1. **Policy Statement**

Researchers shall report protocol deviations and violations in the conduct of approved research within a week from the detection of the protocol violation/deviation.    Major protocol violations undergo full review

1. **Objective of the Activity**

To ensure that the safety and welfare of human participants in the study are safeguarded and that the credibility and integrity of data are maintained.

1. **Scope**

This SOP applies to the review of reports of protocol deviations or violations in the conduct of previously approved studies. This begins with the receipt and documentation of the report of protocol violations and deviations in the logbook and ends with the filing of all related documents and update of the database.

1. **Workflow**

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| **ACTIVITY** | **RESPONSIBLE PERSON** |
| 1. Receipt and documentation of report of protocol violations and deviations in the logbook/database | ISU-IREB Secretariat |
| 2. Determination of type of review and deliberation for appropriate action | ISU-IREB Chairperson |
| 3. Forward protocol violation/ noncompliance / deviation report to appropriate IREB Member/s | ISU-IREB Secretariat |
| 4. Review of Study Protocol Noncompliance Report | ISU-IREB Chairperson/ Members |
| 5. Communication of decision to the Researcher/s | ISU-IREB Secretariat |
| 6. Filing of all related documents | ISU-IREB Secretariat |

1. **Description of Procedures**

**5.1. Receipt and documentation of report of protocol violations and deviations in the logbook/database**

5.1.1. The ISU-IREB Secretariat receives the Form 10A PROTOCOL DEVIATION/NONCOMPLIANCE/VIOLATION REPORT associated with any non-compliance to the previously approved protocol and other related documents.

5.1.2.   The Secretariat checks the submission for completeness and gives a receiving copy of Form 10A  PROTOCOL DEVIATION/NONCOMPLIANCE/VIOLATION REPORTto the researcher/s or his/her representative.

5.1.3.   The Secretariat logs the date of submission.

**5.2. Determination of type of review and deliberation for appropriate action**

5.2.1. The IREB Chairperson classifies the submission as either full board or expedited review.

5.2.2.  Protocol violation in a research study that involves more than minimal risk must be reviewed by full board committee while protocol violation in a research study that involves minimal risk maybe eligible for expedited review by the primary reviewers who did the initial protocol review.

5.2.3    If the violation involves a drug, device, biologic or other interventional activity of the study, a medical or scientific primary reviewer who did the initial review must do the review while if the reported violation involves the consent process or non-interventional activity of the study, anyone of the primary reviewers should do the review process.

**5.3. Forward protocol violation/ noncompliance / deviation report to appropriate IREB Member/s**

5.3.1 The secretary staff logs the report in LOGBOOK 2  OF OUTGOING DOCUMENTS and forwards the package to the primary reviewer/s at least 10 days before the full committee meeting.

5.3.2 The primary reviewer/s assess if the protocol violation / noncompliance / Deviation altered the risk benefit balance of the study or the integrity of the   data and shall return the completely accomplished Form 10A DEVIATION/NONCOMPLIANCE/VIOLATION REPORT.

**5.4 Review of Study Protocol Noncompliance Report**

5.4.1. The Secretariat distributes the study protocol noncompliance report package to the IREB Members along with the meeting agenda.

5.4.2.  The primary reviewer/s present the result of their assessment to full committee who deliberate on effects of the protocol violation/deviation on the rights and safety of research participants

5.4.3 The IREB Chairperson / members shall review the information available and take a decision depending on the seriousness of the violation.

5.4.4 Possible review decisions are as follows:

a. Acknowledged – no further information or action required

b. Additional information required – additional information is needed in order to properly evaluate the violation

c. Correction and/or corrective action are required which can be

i. suspension until further notice

ii. suspension of recruitment of participants until corrective actions are taken

iii. modify the protocol

iv. observe ICF process

v. change continuing review timeline

vi. requires training of investigator/researcher

viii. etc

5.4.5 If the protocol deviation/noncompliance/violation report is by expedited review, decision is finalized at the level of the primary reviewers or the IREB Chairperson/member-Secretary who then accomplished the Form 10A DEVIATION/NONCOMPLIANCE/VIOLATION REPORT and return the entire package to the secretariat with a week from the receipt of package.

5.4.6 If the protocol violation/noncompliance/deviation is be expedited review, possible review decisions are as follows

 a. Acknowledged – no further information or action is required

b. Additional information required – additional information is needed in order to properly evaluate the violation

c. Refer for full board committee review – violation appears serious or continuing non-compliance may be involved.

5.4.7. The decision shall be taken to ensure that the safety and rights of the research participants are safeguarded. The decision shall be taken by consensus and if no consensus is arrived at, voting shall be conducted.

**5.5. Communication of decision to the Researcher/s**

5.5.1. The IREB Chairperson notifies the Researcher/s of the IREB  SOP 21 COMMUNICATING IREB DECISIONS using Form 5C Decision Letter

5.5.2. If corrective action/s are required, the researcher/investigator is requested to provide information. Depending on the magnitude of risk to research participants the IREB Chairperson may request suitable IREB members to conduct a study site monitoring visit to verify if the researcher/investigator has followed the recommended course of action. Refer to SOP 16  CONDUCT OF SITE MONITORING.

5.5.3. The study approval may be temporarily or permanently withdrawn in the following case/s.

5.5.3.1.   Repeated deviation which compromises the safety and well-being of study participants

5.5.3.2.    Implementation of a protocol or related documents with major amendments without approval from the committee

5.5.3.3.    No action required for protocol deviation which is deemed minor and will not impact the study performance and outcome and will not compromise patient safety.

**5.6 Filing of all related documents**

5.5.1. The IREB Secretariat records and files all related documents in the study protocol folder.

1. **Glossary**

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

**Expedited Review**- is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.

**Full Review** -  is the ethical evaluation of a research proposal and other protocol-related

documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.

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

**Protocol Deviation** – non-compliance with the approved protocol that does not increase risk or decrease benefit to participants or does not significantly affect their rights, safety or welfare or the integrity of data. Example: missed visit, non-submission of a food diary on time.

**Protocol Violation** - non-compliance with the approved protocol that increases risk or

decreases benefit to participants or  significantly affects  their rights, safety or welfare orthe integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.

**Researcher-** is the individual primarily responsible for the conceptualization, planning and implementation of a study.

**Protocol File** – is an organized physical or electronic compilation of all documents related to a Protocol

**Site Visit** – is an activity of the IREB where an assigned team goes to the research site or office for specific monitoring purposes.

1. **Forms**

       Form 10A  DEVIATION/NONCOMPLIANCE/VIOLATION 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:   |  |