PERIGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute** **Institutional Review Board**
PELI-IRB SOP 13/08-0-2022	
Version No. 5	**SOP 13** **Review of SAEs and SUSARS**
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Supersedes: Previous SOPs of the PELI-IRB	

SOP 13 Review of SAEs and SUSARs

1. **Purpose**

   To describe the IRB review procedures for Serious Adverse Events (SAE) and Suspected Unexpected Serious Adverse Reactions (SUSAR).

2. **Scope**

   This SOP applies to the review of Serious Adverse Events (SAE) and Suspected Unexpected Serious Adverse Reactions (SUSAR) submitted by investigators and sponsors to the PELI-IRB to comply with the ICH-GCP. The IRB reviews such reports to determine appropriate action to protect the safety of participants in an approved study. ICH-GCP E6 defines a serious adverse event (SAE) or a serious adverse drug reaction (SAR) as any untoward medical occurrence that at any dose:
   - Results in death
   - Is life-threatening
   - Requires hospitalization or prolongation of existing hospitalization
   - Results in persistent or significant disability or
   - Results in a congenital anomaly or birth defect.

   A suspected unexpected serious adverse reaction (SUSAR) is a serious event the nature and severity of which is not consistent with the applicable product information. In the case of an unapproved investigational product, the event is not consistent with the investigator's brochure (IB). In the case of a licensed product, the event is not consistent with the approved package insert or summary of product characteristics.

3. **Responsibility**
   - The primary responsibility of the PELI-IRB is to conduct an appropriate review of SAE and SUSAR reports to ensure oversight on the safety of participants enrolled in the study and compliance to ICH-GCP guidelines of timelines of reporting such as the following:
     - IRB shall ensure that Site informed the sponsor within twenty-four (24) hours upon knowing occurrence of an SAE.
     - IRB shall ensure that Site inform IRB within seven (7) days upon knowing occurrence of an SAE

- The IRB should also make sure that researches are made aware of its policies and procedures concerning SAE reporting.
- The PELI-IRB sets up necessary mechanisms to receive SAE and SUSAR reports from investigators and sponsors of researches that it has approved.
- The primary responsibility of the PELI-IRB is to receive and review SAE and SUSAR reports from its own site and to take necessary action to ensure the safety of participants in the study.
- The evaluation of the SAEs and SUSARs shall be conducted by a reviewer assigned by the Chair, whose recommendation shall be submitted to the IRB for final action.
- In multicenter studies, the IRB also receives SAE and SUSAR reports from the other sites within and outside the country. It is the responsibility of the PELI-IRB to be updated about safety issues related to studies that it has approved.
- The PELI-IRB has the authority to suspend or terminate approval of research at its site when the safety of the participants is no longer assured. When PELI-IRB takes such action, it is required to provide the reasons for its action and to promptly report such decision to the investigator, the sponsor, the institution and relevant regulatory authorities.

4. Process Flows/Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Report SAE and SUSAR to the IRB	Principal Investigator	within 7 days of knowing occurrence
2	Receive , check completion and log SAE/SUSAR report	Staff Secretary	On day of receipt of report
3	Notify Chair	Staff Secretary	1 day from receipt of report
4	Delegate SAE reviewer per study	Chair	1-2 days of being informed of initial SAE report of study
5	Distribute SAE reports to delegated SAE reviewer	Staff Secretary	1 day upon being informed of delegated SAE reviewer
6	Review SAE and SUSAR reports and make a recommendation	SAE Reviewer	1 week upon receipt of the report
7	Inclusion of report of SAE Reviewer in IRB meeting agenda	Chair and Staff Secretary	2 weeks before full board meeting
8	Summarize and report to full board for appropriate action	SAE reviewer	Not applicable
9	Inform Principal Investigator of IRB decision	Staff Secretary	1-3 days from full board meeting
10	Update database for SAE reports	Staff Secretary	1-3 days from full board meeting

5. Detailed Instructions

Step 1 The IRB should inform the Principal Investigators that they are required to report SAE and SUSARs to the IRB for all studies within 7 days of knowing of the occurrence.

Step 2 Receipt and documentation of submission of report of SAEs and SUSARs in the logbook/database:

For On-site SAE's the Staff Secretary shall receive the following SAE report submission packet:

a. Cover Letter
b. **Form 3.1**Serious Adverse Event Report Form (section 1 for the PI)

For Off-site SAE's, the PI receives notification of these events from the Study Sponsor, usually referred to as Sponsor Safety Reports or Safety Memos, and a copy of the said report is given to PELI-IRB.

The staff secretary shall ensure that the forms for On-site SAE's are properly accomplished, enters the submission of on-site and off-site SAE's into the logbook, and notes whether the submission is within the required timeline of within 7 days of knowledge of the occurrence.

Step 3 The Staff notifies and sends the report and the retrieved documents to the Chair by SMS and email within one day of receipt.

Step 4 The Chair designates a reviewer for the SAE/SUSAR within 1-2 days after receiving the report and informs the Staff Secretary.

Step 5 The Staff Secretary distributes the SAE/SUSAR report to the designated reviewer one (1) day upon assignment of reviewer by the Chair.

Step 6 The designated SAE reviewer shall review the report and recommend an action within 7 days from receipt of report with the following guidelines:

- For multi-center international studies, note the trend of occurrence of SAE/SUSAR in study sites in foreign countries and other local sites.
- For multi-center, national studies, note the nature (related or expected) of the SAE or SUSAR.
- For SAEs that occur onsite, the PELI IRB should analyze the investigator/sponsor agreement (related, unexpected) and may need to recommend action to the investigator to ensure the safety of the participants. The designated IRB members should inform the Chair about their recommendation for appropriate IRB action.

Step 7 All SAE/ SUSAR reports are added to the agenda of the next full board meeting before decision is made unless a need to give prompt IRB recommendation is foreseen by

the Chair and the delegated SAE reviewer due to the significant delayed or lack of action from site, to ensure safety of the study participant.

Step 8 The designated SAE/SUSAR reviewer shall summarize the report, or Sponsor Safety Report/ Safety Memo if the SAE or SUSAR is off-site, and give the recommended action for ratification discussion and final decision by the board **Form 3.1** Serious Adverse Event Form (section 2 for recommended action) in possible actions of the board include:

- Notation with no further action required
- Further information or action required
- Request amendment to protocol
- Suspension or termination of study

Step 9 The Staff secretary shall have 1-3 days after the full board meeting to send a notification letter **Form 2.8** Approval Letter for Post-approval Procedures with signature by the Member Secretary and Chair to inform the investigator about the IRB decision. See SOP on Communicating IRB decisions.

Step 10 The Staff Secretary shall keep an updated database to track all SAE occurrences and shall ensure access to the SAE reviewers, members and officers. See SOP 29 Management of Active Files.