UC San Diego
HEALTH SCIENCES

Department of Neurosciences
UCSDSOG-011 Safety and Adverse Reporting

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Revision History		
Version No.	**Effective Date**	**Description**
v2	9 FEB 2026	Included detailed SUSAR Reporting Information

1 PURPOSE

1.1 This procedure outlines the process for Principal Investigators (PIs) and research personnel under the PI's supervision to follow when monitoring for, managing, reporting and documenting study events that may affect study participant safety. Events may include, but are not limited to, adverse events (AEs), serious adverse events (SAEs), unanticipated problems involving risk to subjects or others, unanticipated adverse device effects, protocol deviations, and non-compliance.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 REQUIREMENTS

3.1 Adverse events and non-compliance may be identified by any of these or other means:

- 3.1.1 Reporting by the study participant
- 3.1.2 Observation by research personnel
- 3.1.3 Report to research personnel by participant's family or medical providers
- 3.1.4 Documentation in the participant's medical records, including data in lab or other diagnostic reports.

3.2 21 CFR 312.60 General responsibilities of investigators states that investigators are responsible for "protecting the rights, safety, and welfare of subjects under the investigator's care", and for "ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan [protocol], and applicable regulations." To comply with this requirement, investigators must adhere to adverse event reporting requirements described in the study protocol, including specific timelines, types of events, and reporting processes.

3.3 21 CFR 312.64 [Investigator] Safety Reports states that an investigator must immediately report to the sponsor any serious adverse event, whether or not considered drug related, including those listed in the protocol or investigator brochure and must include an assessment of whether there is a reasonable possibility that the drug caused the event. Typically, this is interpreted to mean reporting within 24-48 hours or as specified in the study protocol.

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3.4 21CFR Part 312.3 defines sponsor-investigator and explains that an individual who both initiates and conducts an investigation must fulfill the requirements of both an investigator and a sponsor.

3.5 21 CFR 312.32 (c)(1) IND safety reporting states that "the sponsor must notify FDA and all participating investigators… in an IND safety report of potential serious risks, from clinical trials or any other source, as soon as possible, but in no case later than 15 calendar days after the sponsor determines that the information qualifies for reporting…"

3.5.1 Definition of Reportable Event (SUSAR vs IND Safety Report):

A SUSAR (Suspected Unexpected Serious Adverse Reaction) is an ICH term used to describing an adverse event that is:

- Serious (meet seriousness criteria such as hospitalization, life-threatening event, disability, death, etc.),
- Unexpected (not consistent with current Investigator Brochure, protocol, labeling), and
- Suspected to be related to the investigational product (drug).

In the U.S. regulatory framework, SUSARs are typically communicated through an IND Safety Report, although not all IND Safety Reports are SUSARs. IND Safety Reports may also include other safety findings (e.g. significant increased frequency of known reactions, animal data suggesting risk, or important safety signals from other studies). The term "SUSAR" is most commonly used by global and in multi-site sponsor communications.

3.5.2 Principal Investigator Responsibilities Upon Receipt of an IND safety report (SUSARs): Upon receipt of an IND Safety Report (which may include SUSARs), the principal investigator is responsible for reviewing the report and determining[1] whether the event meets the criteria for IRB submission. If reporting is required, submission to the IRB should occur as soon as possible, but no later than 10 calendar days from receipt.

3.5.3 Events Not Requiring Immediate IRB submission:

Events not meeting the IRB criteria from prompt reposting (not serious, not unexpected, or not reasonable related to the investigational product) should be summarized and reported to the IRB at the time of continuing review in a cumulative tracking format such as an Excel table.

3.6 21 CFR 312.32(c)(2) Unexpected fatal or life-threatening suspected adverse reaction reports states that "the sponsor must also notify FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than 7 calendar days after the sponsor's initial receipt of the information. Additionally, 21 CFR 312.53 (c)(1)(vi)(e) Obtaining information from the investigator indicates sponsor must obtain a commitment by the investigator for reporting "to the sponsor adverse experiences that occur in the course of the investigation(s), in accordance with 312.64 Investigator reports."

3.7 FDA Form 1572 Statement of Investigator identifies the commitments of the investigator when conducting clinical trials and includes the following statements:

3.7.1 "I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects."

3.7.2 "I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug."

3.8 Good clinical practice guidelines E6 (R2) established by the International Council on Harmonization (ICH), provide guidance on AE and SAE reporting requirements, stating that "adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol (section 4.11.2); and "all SAEs should be reported immediately to the sponsor, except for those SAEs that the protocol or other document identifies as not needing immediate reporting (section 4.11.1)."

3.9 For device studies, the investigator must report unanticipated adverse device effects to the sponsor and to the IRB within 10 days of awareness. Investigational device exemption regulations at 21 CFR 812.150(a)(1) Unanticipated adverse device effects state that "an investigator shall submit to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect."

3.10 For studies under Office for Human Research Protections (OHRP) oversight, the regulations at 45 CFR 46.108 (a)(4) require procedures to ensure prompt reporting to the IRB and subsequently the OHRP of "any unanticipated problem involving risks to subjects or others or any serious or continuing noncompliance with [OHRP] policy or determinations of the IRB."

3.11 OIA-103 IRB Handbook "What are my obligations after IRB approval?" and "Appendix A Prompt Reporting Requirements" specifies post-approval reporting requirements at UC San Diego. The PI is responsible for following all IRB policies and procedures for adverse event reporting.

