Clinical Research Enterprise (CRE)

Standard Operating Procedures

Adverse Event and Serious Adverse Event (AE/SAE) Reporting SOP

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Purpose

The purpose of this SOP is to outline the general responsibilities and processes for AE and SAE reporting by the Clinical Research Enterprise (CRE), in alignment with protocol-specific requirements, IRB policies, and sponsor instructions.

References

- Study Protocol (Sponsor-Specific AE/SAE Reporting Plan)
- Sponsor AE/SAE Reporting Manual or Reference Guide
- UAB IRB Guidance on Unanticipated Problems / AE Reporting: https://www.uab.edu/research/home/irb-guidance-ae
- FDA Guidance 21 CFR 312.32 – IND Safety Reports
- FDA Guidance 21 CFR 812.150 – IDE Reporting Requirements
- WCG IRB Reporting Requirements for Unanticipated Problems and SAEs: https://www.wcgirb.com/for-researchers/reporting-requirements/
- Advarra IRB SAE and Unanticipated Problem Reporting Guidance: https://www.advarra.com/resources/guidance/unanticipated-problems-reporting/

Scope

This SOP applies to all clinical research studies managed by CRE that involve AE or SAE documentation and reporting. It is not a substitute for study-specific or sponsor-mandated procedures.

Allowable Exceptions

This SOP is meant to be followed without deviation unless otherwise specified by sponsor.

A. Procedure

- AE and SAE reporting will be conducted per the protocol and sponsor's guidelines.
- All AEs/SAEs must be reviewed and assessed for causality and severity by the Principal Investigator (PI).
- The study team will document AEs/SAEs in the source documents and, when required, in the electronic data capture system (e.g., EDC, CRFs, etc.).
- If applicable, the IRB will be notified of SAEs in accordance with the reporting requirements of the reviewing IRB (e.g., UAB IRB, WCG IRB, Advarra).
- For investigator-initiated studies, CRE staff will assist in submission of FDA MedWatch reports when required.