SOP-14: Research Specimen Management

1. Objective

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 Ochsner Health, hereafter called the investigational site. These detailed instructions promote compliance in conducting clinical research. The objective of this SOP is 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 related to Good Clinical Practices (GCP), the investigational plan, applicable regulations, guidance, and institutional policies.

SOP-14 describes the process for the proper collection, handling, and management of biospecimens for clinical research. Attachment templates include:

A: Research Specimen Shipping Log

B: Research Specimen Destruction Log

2. Responsibility

Ochsner Research develops, implements, and maintains 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 Centers of Excellence (COEs) and research teams conducting human subjects research. COEs 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 Principal Investigator (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**

<table>
<thead>
<tr>
<th>Role</th>
<th>Title</th>
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</thead>
<tbody>
<tr>
<td>Principal Investigator</td>
<td>Clinical Research Coordinator</td>
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<tr>
<td>Sub-Investigator</td>
<td>Associate Clinical Research Coordinator</td>
</tr>
<tr>
<td>Clinical Research Manager</td>
<td>Data Coordinator and Regulatory Specialist</td>
</tr>
<tr>
<td>Clinical Research Supervisor</td>
<td>Other Research and Administrative Support Staff</td>
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</tbody>
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3. Definitions

Please refer to the SOP Glossary document for 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 a 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 and 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, among others. The PI or research team members will contact the Department of Pathology and Laboratory Medicine to determine if the research testing requires CLIA oversight.

The PI and delegated research team members will ensure that the facilities and equipment utilized for obtaining, processing and storing biospecimens are reviewed at regular intervals by Ochsner Health Safety.

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, or refrigerators) it is the responsibility of the research team members to arrange at a minimum yearly calibrations and maintenance with an approved Ochsner 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. The specimen must be labeled 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 PI or sponsor provided 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, 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, the samples must be placed in a biohazard bag and transported within a secondary closed container that is sealable to reduce the risk of accidental exposure.

Destruction
If samples are to be destroyed by research team members, the samples must be placed in an appropriate biohazard container for proper waste disposal according to the health system and clinical laboratory policies (See Attachment B Research Specimen Destruction log)

The PI and delegated research team members will maintain a research specimen collection, processing, and shipping log (See Attachment A Research Specimen 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.

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Revised:
Approved by W. Mark Roberts, MD, Dean of Research

Signature: [signature]
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