3.12 OIA-001 SOP: Definitions describes relevant definitions related to safety reporting, including definitions of AEs, SAEs, and serious and continuing non-compliance.

3.13 For studies reviewed by a Central IRB, investigators must also adhere to the reporting guidance and requirements of the IRB of Record.

4 RESPONSIBILITIES

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4.1 The PI retains ultimate responsibility for study event monitoring and reporting; the PI may delegate[1] this duty to a research team member provided the delegation is appropriately documented.

4.2 All clinical research personnel are responsible for safeguarding research participants' safety and for reporting safety information to the PI.

5 PROCEDURE

5.1 When the PI or designee is made aware that a study participant experienced or may have experienced an AE:

5.1.1 The PI or designee will document the event(s) in the participant's study file.

5.1.2 A qualified investigator will assess each event to determine and document its severity, seriousness, expectedness, and causality/relationship to study participation or study intervention(s).

5.1.2.1 Departmental AE log template provide an example of the data points to be evaluated in assessing an AE.

5.1.3 The PI or designee will determine whether the event meets sponsor and/or IRB prompt reporting criteria.

5.1.3.1 If prompt reporting to the sponsor is required:

5.1.3.1.1 The PI or designee will submit the report to the sponsor within the required timeframe, providing all relevant, available information.

5.1.3.1.2 As additional information becomes available, the PI or designee will provide updated reports to the sponsor in a timely manner.

5.1.3.2 If prompt reporting to the IRB is required:

5.1.3.2.1 The PI or designee will report the event to IRB as a reportable event, using the IRB electronic submission system.

5.1.3.3 If prompt reporting to the sponsor is not required:

5.1.3.3.1 The PI or designee will maintain the event documentation in the participant's study file, including the outcomes of the event, for further evaluation and monitoring by the sponsor.

5.1.3.3.1.1 Departmental AE log template provide an example of a recording log that may be used

[1] UCSDSOG-004 - Delegation of Authority

[2] FDA IND Safety Reports (SUSARs) Worksheet (Neurosciences Webpage)

to maintain AE data for subsequent monitoring and evaluation.

5.1.3.4 If prompt reporting to the IRB is not required:

5.1.3.4.1 The PI or designee will maintain a log of the events, noting any relevant trends, for reporting to the IRB at continuing review or at other intervals required by the IRB.

5.1.3.4.1.1 Departmental AE log template provides an example of a recording log that may be used to maintain AE data for subsequent monitoring and evaluation.

5.1.4 If the investigation is being conducted by the PI as a sponsor-investigator, the PI will determine whether prompt reporting to the FDA is required.

5.1.4.1.1 If prompt reporting to the FDA is required, the PI or designee will report the event to FDA, following appropriate FDA reporting procedures.

5.1.4.1.2 If prompt reporting to the FDA is not required, the PI or designee will maintain the event documentation in the study file, including the outcomes of the event, for further evaluation and monitoring.

5.1.4.1.2.1 Departmental AE log may be used to AE data for reporting, subsequent monitoring and evaluation.

5.2 When the PI or designee is made aware that a study deviation has occurred:

5.2.1 The PI or designee will document the event(s) in the participant's study file, or, if the deviation is not related to a specific participant, in the study regulatory file.

5.2.2 A qualified investigator will assess the event to determine its impact or potential impact on study participant safety and data integrity. Note that the IRB does not generally require reporting of minor deviations, defined in OIA-103 as "a change to, or failure to adhere to, the research protocol or applicable OIA requirements that does not pose a risk of harm to the human subject's rights, safety or welfare, or to the integrity of the research data, and does not rise to the level of non-compliance.

5.2.3 The PI or designee will determine whether the event meets sponsor and/or IRB prompt reporting criteria and will follow the appropriate reporting steps in 5.1.3 or 5.1.4 above.

5.3 Following the reporting of an SAE or an unanticipated problem:

5.3.1 The PI will ensure that participants are appropriately monitored and that any necessary clinical care and follow-up are provided.

5.3.2 The PI will consider whether modifications to the protocol are required for participant safety, following the applicable regulatory requirements for prompt implementation or submission to IRB for approval before implementation.

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5.4 Documentation of all study events will be maintained and retained for the duration of the study and for the required record retention period. All documentation must be available for audit or regulatory inspection.

6 MATERIALS

6.1 UCSDSOG-004 Protocol Deviation Tracking
6.2 Departmental AE Log Template (Neurosciences Webpage)

7 REFERENCES

7.1 OIA-001 SOP: Definitions
7.2 OIA-103 IRB Handbook
7.3 45 CFR Part 46 Protection of Human Subjects
7.4 45 CFR 46.108 (a)(4) IRB functions and operations
7.5 21 CFR Part 312 Investigational New Drug Application
7.6 21 CFR 312.32 (c)(1) IND Safety Reporting
7.7 21 CFR 312.32(c)(2) Unexpected fatal or life-threatening suspected adverse reaction reports
7.8 21 CFR 312.53 (c)(1)(vi)(e) Obtaining information from the investigator
7.9 21 CFR 312.60 General responsibilities of investigators
7.10 21 CFR 312.64 Investigator reports
7.11 FDA Form 1572 Statement of Investigator
7.12 21 CFR 812 Investigational Device Exemptions
7.13 21 CFR 812.150(a)(1) Unanticipated Adverse Device Effects
7.14 ICH E6 (R2) Guideline for Good Clinical Practice
7.15 Adverse Event Reporting to IRBs – FDA Guidance
7.16 Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events: OHRP Guidance
7.17 UC San Diego Health Sciences Research Policies