SOP-13: Adverse Event Reporting

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-13 describes the process for adverse event reporting for clinical research. Attachment templates include:

A: Adverse Event Log

B: IND Safety Report Cover Letter

C: IND Safety Report Note to File

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

3. **Definitions**

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

4. **Procedures**
The PI is responsible for ensuring an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations and any conditions of approval imposed by an IRB or FDA. The PI is responsible for protecting the rights, safety, and welfare of subjects under the investigator’s care as well as for the control of IP under investigation.

The PI and delegated research team members will conduct the clinical research study in compliance with the IRB approved protocol. 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 of an amendment, except where necessary to eliminate an immediate hazard to clinical research study subjects, or when the changes involve only logistical or administrative aspects of the clinical research study (e.g., change of monitor, change of telephone numbers). 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.

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, the IRB, and other regulatory agency, as applicable.

The investigator should promptly provide written reports to the sponsor, the IRB, and where required by the applicable regulatory requirements, the institution on any changes significantly affecting the conduct of the clinical research study, and/or increasing the risk to subjects.

A. Adverse Events

The PI and delegated research team members will conduct a review of systems and document the subject's baseline state, per the protocol, prior to any clinical research study intervention. They will review the subject's systems at regular intervals as outlined by the protocol and document any adverse change in health or well-being.

All adverse events observed will be documented noting the event description, seriousness, severity, relationship to the clinical research study intervention, start date, outcome, stop date and any medical care given to manage the adverse event. All adverse events will be recorded on case report forms (CRFs) or as outlined in the protocol. The site will maintain any supportive documentation as source documentation (See Attachment A Adverse Event Log).

All adverse events will be reported to the IRB, sponsor, and other regulatory bodies (e.g., FDA) according to thereporting requirements and within the time periods specified by the protocol and applicable policies and regulations. Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported according to the reporting requirements and within the timeline specified by the sponsor in the protocol.

During and following a subject's participation in a clinical research study, the PI should ensure that adequate medical care is provided to a subject for any adverse events, including clinically significant laboratory values, related to the clinical research study.

The PI and research team members will follow up appropriately when a research subject experiences any adverse change from baseline or pretreatment condition, ensuring all appropriate resources are directed toward subject safety and well-being. The subject should be followed until the event has resolved, or as specified in the protocol.
The research team should follow the clinical research study's randomization procedures, if any, and should ensure that the code is broken only in accordance with the protocol. If the clinical research study is blinded, the investigator should promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product(s). If possible, the sponsor should be consulted before unblinding occurs.

**B. Serious Adverse Events**

A serious adverse event (SAE) may include, but is not limited to, an adverse event that is fatal or life threatening, permanently disabling, requires or prolongs hospitalization, or results in significant disability, congenital anomaly, or birth defect.

Events requiring prompt reporting to the IRB may be unanticipated problems involving risks to subjects or others such as:

- Adverse events or injuries that are serious, unexpected, and related.
- Adverse device effects that are unanticipated.
- Protocol deviations or violations involving risks or with the potential to recur.
- Events requiring prompt reporting according to the protocol or sponsor.

All serious adverse events observed will be documented noting the event description, seriousness, severity, relationship to the clinical research study intervention, start date, stop date (if applicable), outcome, any medical care given to manage the adverse event and date the research team was notified of the serious adverse event.

The PI and the delegated research team members will immediately report all SAEs to the sponsor according to protocol requirements and will also comply with the applicable regulatory requirements related to the reporting of unexpected serious adverse drug/device reactions to the FDA and the IRB.

The initial report should be followed promptly by detailed, written reports. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the clinical research study subjects and protocol number. Subjects should not be identified by name or initials.

For reported deaths, the investigator should supply the sponsor and the IRB with any additional requested information (e.g., autopsy reports, death certificates, and terminal medical reports).

Event reporting information and a link to the event reporting form for Ochsner's Office of Human Research Protection can be found by emailing irb@ochsner.org.

Event reporting information and a link to the event reporting form at Western Institutional Review Board can be found at www.wirb.com.

For all other reviewing IRBs, please refer to their event reporting guidelines.

The PI and delegated research team members will ensure the IRB is notified of all serious or reportable events occurring at this site during the approval period for the ongoing study. The PI should ensure all adverse events are reviewed as part of the site's periodic or annual reporting requirements.
C. Managing Safety Reports

The PI and research team will not review, acknowledge, or store individual safety reports which are sent from the sponsor regarding SAEs experienced at other sites. Safety reports received from sponsors will not be submitted to the IRB, unless they meet the criteria noted in the IRB’s SOP (See Attachment B  HRPP Written SOP – Review of Adverse Events)

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

Signature: [Signature]

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