1. **Policy Statement**

The ISU-IREB shall require the submission of reports of  Serious Adverse Events  (SAE) and Suspected Unexpected Serious Adverse Reaction (SUSAR) reports within 48 hours 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 IREB for final action.

1. **Objective of the Activity**

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.

1. **Scope**

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 reports of SAEs and SUSARs in the logbook and ends with the filing of all related documents and update of the protocol database.

1. **Workflow**

|  |  |
| --- | --- |
| **ACTIVITY** | **RESPONSIBLE PERSON** |
| 1. Receipt and documentation of submission of report of SAEs & SUSAR’s the logbook/database | ISU-IREB Secretariat |
| 2. Notification of ISU-IREB Chairperson and assessment of report | ISU- IREB Chairperson |
| 3. Inclusion of report in the agenda of the next IREB meeting | ISU-IREB Secretariat |
| 4. Communication of IREB recommendation to the Researcher/s | ISU-IREB Secretariat |
| 5. Filing of all related documents | ISU-IREB Secretariat |

1. **Description of Procedures**

**5.1. Receipt and documentation of submission of report of SAEs and SUSARs in the logbook/database**

5.1.1. The researcher/investigator is required to report all the SAEs and SUSARs to the IREB and should follow the format outlined in Form 11B SERIOUS ADVERSE EVENT (SAEs) and Suspected Unexpected Serious Adverse Reaction (SUSAR) Reports

5.1.2. The Secretariat receives the report, check for completeness and appropriateness of the code number and form and updates the database.

5.1.3. SERIOUS ADVERSE EVENT (SAEs) and SUSPECTED UNEXPECTED SERIOUS ADVERSE REACTION (SUSAR) REPORTS are events temporally associated with the subject’s participation in research that meets any of the following criteria:

1. Death
2. Life threatening
3. Hospitalization (initial or prolonged)
4. Disability or permanent damage
5. Congenital anomaly/ birth defect
6. Required intervention to prevent permanent impairment or damage (devices)
7. Other serious (important medical) events whether or not it is related to the study intervention

**5.2. Notification of IREB Chairperson and assessment of report**

5.2.1. The IREB Secretariat notifies the chairperson of the report received.

 5.2.2. The IREB Chairperson or the assigned member recommends an appropriate action which may be a site visit, review of the protocol deviation, etc. as necessary.

**5.3. Inclusion of report in the agenda of the next regular IREB meeting**

5.3.1. The IREB Secretariat includes the SAE and SUSAR reports.

5.3.2. All SAE-SUSAR assessed to be included in the full board review shall be discussed during full board meeting.

5.3.3. After deliberation, the IREB Chairperson or member may request for a consensus to either:

5.3.3.1. Request for additional information or follow up reports

5.3.3.2. Request amendment of protocol or informed consent

5.3.3.3. No additional action necessary

**5.4. Communication of IREB recommendation to the researcher/s**

5.4.1. The IREB Chairpetson notifies the Researcher/s of the recommended action in writing (SOP 21 : COMMUNICATING CVHRDC REC. DECISIONS).

**5.5. Filing of all related documents**

5.5.1. The IREB Secretariat files all related documents in the appropriate study protocol folders.

1. **Glossary**

**Principal Investigator** - the lead person selected by the sponsor to be primarily responsible for the implementation of a sponsor-initiated clinical drug trial.

**Researcher-Initiated Studies** – are research activities whose conceptualization, protocol development and implementation are done by a researcher or group of individuals who may request for external funding support.

**SAE (Serious Adverse Events)** – is an event observed during the implementation of a study where

the outcome is any of the following:

* Death
* Life threatening
* Hospitalization (initial or prolonged)
* Disability or permanent damage
* Congenital anomaly/ birth defect
* Required intervention to prevent permanent impairment or damage (devices)
* Other serious (important medical) events whether or not it is related to the study intervention.

**SUSAR (Suspected Unexpected Serious Adverse Reactions)** - is a noxious response to a drug that is not described in the Investigator’s Brochure nor in the drug insert.

**Sponsor**- an individual, company, institution or organization which takes responsibility for the initiation, management, and financing of a clinical trial.

1. **Forms**

Form 11B    SERIOUS ADVERSE EFFECTS (SAE) AND SUSPECTED UNEXPECTED SERIOUS ADVERSE REACTION (SUSAR) REPORT

Logbook

Database

1. **History**

|  |  |  |  |
| --- | --- | --- | --- |
| **Version No.** | **Date** | **Authors** | **Main Change** |
| 0 |  | ISU-IREB SOP Team |  |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |

1. **References**

Forum for Ethical Review Committees in the Asian and Western Pacific Region (FRECAP) Development of Standard Operating Procedures for Ethics Committees

WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

    Philippine Health Research Ethics Board Standard Operating Procedures 2020

National Ethical Guidelines for  Research Involving Human  Participants 2022

|  |  |
| --- | --- |
| Prepared by: |  |
| Recommending Approval: |  |
| Approved by: |  |
| Approval Date: |  |