1. **Policy Statement**

The ISU-IREB shall require the submission of documents as a proof of compliance to the approved research protocol and the committee should be knowledgeable of any necessary changes that may happen as the research study progresses until its completion. This is to ensure protection of the human research participants of their rights and safeguarding them from any harm the research study may implicate.

1. **Objective of the Activity**

To describe the review procedures related to proponents’ submissions required by ISU-IREB after approval has been granted towards the implementation of the study until its completion and 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.

1. **Scope**

This SOP applies to the management and review of progress submitted by the proponent while the study is on-going or has ended. This SOP begins with the receipt and entry to logbook of incoming documents and the protocol database and ends with filing of progress report and committee decision in the protocol file

1. **Workflow**

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| --- | --- |
| **ACTIVITY** | **RESPONSIBLE PERSON** |
| 1. Receipt and entry to logbook and database of the document application for review | ISU-IREB Secretariat |
| 2. Determine the type of review and identify the primary reviewer | ISU-IREB Chairperson |
| 3. Forward the Study Protocol Submission Package to Primary Reviewers | ISU-IREB Secretariat |
| 4. Deliberate or report the review results to the committee meeting | ISU-IREB Secretariat |
| 5. Communication of committee decision to researcher/investigator | ISU-IREB Secretariat |
| 6. Filing of all related documents and update database | ISU-IREB Secretariat |

1. **Description of Procedures**

**5.1 Receipt and entry to logbook and database of the document application for review**

1. The IREB Secretary staff logs the date of the receipt of the completely accomplished form. (Form 8A PROGRESS REPORT FORM)

1. Ethical clearance or approval is typically granted for a period of one year. After approval, a progress report is required to be done at least once, depending on the risk assessment of the study protocol, and duration of study and determined during initial review. This is facilitated through the submission of Form 8A PROGRESS REPORT FORM.

1. The frequency of progress report is indicated in FORM 5C DECISION/ACTION FORM which is provided to the researcher/investigator upon approval of the study.

The secretary staff sends Form 8B Reminder Letter for Progress Report once (one month) before the due date of the report.

1. For long-term (three years or more) clinical research/es, the researcher/investigator Update Training together with the Form 8B PROGRESS REPORT FORM for further extension of ethical clearance.

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

1. The ISU-IREB Secretariat shall immediately determine the type of review and notify the PR

1. For PROGRESS REPORT

1. The continuing review protocol initially reviewed by full board review is also by full board review. If it is initially reviewed by expedited review, then the review remains expedited provided there is no amendment, violation or deviations from the previously approved protocol.

1. The secretariat identifies the primary reviewer who did the initial review. If the primary reviewer is not available to do the review, the ISU-IREB Chairperson and/or Member-Secretary will do the review provided they do not have conflict of interest (COI). Otherwise, the ISU-IREB Chairperson designates a qualified member to do the review.

1. **Forward the Study Protocol Submission Package to Primary Reviewer**

1. For PROGRESS REPORTS
	1. The secretary staff photocopies relevant documents of previous review/s of the protocol like the current version of the protocol, current version of the ICF, protocol amendments (if any), protocol deviations and on-site SAE/SUSARs since the last progress report that will provide the primary reviewer/s with background information that will facilitate the assessment of the risk-benefit ratio of the approved study protocol or the primary reviewer/s may go to the ISUIREB office (building in progress) to review the pertinent documents in the protocol file to determine whether there is a change in the risk-benefit ratio in continuing the approved protocol.
	2. The secretary staff logs the Study Protocol Submission Package for progress report reviews to the LOGBOOK II Logbook of Outgoing Documents.
	3. The secretary staff sends the photocopied relevant documents to the primary reviewer/s within 10 working days before the full board committee meeting Form 4? NOTIFICATION LETTER.

5.3.1.4 The primary reviewer or his/her alternative reviews the given documents to assess if the protocol file folder complies with the latest approved protocol with the following key points 1. Risk assessment, 2.  Adequacy of ICF 3. Local issues 4. Trial progress

5.3.1.5 The secretary staff places the study protocol progress re on the next meeting agenda

1. **Deliberate or report the review results to the committee meeting**

1. For PROGRESS REPORTS
	1. The Secretariat arranges the comments of the primary reviewer and includes the application for renewal of the ISU-IREB approval agenda.
	2. The protocol file for progress report review should include the relevant ISU-IREB meeting minutes. It should be made available to ISU-IREB members prior to the committee meeting to allow members to resolve any questions that may arise.
	3. The primary reviewers should present a summary of the progress of the research, any significant issues and recommendations to the convened meeting.
	4. The ISU-IREB determines the need for the researcher/investigator to elaborate, explain or clarify any aspect of the progress/annual report as deemed necessary.
	5. The following are the possible ISU-IREB decisions for progress reports:

a. renew approval

            b. request additional information

     c. recommend modification

            d. suspend: - enrolment of new subjects

                                -research procedures in currently enrolled subjects

 - entire study

            e. disapprove renewal

1. If the ISU-IREB decision is to renew the approval, start- and end-date of the approval period should be specified. If the progress report is submitted on time, the start-date should be the same as the date of first approval/anniversary date.
2. Approval of the progress report reviewed by the primary reviewers by expedited procedure is reported to the meeting by the ISU-IREB chairperson/member-secretary.
3. The entire document package to the ISU-IREB secretariat within 5 working days from the date this was forwarded

1. **Communication of committee decision to researcher/investigator**

1. For PROGRESS REPORTS
	1. ISU-IREB could arrive at any one of the following decisions during the meeting:
2. Uphold original approval with no further action with the renewal of approval of the protocol and related documents to enable the Researcher/s to continue the conduct of the research.
3. Request for further information, specifying information that is required prior to renewal of approval.
4. Recommend further action, specifying action required prior to renewal of approval.

**5.6 Filing of all related documents**

5.6.1. The ISU-IREB Secretariat maintains a copy in the protocol files of the forms, documents, and reports signed by the primary reviewers and the ISU-IREB Chairperson or ISU-IREB Member Secretary.

5.6.2. The ISU-IREB Secretariat marks the folder of the completed protocol, updates the database and archives the entire study protocol.

1. **Glossary**

**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 Signture of the Receiving Person and Action done.

**Primary Reviewer** – a member 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

**Progress Report** –  description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Form 8B. An on-going report or assessment that takes place during the conduct of the research study that conveys details such as objectives that are accomplished, resources expended, problems encountered, and whether the research is expected to be completed on time and within budget.

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1. **Forms**

Form 8A Progress Report Form

Form 8B Reminder Letter

Logbook 2 OUTGOING COMMUNICATION

Database

1. **History**

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| --- | --- | --- | --- |
| **Version No.** | **Date** | **Authors** | **Main Change** |
| 0 |  | ISU-IREB SOP TEAM |  |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |

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:   |  |