1. **Policy Statement**

When a decision for early termination of the research has been made, the well-being and safety of study participants that have already been recruited shall be a primary consideration and the plan for termination shall reflect this concern. Early termination reports shall undergo full review.

1. **Objective of the Activity**

Review of early termination reports aims to ensure that the decision takes into consideration the safety and welfare of study participants that have already been recruited and that there is adherence to the principle of fairness for all concerned.

1. **Scope**

This Standard Operating Procedure (SOP) applies to the review of early termination reports.  This SOP begins with the receipt and entry to logbook of the early termination reports and ends with the communication of committee action to the researcher/investigator and updating of the protocol database.

1. **Workflow**

|  |  |
| --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** |
| 1: Receipt of the early termination report and entry into the logbook (SOP 23 Management of Active Files) | Staff |
| 2: Retrieval of pertinent protocol file | Staff |
| 3: Notification of Chair and Primary Reviewers | Staff |
| 4: Full review (SOP on Full Review (SOP 5) | Primary Reviewers and Members |
| 5: Communication of committee action (SOP 21 Communicating ISU-IREB) and update of the protocol database (SOP 23 Management of Active Files) | Chair, Staff |

1. **Description of Procedures**

**5.1 -** **Receipt and entry to the logbook and database of early termination reports, for review**: The IREB staff receives the early termination report and enters the appropriate information into the log book (SOP 23 Management of Active Files)

**5.2 - Retrieval of pertinent protocol file**: The IREB Staff retrieves the protocol folder and summarizes the documents that have been submitted.

**5.3 - Notification of Chair and Primary Reviewers**: The IREB staff informs the Chair and the primary reviewers by email about the report and the summary of documents that have been submitted. S/he waits for further instructions.

**5.4 - Full review**: The Chair instructs the staff to include the report in the agenda of the next meeting and to ensure that the primary reviewers are given the necessary documents so that s/he can prepare the presentation during the next meeting (SOP 5 Full Review). The review should ensure implication of the early termination on the rights, safety, and welfare of the study participants, in the form of a termination package with a set of procedures. The procedures may include adapting specific provisions for continued access to protective mechanisms and information by the study participants.

**5.5 - Communication of committee action and Update of the Protocol Database**:The IREB considers the following possible decisions in the review of an early termination report:  acceptance of the decision with no further action; request for additional information; or requirement for further action. The staff prepares a draft of the committee decision based on the minutes of the meeting (SOP 21 Communicating IREB Decisions) for signature of the Chair. S/he updates the protocol database accordingly.

1. **Glossary**

Early Termination - refers to the decision of the researcher, principal investigator, the institution, or sponsor to end the implementation of a study before its completion.

Termination package - refers to the entitlements of study participants in the event of discontinuance of the study, which can come in the form of access to the study intervention, treatment, or information, for purposes of adherence to the principle of fairness for all concerned

Primary Reviewers – are members of the Research Ethics Committee (usually a scientist and a non-scientist) assigned to do an in-depth evaluation of the research-related documents using technical and ethical criteria established by the 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.

Logbook – a  real-time, chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signature of the Receiver and Action done.

Database – a collection of information (e.g. regarding a protocol/s) that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

1. **Forms**

Form 14A Early Termination Report Form

Form 12B Decision Letter Template

Logbook

Database

1. **History**

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

1. **References**

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: |  |