1. **Policy Statement**

A full review shall be conducted when a proposed study protocol entails more than minimal risk to study participants belonging to vulnerable groups or when a study generates vulnerability to participants. Full review shall be conducted through a primary review system.

The whole review process shall be completed within 25 working days from the receipt of a complete set of documents. Only protocols submitted with complete documentation on every first Friday of the month prior to the scheduled regular monthly meeting shall be included.Full review is done with a 50% +1 quorum.

No direct communication regarding the protocol shall take place between the reviewers and the researcher/s in the course of the review. All matters concerning the protocol shall be coursed through the Secretariat.  Any contact/meeting with the researcher should be documented.

1. **Objective of the Activity**

A full review aims to ensure compliance with the technical and ethical standards in the conduct of research involving human participants and identifiable human data and materials.

1. **Scope**

This SOP shall apply to initial, revisions, and post-approval submissions on protocols which involve study participants belonging to vulnerable groups or generates vulnerability to participants. This SOP begins with the assignment of the primary reviewers and ends with the updating of IREB database and logbook.

1. **Workflow**

|  |  |
| --- | --- |
| ***ACTIVITY*** | ***RESPONSIBILITY*** |
| *1: Assignment of primary reviewers or Independent Consultant/s (SOP on Appointment of Independent Consultants (SOP#3))* | *Chair* |
| *Step 2: Notification of primary reviewers or Independent Consultants* | *Staff* |
| *Step 3: Provision of protocol and protocol-related documents and assessment forms to reviewers* | *Staff* |
| *Step 4: Provision of protocol and protocol-related documents to the rest of the committee members* | *Staff* |
| *Step 5: Presentation of review findings and recommendations during a Committee meeting (SOP on Conduct of Meeting (SOP# 19))* | *Primary Reviewers* |
| *Step 6: Discussion of technical and ethical issues* | *Committee members* |
| *Step 7: Summary of issues and resolutions* | *Chair* |
| *Step 8: Committee action* | *Committee members and Chair* |
| *Step 9: Documentation of Committee deliberation and action (SOP on Preparing the Meeting Minutes (SOP# 20))* | *Staff* |
| *Step 10: Communication of Committee Action to the researcher(SOP Communicating IREB Decisions (SOP#21))* | *Chair and Staff* |
| *Step 11: Filing of protocol-related documents and Updating of the Protocol Database* | *Staff* |

1. **Description of Procedures**

**5.1 -** Assignment of Primary Reviewers (PR) and/or Independent Consultants

5.1.1. The ISU-IREB Chairperson assigns the PR based on their expertise and the type of research to be reviewed.

5.1.2. Independent consultants may be sought to review if the research requires a certain expertise.

**5.2 - Notification of primary reviewers and/or Independent Consultants**

  5.2.1. The ISU-IREB Secretariat notifies the assigned primary reviewers and/or independent consultants using Form 6? NOTIFICATION LETTER within 5 working days prior to the meeting through the agenda.

  5.2.2. The Primary Reviewer/s and/or independent consultants notifies the Secretariat if they can do review, otherwise, the ISU-IREB Secretariat appoints another PR.

**5.3 - Provision of protocol and protocol-related documents and assessment forms to primary reviewers/independent consultants**:

5.3.1. The ISU-IREB Secretariat forwards the proposal package to the Primary Reviewers via email/courier.

5.3.2. The Primary Reviewers may request clarifications from the Secretariat regarding the research and the Secretariat shall contact the researcher/s.

**5.4 - Provision of protocol and protocol-related documents to the rest of the committee members**

5.4.1. The ISU-IREB Secretariat sends the proposal to the rest of the ISU-IREB members for advance reading so they can participate actively during deliberations within 7 working days

5.4.2. The ISU-IREB Chairperson with the Secretariat shall prepare the proposals to be discussed at the meeting. The copies will be either in hard or soft depending on the preference of the reviewer.

**5.5 – Attendance, Quorum and Decision making**

 5.5.1. A quorum of 50% +1 of the members is needed to review a study.In case there is no quorum, the meeting shall be rescheduled or a notification to alternate members contacted by the secretariat.

5.5.2 When there is a quorum, a decision is arrived at by a consensus.

**5.6 - Presentation of review findings and recommendations during a committee meeting**

5.6.1 Primary Reviewers of study protocols for initial review should be present in the board meeting. In case of unavailability of the primary reviewers to attend, said members are required to forward the completed assessment forms to the Secretariat Staff five (5) working days before the meeting. The findings summarized therein will be presented by the IREB Chairperson or his/her designee when the study protocol is deliberated on so that the meeting can proceed.

5.6.2 The Primary Reviewers or the designated member will present findings, with his comments and recommendations, using the different assessment forms in the protocol package review.

**6 - Discussion of technical and ethical issues**

**6**.1 The ISU-IREB members contribute their own observations as inputs for a comprehensive review and decision- making.

6.2. Deliberations within the committee shall follow, giving emphasis on the issues raised by the Primary Reviewer/s.

6.3. In case there are issues not discussed by the primary reviewer with the research proponents, the proponents should make themselves available for at least 4 hours during the day via a phone call or attendance in a virtual online platform to clarify issues from both sides. The research proponent should be notified of the schedule of review at least a week before the date of the board meeting. If via virtual online platform, a link should be provided a day before and advised to wait in the virtual waiting room.

