Clinical Research Enterprise (CRE)

Standard Operating Procedure for
Sponsor Generated IND/Safety Reporting

SOP #: 3.01

Version: 1.0

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Approval:

Approved By	Date
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Revision History:	**Version**	**Effective Date**	**Description**

Purpose

The purpose of this SOP is to explain the process for submitting Sponsor generated IND/Safety Reports

References

- 21 CFR 312.32

Scope

This SOP applies to the following – Study Personnel, Regulatory Affairs, Industry Sponsors and the FDA (if applicable).

Allowable Exceptions

This SOP is meant to be followed without deviation. However, it is an allowable exception to follow procedures specified in a protocol or by the sponsor. If a deviation from this SOP occurs, a description of this event will be written and filed with this list of SOPs and the protocol.

I. Definitions

a. IND Report: Safety report from the study Sponsor that provides information related to an adverse event or serious adverse event that has occurred during the study.

   i. Will be provided in a standard format (i.e. MedWatch, SUSAR)

II. Receipt of IND Reports and Obtaining Proper Signatures

a. Safety reports may be received via mail, email, or fax sent to the attention of the Investigator or study personnel.

b. Once received, the reports should be submitted to the study investigator for review and signature.

   i. If received by the study coordinator, they may put the IND reports in the

outbox to be routed for signature.

ii. Once signed and returned to coordinator, reports should be given to Clinical Trials Administrator to be filed in Regulatory Binder.

III. Reporting

a. Safety Reports received before the study has opened will be collected and submitted to the IRB at one time, before the study opens, via mail courier.

b. IND reports will be submitted per the Sponsor policy to the study's IRB.

i. The Clinical Trials Administrator will ensure that all safety reports are submitted and filed in the appropriate study binder.

c. The site will not be responsible for maintaining any reporting logs.

Training