SOP-03: New Employee Orientation

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-03 describes the process and documentation required for the initial and ongoing education and orientation of research team members involved in clinical research. Attachment templates include:

A: New Employee On-Boarding Checklist

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

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

A. New Employee Orientation

All new employees of the research team are required to complete all applicable training as determined by institutional policies and their supervisor.

The PI and delegated research team members will ensure that all persons assisting with the study are adequately informed about the protocol, the investigational product(s), and their study-related duties and functions. These individuals will be informed about their obligations and will have adequate and appropriate education and training to conduct the tasks delegated.

Research team members engaged in clinical research activities will have IRB approval as key personnel or as a Sub-Investigator prior to performing study-specific tasks.

All new employees are expected to complete the following prior to independently conducting delegated tasks of a clinical research study:

- Complete appropriate eLearning Modules through Ochsner Learning Network within the first 30 days of employment.
- Complete Collaborative Institutional Training Initiative (CITI) Biomedical Human Subject Protection modules, Good Clinical Practice modules, and Responsible Conduct of Research modules within the first 30 days of employment.
- Complete research conflict of interest disclosure certification (eCOI).
- Complete appropriate EPIC electronic medical record (EMR) training sessions and computer-based learning sessions prior to gaining access to any electronic medical records.
- Complete appropriate biosafety for all employees who will be in direct contact with patients, biohazardous materials, or who work in the clinical setting.
- Obtain appropriate tests and immunizations related to their specific job requirements from Employee Health Services prior to independently conducting delegated tasks of a clinical research study.
- Complete sponsor-required training to ensure adherence to protocol requirements.

The new employee will be instructed, according to their role, in various aspects of conducting a clinical research study including but not limited to:

- Study implementation and design
- Regulatory requirements
- Fiscal and contractual requirements
- Orientation to appropriate clinics and labs
- Patient screening and recruitment procedures
- Consent process
- Source documentation and case report form completion

All new clinical research team members will complete an On-Boarding checklist. (See Attachment A On-Boarding Checklist) The new employee's supervisor or manager will ensure the new employee has successfully completed all required training as outlined on the On-Boarding Checklist. Once completed, the original On-Boarding checklist will be maintained in the employee file.
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Revised.

Approved by W Mark Roberts, MD, Dean of Research

Signature: [Signature]

Date: 9/21/21