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## PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to provide instruction for handling a Serious Adverse Event (SAE) or Suspected Unexpected Serious Adverse Reaction (SUSAR) in a clinical trial in which the Investigational New Drug (IND) is sponsored by a NACHO Investigator (Study Chair).

## POLICY

All NACHO research protocols containing an IND will have clearly defined reporting criteria for SAEs and SUSARs written within the protocol. The research protocol should have an IND Safety Report form specific to that protocol or specify if the MedWatch form should be used. Per CFR 312.32 the sponsor-investigator is required to notify the FDA and all participating investigators in a written IND safety report of any adverse experience associated with the use of the drug that is both serious and unexpected.

## PROCEDURES

### I. Definitions

A. Sponsor-Investigator/Study Chair (SI/SC) is an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The sponsor investigator is the signature on the 1571 form. Refer to NACHO SOP "IND Sponsor Investigator Instructions" for more information.

B. SAE is the outcome of an adverse event that meets one of the following criteria:
   1. Death
   2. Life-threatening
   3. Hospitalization (initial or prolonged)
   4. Resulted in disability
   5. Congenital anomaly
   6. Important medical event

C. SUSAR is a serious adverse reaction in participants that may occur during the conduct of the protocol that may or may not be related to the investigational drug, but are unexpected, as they are not consistent with current information.

D. MedWatch Form is an FDA Form 3500A used to report SAEs and SUSARs which are felt to require filing with the FDA and/or other regulatory bodies.

### II. Reporting Requirements to NACHO Operations Center – Institutional Principal Investigator (site PI)

A. When applicable, all urgent SAEs and SUSARs will be reported to the SI/SC at the protocol specified contact information and the Clinical Studies Committee (CSC) within 48 hours of the event.

B. Each written notification shall be made as soon as possible, and in no event later than 10 calendar days after the SI/SCs initial receipt of the information.

C. Each written notification must be submitted on the protocol specified IND Safety Report Form.

D. Follow-up information to the safety report should be submitted as soon as the relevant information is available.

**III. Sponsor-Investigator Responsibilities**

A. Review all serious or unexpected adverse events reported.
B. Make final determination of attribution
C. Must inform the FDA of any SAE/SUSAR that is determined unexpected and related, as well as the IRB of record.
D. If FDA determines that additional data is needed, the SI/SC, with assistance from the site PI, will submit the additional requested data.
E. Amend the protocol and/or revise the consent forms as necessary.
F. Final report with action plan will be sent to the CSC

**IV. NACHO Study Manager (SM)**

A. Will submit Safety Reports to the NACHO OC
B. Will notify participating site investigators of all SAEs, SUSARs by email and post the IND Safety Report on the NACHO website on the protocol specific page.
C. If the FDA, IRB, or the SI/SC along with the NACHO CSC determines that the study should be immediately suspended, the NACHO SM will notify the consortium members of the suspension via numbered memos, and posting on the NACHO website on the protocol specific page.
D. Will notify participating site investigators of any corrective actions that must be taken as a result of the event.
E. Notify participating site investigators of changes that will be made to the research protocol and /or protocol documents.

**V. Participating Institutions (Site)**

**A.** The Institutional Principal Investigator will review all IND Safety reports and submit to the IRB of record.
B. Review all research protocol amendments and informed consent form revisions and submit to the IRB of record.
C. File the IND Safety Reports in the study binder.

**MAINTENANCE RESPONSIBILITY**

The NACHO SOP Ad Hoc Committee is responsible for the annual review of this SOP. Suggested changes must be proposed to and approved by the NACHO Executive Committee.

**AUTHORIZATION**

This SOP was developed by the SOP Ad Hoc Committee and reviewed and approved by the NACHO Executive Committee.

**VERSION/REVISION HISTORY**

| Approval Date | Version | Version/Revision Summary |
|---|---|---|
| 04/28/2021 | V 1.0 | Original documentation/publication. |
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