UNIVERSITY OF SOUTH ALABAMA

# CT-314 EXTERNAL SAFETY REPORTS

EFFECTIVE DATE: March 2024

## Purpose

This standard operating procedure describes the operations followed by the USA Health Clinical Trials Office (CTO) for the maintenance of sponsor-provided external safety reports. Adherence to this SOP ensures that the CTO receives and reviews current safety information to enable the site investigator to make appropriate decisions regarding participant safety.

## Scope

This SOP applies to all research performed through the Clinical Trials Office at the University of South Alabama. Applicable studies are not limited to IND trials and could include device and/or Investigator-Initiated trials.

## Definitions

**Adverse Event:** Any untoward medical occurrence in a clinical investigation subject.

**External Safety Report:** A report generated by the sponsor describing an adverse event occurring at an external site that meets the definition of a Serious Adverse Event, Unexpected adverse event, and suspected adverse reaction. Sometimes called an Outside Safety Report (OSR), Suspected Unexpected Serious Adverse Reaction (SUSAR), or Investigational New Drug (IND) safety report.

**Serious Adverse Event (SAE):** An adverse event that results in any of the following outcomes:

a. death;

b. a life-threatening adverse experience;

c. inpatient hospitalization or prolongation of existing hospitalization;

d. a persistent or significant disability such to disrupt a person's ability to conduct normal life functions;

e. a congenital anomaly/birth defect;

f. certain medical events that may not result in death, be life-threatening, or require hospitalization, may also be considered a serious adverse event when appropriate medical or surgical intervention is necessary to prevent one of the outcomes listed above.

**Unanticipated Problem:** An event not previously identified involving risk to the participant or others.

## Policy

The sponsor is responsible for informing the FDA and all participating investigators when a determination has been made that any event(s) meet the criteria for a serious and unexpected adverse event in the form of a safety report according to regulatory requirements. The Food and Drug Administration (FDA) and the Office of Human Research Protections advises that it is neither useful nor necessary for reports of individual adverse events occuring in subjects enrolled in multicenter studies to be distributed routinely to investigators or IRBs at all institutions conducting the research.

It is the responsibility of the Principal Investigator to review and acknowledge applicable external safety reports. The PI, or designee, is responsible for reporting external safety reports to the IRB of record per their reporting requirements.

## Procedure

External Safety Reports must be screened and reviewed from the time a study is initially approved by the IRB, at which time the PI is representing that the safety information in study documents accurately reflects the currently available information. Screening and review are necessary after that time point to ensure that any safety-related changes to the protocol and/or informed consent form are identified and implemented. Review is no longer necessary once all participants have completed study at the site.

Communicate this SOP to the sponsor prior to study initiation. The ideal time is during the feasibility stage or at the Site Qualification Visit.

### A. Receipt and Review Process

1. Only the primary study coordinator should be granted access to any sponsor required safety report portal, if applicable.

2. Only safety reports that meet *all three* of the following requirements will be reviewed by the PI:
    i. Serious adverse events or unanticipated problems or events that otherwise have implications for the conduct of the study (e.g., a significant change such as revising inclusion or exclusion criteria, adding a safety monitoring requirement, revising the informed consent, or revising the Investigator's Brochure).
    ii. Sponsor's assessment of causality indicates the event was an adverse reaction (caused by the investigational product or device) or a suspected adverse reaction (there is evidence to suggest a causal relationship between the drug and the adverse event). This may be reflected by language such as "related" or "probably related" rather than using the term suspected adverse reaction.
    iii. Sponsor's determination that the event is unexpected or represents an "unanticipated problem."
    b. Applicable external safety reports will be reviewed by the PI, in batches, on a regular basis. The PI will not use any sponsor portal for sign-off. Rather, the PI will use the site's electronic signature process or sign via wet ink.

**Reporting to the IRB**

External reports will be reported to the IRB per the IRB of record's reporting requirements. The site will not report to the IRB based on the sponsor's request. However, if a central IRB is being utilized, the sponsor is permitted to report to the IRB on the site's behalf.

**Retention of external safety reports**

Only the safety reports that the PI has reviewed will be retained in the study's regulatory file. Any applicable IRB documents will be retained. Records will be stored according to SOP CT 312: Record Archiving and Retention and federal regulations.

## Additional Resources

FDA GUIDANCE FOR INDUSTRY AND INVESTIGATORS: SAFETY REPORTING REQUIREMENTS FOR INDS AND BA/BE STUDIES

OHRP GUIDANCE ON REVIEWING AND REPORTING UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS AND ADVERSE EVENTS**,**

**RELATED SOPS:**

CT 312: Record Archiving and Retention

## History

**Next Review Date:** March 2027

## Responsible Party

Director, Clinical Trials Office