SOP-12: Protocol Compliance

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-12 describes the process for ensuring protocol compliance and documenting and reporting protocol deviations for clinical research. Attachment templates include

A: Baseline Checklist
B: Post-Visit Checklist
C: Note to File
D: Protocol Deviation 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**

- Principal Investigator
- Sub-Investigator
- Clinical Research Manager
- Clinical Research Supervisor
- Clinical Research Coordinator
- Associate Clinical Research Coordinator
- Data Coordinator and Regulatory Specialist
- Other Research and Administrative Support Staff

Page 1 of 3
3. Definitions

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

4. Procedures

A. Protocol Compliance

The PI's responsibility includes, but is not limited to,

- ensuring that clinical research is conducted according to the signed investigator statement, the investigational plan, and applicable regulations and any conditions of approval imposed by an IRB, sponsor, or other regulatory body,
- protecting the rights, safety, and welfare of subjects under the investigator's care,
- control of investigational product,
- accurate and adequate data and case histories,
- timely reporting of adverse events and study data,
- and assurance of IRB review.

The PI and delegated research team members will conduct the clinical research study in compliance with the IRB approved protocol (See Attachment A Baseline Checklist and Attachment B Post Visit Visit Checklist). The investigator/institution and the sponsor will sign the protocol or an alternative contract to confirm their agreement, as applicable.

The PI and delegated members of the research team will not implement any deviation from or changes to the protocol without agreement by the sponsor and prior review and documented approval from the IRB, except where necessary to eliminate an immediate hazard to a subject, or when the changes involve only logistical or administrative aspects of the study (e.g., change of monitor, change of telephone numbers).

The PI or delegated research team members will document and explain any deviation from the approved protocol and report the deviation promptly to the sponsor, IRB, and other regulatory agency as applicable.

The PI or delegated research team members may implement a deviation from, or a change in, the protocol to eliminate an immediate hazard to clinical research study subjects without prior IRB approval. The implemented deviation or change should be submitted to the IRB for review and approval, to the sponsor for agreement, and (if required) to the appropriate regulatory authorities within the required timeframe.

Noncompliance with the protocol, SOPs, GCP, and/or applicable regulatory requirements by an investigator or by members of the research team may lead to prompt action by the sponsor, IRB, and/or FDA to ensure compliance.

If monitoring and/or auditing identifies serious and/or persistent noncompliance on the part of an investigator or members of the research team, the research may be terminated at the site. If investigational site participation is terminated because of noncompliance, the regulatory authorities should be promptly notified.

B. Preventative Measures

If not already provided by the sponsor, the delegated research team member will appropriately create worksheets, flow sheets, study calendars, electronic health record smart phrases, paper orders, electronic order sets and other tools to be used for source documentation and/or as a reminder to
clinical research team members to perform protocol specific evaluations, assessments, and tests. These tools will be developed and shared with key personnel and clinical support staff prior to protocol implementation to ensure that all key members of the protocol management team are trained and educated on the expectations of the protocol.

The delegated research team members will meet regularly with the key personnel and clinical support staff involved in the conduct of the clinical research study. This will ensure that the tools created are utilized appropriately and are successful in preventing protocol deviations. Delegated research team members will ensure tools remain current should protocol changes arise and that appropriate approvals are obtained by the IRB, if applicable.

C. Protocol Deviations

If the PI or Sub-Investigator foresees the need for a protocol deviation waiver, they must receive sponsor approval prior to the deviation and, if necessary, obtain IRB approval. Protocol waivers should be used in very rare situations where compliance is not feasible and where the protocol cannot be amended in a timely manner to avoid the deviation.

The PI or Sub-Investigator may deviate from the protocol to eliminate immediate hazard to the patient without prior sponsor or IRB approval. The delegated research staff will document the deviation in a note to file or as part of the subject medical record as a research note and appropriately report the deviation to the sponsor and IRB (See Attachment B Note to File), as applicable.

If a member of the research team discovers a protocol deviation or subject non-compliance, they will document the deviation as part of the study records, subject medical record, or research chart. They will appropriately report the deviation to the sponsor, IRB, and other regulatory authorities, as applicable, and as specified in the reporting requirements of the protocol (See Attachment C Protocol Deviation Log).

Protocol deviations will be reviewed at regular intervals with the PI, delegated research team members, and clinical support staff. If consistent deviations are noted, attempts should be made to implement a new process or create tools to prevent future deviations. If the implementation of a new process or tool is unable to correct the problem, the PI should work with the sponsor to assess whether a protocol amendment is feasible.

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

Signature

Date 9/21/21