SOP-01: Writing, Training, and Maintenance of SOPs

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-01 describes the process for writing, training, and maintaining standard operating procedures for clinical research. Attachment templates include:

A: SOP Template
B: RPA Template
C: SOP Training & Compliance Form
D: SOP Revision History 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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<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>
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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. Procedure for Writing SOPs or RPAs

The writing of a research SOP is the responsibility of the Office of Research.

The writing of a COE-specific RPA may be delegated to an appropriate member of a clinical research team.

The SOP or RPA content will contain enough details to guide clinical research team members through a particular procedure and establish uniformity in the daily operations of the system or department, respectively. Processes should be established that can be followed without deviation and that can be easily implemented.

The SOP format, at a minimum, will contain the following elements: Title, Effective Date, Signature and Approval Date lines, Objective, Responsibility, Definitions, Procedures, Applicable Regulations, Guidelines and References to other SOPs, and Attachments (See Attachment A: SOP Template).

The RPA format, at a minimum, will contain the following elements: Addendum Title, Reference of SOP Title and, Addendum Effective Date, Objective, and Procedures (See Attachment B: RPA Template).

The Dean of Research or the appropriate Clinical Research Director will review, sign and date the final SOP or RPA for approval, respectively. Addendums developed by the COE will be maintained with the referenced SOP. Final documents with original signature and date will be kept on file.

B. Procedure for Distribution and Training on SOPs

Managers and/or supervisors will ensure that each new research team member reviews all applicable SOPs prior to undertaking any responsibilities and will document the date of review and training of each SOP.

Managers and/or supervisors will also ensure that each current research team member has continuous, documented training on the new or revised SOP [See Attachment C: SOP Training & Compliance Form]. Training should be re-documented on an annual basis.

Documentation of training for SOPs will be kept on file for all research team members and available for review upon request.

C. Procedures for Maintaining SOPs and RPAs

All research SOPs and RPAs should be reviewed by the appropriate team members to assess applicability and revise and/or edit the document a minimum of every 3 years.

If revisions or additions are required at any time, the procedures will be followed as outlined above.

If no changes are required, the SOP Revision History Log will be updated to reflect the date of last review [See Attachment D: SOP Revision History Log]
Effective Date 01-SEP-2021

Issued: 01-SEP-2021
Revised.
Approved by W Mark Roberts, MD, Dean of Research

Signature. [Signature]

Date. 9/21/21