Addendum (RPA) to expand on an existing SOP, however this need should be limited.

The PI is ultimately accountable for all clinical research activities and is responsible for the appropriate delegation of tasks to individuals with adequate training and education to perform such tasks. It is the responsibility of all members of the clinical research team involved in supervising, managing, or conducting study-related activities to follow the SOPs. The clinical research team may include but is not limited to the following members:

Research Team Members

Principal Investigator (PI)	Clinical Research Coordinator (CRC)
Sub-Investigator (Sub-I)	Other Research Staff
Clinical Research Nurse Coordinator (CRNC)	Administrative and Support Staff

3. DEFINITIONS

Biologic Product: Any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product or analogous product applicable to the prevention, treatment or cure of diseases or injuries to humans.

Please refer to the SOP Glossary document for other detailed definitions of commonly used clinical research terminology.

4. PROCEDURES

All research team members who will be in direct contact with patients, biohazardous materials or work in the clinical setting will complete appropriate biosafety and occupational health training and obtain appropriate tests and immunizations related to their specific job requirements from employee health prior to engaging in delegated tasks for a clinical research study.

Clinical research studies that produce results (either qualitative or quantitative) from biospecimen research tests that impact clinical decision making are recorded in the subject's electronic health record or that are communicated to the subject directly, must be conducted in a CLIA approved laboratory or have appropriate CLIA certificate waivers. This includes point of care testing such as pregnancy, glucose, creatinine, urine testing, etc.

The PI and delegated research team members will ensure that the facilities and equipment utilized for obtaining, processing and storing biospecimens is reviewed at regular intervals by Environmental Health and Safety (EHS) or other delegated office.

The PI and delegated research team members will ensure that when obtaining, processing and storing biospecimens, Occupational Safety and Health Administration (OSHA) safety guidelines, including the use of personal protective equipment (PPE) are followed.

If equipment needs to be calibrated (e.g., centrifuges, scales, refrigerators, etc.) it is the responsibility of the research team members to arrange at a minimum yearly calibrations and maintenance with an approved LSU Health vendor.

A. Specimen Collection, Processing, Storage, Shipping Transportation and Destruction

Collection

The PI or delegated research team members will have appropriate training and practice the necessary precautions when collecting biospecimens from subjects.

The PI or delegated research team members will appropriately document the subject name, study ID number, date and time of collection, type of specimen collected, and any relevant information pertaining to the subject's status at the time of the specimen collection. Appropriately label the specimen with subject identifiers, date, time, type of specimen and any other protocol-required information. Any protected health information (PHI) will be kept confidential and secured per institutional policies.

Processing

The PI or sponsor provides specimen processing guidelines (outlined in either the protocol or a lab manual), which must be followed by the investigational site. This may include instructions related to centrifuge settings, temperature, time, speed, and number of aliquots.

When handling or processing specimens, research team members must have access to personal protective equipment (PPE). PPE includes but is not limited to gloves, protective face shields, and lab coats. Lab coats worn to process samples should not be the same coats worn in patient care clinics.

Storage

Storage requirements, specified in the protocol or lab manual, must also be followed by the investigational site. This may include required labels for specimens, appropriate storage containers, temperature, and duration of storage. Research specimens should not be stored with investigational products, food, or beverages.

Shipping

Shipping requirements, specified in the PI or sponsor provided protocol or lab manual and in compliance with IATA/DOT requirements, will also be followed by the investigational site. This may include completing the laboratory requisition slip to send with the specimens, specific

preparations and packaging requirements of the specimens, and acceptable days to ship specimens.

Transportation
If samples are transported by research team members to another location, it is required that they are placed in a biohazard bag and transported within a secondary closed container that is sealable to reduce accident and exposure risk.

The research team member responsible for transport should confirm that the samples they are moving to another location are the appropriate, research samples.

Destruction
If samples are to be destroyed by research team members, it is required that they are placed in an appropriate biohazard container for proper waste disposal according to the Health System and Clinical Laboratories policies.

The PI and delegated research team members will maintain a research specimen collection, storage, destruction, and shipping log. A copy of all shipping records for biospecimens will be maintained at the investigational site. Any deviations from the protocol specific collection, processing, or storage requirements will be documented and reported to the sponsor.

5. APPLICABLE REGULATIONS AND GUIDANCE

LSU Health Guidance/Policy	Title
LSUHSC HRP Policies & Procedures	4.10 Use of Discarded Human Tissue
LSUHSC Institutional Biosafety Committee	IBC Requirements for Human Subjects Research
LSUHSC Institutional Biosafety Committee	Institutional Biosafety Committee (IBC) and Institutional Review Entity (IRE) for DURC
LSUHSC Environmental Health & Safety	Environmental Health & Safety Department
LSUHSC Environmental Health & Safety Policy Manual	Shipping Biological Materials
LSUHSC Policy	Records Retention and Disposition Policy
LSUHSC Chancellor's Memoranda	CM-51 Policy on Hurricane Emergency Procedures for LSUHSC-New Orleans
Louisiana Secretary of State	Records Retention Schedule
LSUHSC Clinical & Translational Research Center (CTRC)	PC 305 SOP for Urine Collection
LSUHSC Clinical & Translational Research Center (CTRC)	PC 306 SOP for Sputum Collection

Federal/International Regulation/Guidance/Policy	Title

21 CFR 50	Protection of Human Subjects
45 CFR 46	Protection of Human Subjects
49 CFR 107	Transportation: Hazardous Materials Program Procedures
49 CFR 171	Transportation: General Information, Regulations, Definitions
ICH E6(R2)	Guideline for Good Clinical Practice E6 Integrated Addendum
FDA Guidance for Industry	Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects
Occupational Safety and Health Administration	Occupational Safety and Health Administration

6. MATERIALS

6.1. Research Specimen Shipping Log

6.2. Research Specimen Storage Log

6.3. Research Specimen Destruction Log

Approved by:

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