1. **Policy Statement**

The ISU-IREB shall require the submission of an application for Continuing Review at least 20 working days before the expiration of the ethical clearance of a protocol. Protocols that underwent Full review in its initial submission shall undergo Full review in its application for Continuing review. Similarly, protocols that underwent Expedited review shall undergo Expedited review in its application for Continuing review.

1. **Objective of the Activity**

This activity aims to ensure that the conduct of the study is in compliance with the approved protocol and that the safety and welfare of study participants are promoted and the integrity of data protected beyond the period of initial ethical clearance and up to the end of the study.

1. **Scope**

This Standard Operating Procedure (SOP) applies to the management of an application for Continuing review submitted by the proponent while the study is still on-going but whose ethical clearance is about to expire. This SOP begins with the receipt of an application for continuing review and ends with the entry to logbook and protocol database.

1. **Workflow**

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| **ACTIVITY** | **RESPONSIBILITY** |
| 1: Receipt of the application for Continuing Review and  entry to logbook (SOP 23 - Management of Active Files) | Staff |
| 2: Retrieval of pertinent protocol files | Staff |
| 3: Notification of Chair and Primary Reviewers | Staff |
| 4: Determination of type of review: expedited (SOP 4- Expedited Review ) or (SOP 5- Full Review) | Chair and Primary Reviewers |
| 5: Communication of committee action (Communication IREB Decisions (SOP 21) | Chair |
| 6: Filing of documents in the appropriate protocol folder and Update of the Protocol Database | Staff |

1. **Description of Procedures**

**5.1 -** **Receipt of the application for continuing review****and entry to logbook**: The Staff receives, logs and enters in the protocol database the information included in the application for Continuing review (Form 12A: Application for Continuing Review).

**5.2 - Retrieval of pertinent protocol file**: The Staff retrieves the approved protocol and prepares a summary of the progress reports, protocol deviation/violation reports, SAE/SUSAR reports, report of negative events (RNEs) and corresponding decisions including the type of initial review during the period of effectivity of the initial ethical clearance.

**5.3 - Notification of Chair and Primary Reviewers**: The Staff notifies the Chair and the Primary Reviewers regarding the submission and the summary of the reports submitted and decisions made during the period of effectivity of initial ethical clearance.

**5.4 - Determination of type of review: expedited or full review**: For example, the Secretariat shall determine the type of review based on the policy that protocols that underwent full review in its initial submission shall undergo Full review in its application for Continuing review. Similarly, protocols undergoing Expedited review shall undergo Expedited review in its application for Continuing review (see SOP4: Expedited Review and SOP5: Full Review).

**5.5 - Communication of Board action**: The IREB Staff prepares the draft decision based on the report of the expedited review or the minutes of the meeting in the full review. The Chair finalizes and signs the decision letter (Form 5C). Possible decisions include the following: Approval, Additional information required, submission of an explanation for failure to submit required reports or disapproval.

**5.6 – Filing of documents in the appropriate protocol folder:** The Staff files the application for Continuing review, the recommendations of the reviewers and decision letter in the appropriate protocol folder.

1. **Glossary**

**Continuing Review** - is the decision of the IREB to extend the ethical clearance of a study based on an assessment that the research is proceeding according to the approved protocol and there is reasonable expectation of its completion.

**Progress Report** – A description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Form 8A. The frequency of submission (e.g., quarterly, semi-annually or annually) is determined by the IREB based on the level of risk.

**Amendment** – a change in /revision of the protocol made after it has been approved.

**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 or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.

**SAE** – a Serious Adverse Event – is an event where the outcome observed in a study is any of the following, whether or not it is related to the study intervention

* 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

**SUSAR** – Suspected Unexpected Serious Adverse Reaction – is a noxious response to a

drug that is not described in the Investigator’s Brochure nor in the drug insert

**RNE** – an occurrence in the study site that indicates risks or actual harms to participants and to members of the research team. Examples are brewing hostilities in the research community, natural calamities, unleashed dogs, threats of harassment, etc.,

**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.

**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.

**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 Receiving Person and Action done.

**Database**– a collection of information (e.g. regarding protocols) 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 12A: Continuing Review Application Form

Form 12B: Decision letter template

Logbook 1 Submission

Database

1. **History**

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

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