**7 – Summary of issues and resolutions**

7.1. When a consensus is not possible,the ISU-IREB members will vote.Voting may be in the form of voice vote, show of hands, or by secret ballot, asdetermined by the ISU-IREB Chairperson.

7.2. All members are entitled to one vote.     However, in case ofa tie, the ISU-IREB Chairperson will break the tie.

7.3. The minutes will document each alternate member’s status, vote, andattendance as they relate to ISU-IREB actions and quorum requirements.

7.4. Opinions of absent members that are transmitted by mail or telephone or fax may beconsidered by the attending members during discussion. But absent member cannot be counted as voting member or quorum member for formally convened fullboard meetings.

7.5. Any committee member with a conflict of interest in a proposal will abstain from   deliberations and in the decision-making process on that proposal, except to provide information as requested by the committee. Such abstentions will be recorded in the minutes.

7.6. Decision may only be taken when enough time has been allowed for review and discussion of an application for protocol review in the absence of non-members (e.g., the researcher/s, representatives of the sponsor, independent consultants) from the meeting.

7.7. Independent consultants may be invited to offer their views but should not participate in the decision-making process. However, his / her opinion must be recorded and considered for the members to arrive at a decision.

7.8.The ISU-IREB Chairperson summarizes the technical and ethical issues that were identified.

**8 - Board action**

The Board decides by consensus on whether the proposal is approved, disapproved, or needs minor/major revisions. The decision of the committee may be any of the following:

8.1Approved: The protocol is approved as it has no modifications, revisions or conditions required. The proposal will be given an ethical clearance immediately.

8.2 Disapproved: The ISU-IREB may disapprove a research protocol because of major ethical and scientific problems in the proposed research. The reasons for the disapproval should be clearly identified and included in the IREB evaluation letter to Researcher/s.

8.3. Minor Revisions/ Major Revisions Required: The Board may decide whether the protocol needs minor / major revisions. The protocol may be resubmitted once the revisions are made.

**Step 9 - Documentation of committee deliberation and action**

5.9.1. The ISU-IREB Secretariat drafts using the FORM 20 MINUTES OF THE MEETING, this  will be checked and signed by the ISU-IREB Chairperson.

5.9.2. If the research is approved, an ethical clearance will be prepared by the ISU-IREB Secretariat.

5.9.3. If the research is disapproved or with revision, a decision letter shall be send to the Researcher. FORM \_\_\_\_\_\_ Decision Letter Template

**Step 10 - Communication of Committee Action to the researcher**

5.10.1 The decision of the ISU-IREB will be communicated to the Researcher/s using the FORM \_\_\_\_\_ Decision Letter Template ( SOP 21 communicating ISU-IREB Decisions)

**Step 11 - Filing of protocol-related documents and Updating of the Protocol Database**

5.11.1 The ISU-IREB Secretariat updates the protocol file-package and database accordingly. The study protocol will be logged using the LOGBOOK I Log of Protocol Submission

1. **Glossary**

*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.*

*Vulnerable Groups – participants or potential participants of a research study who may not have the full capacity to protect their interests and may be relatively or absolutely incapable of deciding for themselves whether or not to participate in the research. They may also be at a higher risk of being harmed or to be taken advantage.*

*Minimal Risk – term used when the probability and magnitude of harm or discomfort anticipated in a research are not greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

*More than Minimal Risk - term used when the probability and magnitude of harm or discomfort anticipated in research are greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

*Independent Consultant- Resource person who is not a member of the Institutional Research Ethics Board, whose expertise is needed in the review of a research protocol/proposal and who may be invited to attend a committee meeting but is non-voting during the deliberations.*

*Primary Reviewers – are members 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.  The non-scientist member shall focus on the review of the Informed Consent process and form and reflect on community values, culture and tradition in order to recommend acceptance, non-acceptance or improvement of the informed consent process and form. The primary reviewers shall present their findings and recommendations during the meeting for discussion.*

*Major Modification – is a recommended revision of significant aspects/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data statistical analysis, mitigation of risks, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research.*

*Minor Modification - – is a recommended revision of particular aspect/s of the study or related documents that do not impact on potential risks/harms to participants and on the integrity of the research, e.g. incomplete documentation, incomplete IC elements, unsatisfactory IC format)*

*Resubmissions - revised study proposals that are submitted after the initial review.*

*Protocol-related Documents- consists of all other documents aside from the proposal/protocol itself that required to be submitted for review, e.g., Informed Consent Form, Survey Questionnaire, CV of proponent, advertisements, In-depth Interview Guide Questions,*

*Decision – the result of the deliberations of the IREB in the review of a protocol or other submissions.*

*Voting – the act of expressing opinions or making choices usually by casting ballots, spoken word or hand raising. The rule is majority wins.*

*Consensus – a collective agreement.*

primary review system.

1. **Forms**

What forms/templates/tools are used in the implementation of this SOP? Example:

*Form ## Protocol Evaluation Worksheet*

*Form ## Informed Consent Evaluation Worksheet*

*Form ## Decision letter template*

Form 4A Primary Reviewer Appointment

   LOGBOOK I Log of Protocol Submission

1. **Références**

*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*National Ethical Guidelines for Health and Health-related  Research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

|  |  |
| --- | --- |
| Prepared by:   |  |
| Recommending Approval:   |   |
| Approved by:   |  |
| Approval Date:   |  |