1. **Policy Statement**

The ISU-IREB shall require the submission of Reportable Negative Events (RNEs) reports, at the latest three (3) days after the event has come to the attention of the researcher. A special meeting shall be considered depending on the level of risk involved.

1. **Objective of the Activity**

To ensure that the safety and welfare of human participants and the research team are safeguarded and that information on Reportable Negative Events (RNEs) are properly documented and evaluated.”

1. **Scope**

This SOP applies to the review of Reportable Negative Events (RNEs) of nonclinical studies. It begins with the receipt and documentation of submission of RNE report in the logbook and ends with the filing of all related documents and update of the protocol database.”

1. **Workflow**

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| --- | --- |
| **ACTIVITY** | **RESPONSIBLE PERSON** |
| 1. Receipt and documentation of submission of report of RNEs the logbook/database | ISU-IREB Secretariat |
| 2. Notification of 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 RNEs  in the logbook/database**

5.1.1. The researcher/investigator is required to report all the RNEs to the

IREB and should follow the format outlined in Form 11A REPORTABLE NEGATIVE EVENTS (RNEs)

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

5.1.3. Reportable Negative Events (RNEs) are events temporally associated with the subject’s participation in research that meets any of the following criteria:

5.1.3.1. Negative emotional/psychological effects

5.1.3.2. Treat to safety to researches and participants

5.1.3.3. Requires inpatient hospitalization or prolongation of existing hospitalization

5.1.3.4. Results in a persistent or significant disability/incapacity

5.1.3.5. Life-threatening (places the subject at immediate risk of death from the event as it occurred)

5.1.3.6. Results in death

**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 as necessary.

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

5.3.1. The IREB Secretariat includes the RNE report.

5.3.2. All RNEs 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 Chairperson notifies the Researcher/s of the recommended action in writing (SOP 21 : COMMUNICATING IREB. 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**

**Clarificatory Meeting/ Interview** – is a face-to-face meeting or consultation of the REC with the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the REC.

**Reportable Negative Events (RNE)** - are occurrences in the study site that indicate risks or actual harms to participants and to members of the research team and to integrity of data. Examples are brewing hostilities in the research community, natural calamities, unleashed dogs, threats of harassment, etc.,

**Special meeting** – an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like selection of officer, approval of a revised or new SOP, report of critical research problem that requires immediate action

**Study Site** - physical location of where the study is being conducted, e.g., community, institutional facility.

1. **Forms**

Form 11A  SERIOUS ADVERSE EVENT (SAE) REPORT

Logbook

Database

1. **History**

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

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