1. **Policy Statement**

The ISU-IREB shall require the submission of proposed amendments for review and approval before their implementation. This requirement shall be explicitly stated in the Approval Letter.  This  is to establish a systematic and efficient process for the review of protocol amendments by  ISU-IREB. This policy ensures that protocol amendments are rigorously assessed for scientific, ethical, and regulatory compliance, maintaining the highest standards of research integrity.

1. **Objective of the Activity**

To ensure that the conduct of the study is in compliance with the approved protocol such that any change such as amendments does not impact safety and welfare of study participants*.*

1. **Scope**

This SOP applies to all research projects approved by the ISU-IREB, which require amendments to their original protocols during the course of the study. This also applies previously approved study protocols and related documents that are being amended later and submitted for approval to the ISU-IREB. Any amendment of the study related documents may not be implemented until reviewed and approved by the ISU-IREB. This SOP begins with the receipt and entry of the submission of amendment to logbook of incoming documents and the protocol database and ends with filing of the amendments and committee decision in the protocol file.

1. **Workflow**

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| --- | --- |
| **ACTIVITY** | **RESPONSIBLE PERSON** |
| 1. Receive the protocol amendment package and check its completeness | ISU-IREB Secretariat |
| 2. Determine the type of review and identify the primary reviewer | ISU-IREB Chairperson |
| 3. Forward amendment package to primary reviewers | ISU-IREB Secretariat |
| 4. Discuss major amendment or report the expedited review results to the IREB during full board meeting | ISU-IREB Members |
| 5. Communicate ISU-IREB decision to Principal Investigator | ISU-IREB Secretariat |
| 6. Filing of documents and update protocol file index and the protocol database | ISU-IREB Secretariat |

1. **Description of Procedures**

**5.1. Receive the protocol amendment package and check its completeness**

5.1.1.  The ISU-IREB should properly information the Principal Investigator to submit an application for amendment whenever there is any change regarding the composition of the study team, the study site, the protocol and related documents that it previously approved using the Protocol Amendment Submission Form.

5.1.2 The ISU-IREB checks the completeness of the protocol amendment package submitted by the Principal Investigator. ISU-IREB Secretariat also verifies whether the protocol the Protocol Code No. and forms used are correct.

5.1.3. The IREB Staff Records the submission in the protocol database.

**5.2.  Determine the type of review and identify the primary reviewer**

5.2.1. The ISU-IREB Secretariat reviews documents to determine whether an amendment is major or minor.

5.2.2 Major protocol amendments: Increase risk to study participants and require full board review. This includes but are not limited to the following:

1. Any changes in inclusion/exclusion criteria
2. Change in study design
3. Significance change in the or increased of subjects
4. Any other changes that will entail more than minimal risk.

5.2.3. Minor protocol amendments: those which are unlikely to compromise the integrity of the research or the welfare and rights of the participants and present no new ethical issues; and changes that are administrative in nature can be expedited.

5.2.4. The ISU-IREB Staff identifies the Primary Reviewers who did the initial review and verifies the IREB approval of the initial protocol submission.

5.2.5. If primary reviewers are not available to do the review, ISU-IREB Chairperson and/or member-secretary do the review provided they do not have Conflict of Interest (COI). Otherwise the ISU-IREB Chairperson designates qualified members to do the review.

**5.3. Forward amendment package to primary reviewers**

5.3.1. The ISU-IREB Secretariat prepares protocol amendments package, photocopies relevant documents of previous review/s of the protocol that will provide the Primary Reviewers with background information that will facilitate the assessment of the proposed amendment/s.

5.3.2.The primary Reviewers should go to the IREB office to review the pertinent documents in the protocol file and determine whether the proposed changes in the protocol will cause a change in the risk-benefit ratio of the approved protocol.

5.3.3. IISU-REB staff records the protocol amendment package and relevant documents and previous review/s with the Notice of Review to the Primary Reviewer/s at least 10 days before the full committee meeting.

5.3.4. The Primary Reviewer or his / her alternate reviews the amended documents and compares them with the previously ISU-IREB approved documents in the protocol file folder to asses if the proposed amendments/s would alter the risk/benefit ration and to make appropriate recommendations using the ISU-IREB part of Protocol Amendments submission Form.

5.3.5. Major protocol amendments are reviewed by full board while minor protocol amendments are reviewed by expedited review by the Primary Reviewers/Chair/Member-Secretary.

**5.4. Discuss major amendment or report the expedited review results to the IREB during full board meeting**

5.4.1. For Major Protocol Amendment

5.4.1.1. The Primary Reviewers or his/her alternate presents the results of the review to the ISU-IREB during the full committee meeting.

5.4.1.2. The ISU-IREB decides or explain further the amendment/s. The following are possible review decisions of the Board:

5.4.1.2.1 Approval

5.4.1.2.2 Recommend major changes to the protocol/informed consent form.

5.4.1.2.3 Recommend minor changes to the protocol/informed consent form

5.4.1.2.4 Disapproval

5.4.2. For Minor Protocol Amendment

5.4.2.1. The Primary Reviewer or his/her alternate submits the results of the review using the IREB-portion of the Application Form for Amendment.

5.4.2.2. The review decision is reported to the ISU-IREB during the full committee meeting.

**5.5. Communicate IREB decision to Principal Investigator**

5.5.1. Refer to the SOP 21 Communicating ISU-IREB Decision to the Principal Investigator

5.5.2. The ISU-IREB Staff prepares notification of the ISU-IREB Decision/Approval for Protocol Amendment, for signature of the ISU-IREB Chairperson.

5.5.3. If the amendment is approved, the principal Investigator is requested to submit an amended copy of the study protocol or protocol related document with an updated version no. and date.

5.5.4. The ISU-IREB staff send the notification to the Principal Investigator

**5.6. Filing of documents and update protocol file index and the protocol database**

5.6.1. The ISU-IREB staff ensure that the version no. and the date marked on the amended document are correct.

5.6.2. The ISU-IREB staff stamps the amended protocol or protocol-related document “Approved“ with the approval date

5.6.2. The ISU-IREB staff keeps a copy of all amended related documents in the protocol file folder and updates the protocol file index. (Retention of Documents 3 years)

1. **Glossary**

**Amendment** – Any change or revision in the protocol made after its approval.

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

**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

**Primary Reviewer** – a member of the Institutional Research Ethics Board (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.

1. **Forms**

Form 8A STUDY PROTOCOL AMENDMENT FORM

Form 5C DECISION LETTER TEMPLATE

Logbook

Database

1. **History**

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| --- | --- | --- | --- |
| **Version No.** | **Date** | **Authors** | **Main Change** |
| 0 |  | ISU-IREB SOP Team |  |
| 1 |  |  |  |
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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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| --- | --- |
| Prepared by: |  |
| Recommending Approval: |  |
| Approved by: |  |
| Approval Date: |  |