**Statement of Policy**

The REC shall require the submission of reports of SAEs and SUSARs within 7 days after the event has come to the attention of the researcher. The evaluation of the SAEs and SUSARs shall be conducted by the Subcommittee on SAEs and SUSARs whose recommendation shall be submitted to the REC for final action.

**Objectives of the SOP**

Review of SAE and SUSAR reports aims to ensure that the safety and welfare of human participants in the study site are safeguarded and that information on SAEs and SUSARs are properly documented and evaluated.

**Scope/Applicability**

This SOP applies to the review of reports of SAEs in various studies and SUSARs in clinical trials. This SOP begins with the receipt and documentation of submission of report of SAEs and SUSARs in the logbook and ends with the filing of all related documents and update of the protocol database.

**Flowchart**

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| --- | --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** | **TIMELINE** |
| Step 1: Receipt and documentation of submission of report of SAEs and SUSARs in the logbook. | Staff | 1 day |
| Step 2: Retrieval of pertinent protocol file | Staff | 1-2 days |
| Step 3: Notification of Chair  | Staff | 1 day |
| Step 4: Submission of report REC | Staff | 1-2 days |
| Step 5: Inclusion of report in the agenda of the next regular REC meeting | Staff and Chair | 1-2 days |
| Step 6: Communication of REC action to the Principal Investigator/researcher (SOP on Communication of REC Decisions (SOP# 21)) | Staff and Chair | 1 day |
| Step 7: Filing of all related documents (SOP 23 Management of Active Files) and Update of the protocol database | Staff | 1 day |

**Description of Procedures**

Step 1 - Receipt and documentation of submission of report of SAEs and SUSARs in the logbook/database: The Staff receives the accomplished SAE/SUSARs report forms (Form 019 ) and enters the submission into the logbook. The Staff notes whether the submission is within the required timeline.

Timeline Requirements

1. The Principal Investigator must report to REC panel all SAEs and SUSARs according to the following timelines consistent with FDA Guidelines on Safety Reporting (FDA Circular 2012-007).:

1.1. Fatal or life-threatening unexpected adverse drug reactions that occurred onsite must be reported to the REC panel promptly, no later than 7 calendar days after first knowledge by the PI that a case qualifies, followed by as complete a report as possible within 8 additional calendar days, to

coincide with reporting to FDA.

1.2. All other serious unexpected adverse drug reactions must be reported to REC promptly, no later than 15 calendar days after first knowledge by the PI that a case meets the minimum criteria for expedited reporting, to coincide with reporting to FDA.

1.3. For onsite serious adverse events that are expected and non-life threatening, and all other unexpected serious adverse drug reactions that occurred off-site, a summary listing must be reported to REC attached to the submission of the progress report or final report, whichever will be submitted earlier.

2. Deaths MUST be reported to REC if they occur within thirty (30) days of the study intervention. Any death occurring greater than 30 days after the last dose of the investigational agent/intervention requires expedited reporting if it is possibly, probably, or definitely related to the investigational agent/intervention or if death cannot be determined based on WHO Causality Assessment definitions.

3. The Principal Investigator submits a copy of the SAE submission to REC coinciding with the sponsor’s timeline of the reporting requirement to the FDA.

4. Summary of Timeline Requirements for Reporting of PI

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| --- | --- | --- | --- |
| EVENT TYPE | ONSITE OR OFF-SITE  | EXPECTED OR UNEXPECTED | REPORTING REQUIREMENTS |
| Fatal or lifethreateningserious adverseevent andreaction | Onsite | Unexpected | Report fatal or life-threateningunexpected SAEs and SUSARs within seven (7) calendar days usingForm 019:SAE/SUSAR Report |
| Non-lifethreateningserious adverseevent | Onsite | Unexpected | Report non- life-threateningunexpected ADRs within fifteen(15) calendar days usingForm 019:SAE/SUSAR Report |
| Non-lifethreateningserious adverseevents | Onsite | Expected | Report a summary listing withan annual report or Final report,whichever will be submittedearlier. |
| Serious adversereaction | Off-site | Unexpected | Report a summary listing withan annual report or Final report,whichever will be submittedearlier. |

Step 2 - Retrieval of pertinent protocol file: The Staff retrieves the identity of the primary reviewers (if there is no SAE/SUSAR subcommittee) and a tabulation of earlier SAE/SUSAR reports.

Step 3 - Notification of Chair: The Staff notifies and sends the report and the retrieved documents to the Chair.

Step 4 - Submission of report to REC: The Chair forwards the report and pertinent documents to the primary reviewers for action which should not be later than 3 days prior to the next committee meeting.

Step 5 - Inclusion of report in REC meeting agenda: The suggested action/decision of the primary reviewer is included in the Agenda of the next meeting (see SOP on Preparing the Meeting Agenda). for ratification or discussion and final decision. Possible actions include: notation with no further action required, further information or action required or suspension of recruitment.

Step 6 - Communication of REC recommendation to the Principal Investigator/researcher: See SOP on Communicating REC decisions.

Step 7 - Filing of all related documents and update of the protocol database: See SOP on Managing Active Files (SOP# 23).

**Forms:**

SOP 11B Form 019 SAE/SUSAR Report

Form 008 REC Decision Letter

 **History of SOP**

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| **Version No.** | **Date** | **Authors** | **Main Change** |
| 01 | 01/28/2015 |  |  |
| 02 | 06/21/2019 | krva | Inclusion of Reportable Negative Events (RNE) in SOP on SAE, SUSAR |
| 03 | 09/26/2022 | krva | Revision of SOP on SAE, SUSAR |
| 04 | 02/08/2024 | krva | DOH/FDA timelines |