1. **Policy Statement**

The meetings of the Isabela State University-Institutional Research Ethics Board (ISU-IREB) shall be based presided by the chair or designated substitute, shall proceed only when quorum is declared, and shall be guided by the approved agenda. The presence of a conflict of interest among the members shall be disclosed prior to the discussion of protocols for review.

1. **Objectives**

Meetings of the Isabela State University -Institutional Research Ethics Board (ISU-IREB) are conducted to provide an opportunity for the IREB to arrive at collegial decisions regarding study protocols and IREB operations and to be informed of pertinent administrative matters.

1. **Scope**

This SOP on the Conduct of Meetings describes the manner by which the Institutional Research Ethics Board (IREB)) *c*onducts all its meetings. It covers the IREB actions and activities from the time the meeting is called to order and quorum is declared to the time the meeting is adjourned. This SOP begins with the distribution of meeting materials and ends with the collection, storage, and disposal of meeting materials.

**4. Workflow**

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| **ACTIVITY** | **RESPONSIBILITY** |
| 1. Distribution of meeting materials | IREB Secretariat |
| 2. Declaration  of quorum (formal start) | Member Secretary |
| 3. Approval of the provisional agenda | IREB Members |

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| 4. Declaration of conflict of interest (COI) | IREB Members (who have COI) |
| 5. Approval of minutes of the previous meeting | IREB Members |
| 6. Discussion of “Business arising from the minutes” | IREB Chair |
| 7. Review of protocols and protocol-related submissions consistent with SOP No. 5 Full Review. | IREB Chair and Members |
| 8. Report of results of expedited review consistent with SOP No. 4 on Expedited Review | Designated Reviewers |
| 9. Discussion of operations-related matters | IREB Chair and Members |
| 10. Adjournment | IREB Chair |
| 11. Collection, storage, and disposal of meeting materials | Member Secretary |

1. **Detailed Procedures**

5.1  **Distribution of meeting materials:** The IREB Secretariat distributes through emails and Group Chat the meeting agenda, minutes of the previous meeting, relevant protocol folders, memorandums, administrative documents, for the perusal and reference of meeting attendees. A hard copy of these documents will also be distributed before the formal commencement of meetings.

5.2 **Declaration  of quorum (formal start):** Consistent with SOP No. 18, a quorum is 50% of the members plus 1 present in a meeting. If the meeting is hybrid, the number is determined by those physically present and online. The IREB Chair declares a quorum, confirmed by the Member Secretary.The declaration of a quorum is a confirmation that the meeting may officially commence.

5.3  **Approval of the provisional agenda:** The provisional agenda is read by the Member Secretary for examination by the members, whether there are additions or deletions. A motion for adoption and secondment is required for the finalization of the agenda.

5.4 **Declaration of Conflict of Interest**: A declaration of COI after the presentation of a provisional agenda a conflicted member shall step out of the room or not participate in the decision making process.

5.5  **Approval of minutes of previous meeting**: The minutes of previous meeting  is read by the Member Secretary for vetting by the members, whether there are corrections. A  motion for adoption, seconded by a member, and approved by the members, is required for the finalization of the minutes.

5.6 **Discussion of** “**Business arising from the minutes”:** Any present member may raise a “business arising from the minutes”. The chair takes it up for discussion and deliberation during the meeting. A motion for adoption, seconded by a member, and approved by the members, is required to settle the business arising from the minutes.

5.7 **Review of protocols and protocol-related submissions**: The IREB review assigned members vets the application, consistent with SOP No. 5 - Full Review, whichever is applicable. The independent consultant assigned as reviewer performs his/her role consistent with SOP No. 3 - Independent Consultant. The sequence of the review is, as follows:technical issues, ethical issues, and informed consent process/form issues. The primary reviewers are guided by the assessment form in their presentations. The Chair presents to the body, on behalf of the researchers/principal investigator, unless required. The IREB will decide by consensus.

5.8  **Report of results of expedited review:** The IREB Chair presents the results of expedited review for the information of members, and for documentation of the review results.

5.9 **Discussion of operations-related matters:** What are the usual items that fall under operations-related matters? Which of these items will need to be deliberated upon and approved by the members? Which are for information only?

5.10 **Adjournment:** The IREB Chair adjourns the meeting after all items in the agenda have been discussed and/or resolved. A motion for adjournment , seconded by a member, and approved by the members, is required to settle the business arising from the minutes. In case, there are items in the agenda that were not discussed, the body may decide to take it up in the next meeting or through an approved motion, may create an ad hoc committee to study the matter and make a proper recommendation to the body in the next business meeting.

5.10 **Collection, storage, and disposal of meeting materials:** The secretariat is responsible sort the documents distributed during the meeting. After the meeting ? Are they returned to the shelves? Are extra copies disposed of? What is the manner of disposal? Shredding How does the REC staff keep track of meeting documents? Database See SOPs on Managing Active Files (SOP#25) and SOP 18 Preparation of Agenda

1. **Glossary**

*Quorum– the minimum number (i.e., majority of the members) and type of members  of the IREB that are required to be present in any meeting for  the proceedings to be considered valid.  International and national guidelines require the presence of at least 5 regular members including the non-affiliated and the non-scientist members.*

*Conflict of Interest - a situation in which aims or concerns of two (primary and secondary) different interests are not compatible such that decisions may adversely affect the official/primary duties.*

*Agenda - the list of topics or items to be taken up in a meeting arranged in a sequential manner. It is an outline of the meeting procedure and starts with a “Call to Order”.*

*Adjournment – Formal closure of the meeting. Motion for adjournment and record of the time are minuted.*

*Voting – act of formally manifesting a choice in a meeting.*

*Ballot – voting (indicating the choice)  by writing the choice on a form for the purpose. Ballots are subsequently counted to determine how the majority of members voted for decision-making.*

*Consensus – the process of arriving at a decision without voting but by generating the over all sentiment of a group such that deliberations continue until no more strong objection is registered.*

*Collegial Decision –   a course of action arrived at after a group deliberation where members were considered of equal authority such that the course of action is  considered a group action and is not ascribed to any one member.*

*Meeting Minutes - – the official narration and record  of the proceedings of the assembly of IREB   Members, based on the agenda.*

*REC Operations- the overall activities of the IREB that reflect performance of its functions and responsibilities.*

*Protocol – documentation of the study proposal that includes a presentation of the rationale and significance of the study, background and review of literature, study objectives, study design and methodology, data collection, dummy tables, plan for analysis of data, ethical consideration, and dissemination plan.*

*Protocol-related submissions– other documents that are included (required) in the submission of the protocol, e.g., Informed Consent Forms, study tools (Interview guide, survey questionnaire, FGD guide) and CVs of the proponents and certificates of training.*

*Business Arising from the Minutes – are matters generated from the discussions in the previous meeting that need continuing attention and require reporting.*

*Operations-related Matters – are items included in the agenda that are not directly related to any protocol under review.*

*Clarificatory Interview/meeting – is a face-to-face consultation between the IREB and the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the IREB to make these issues less confusing or more comprehensible.*

1. **Forms**:

Form 19A Attendance Sheet

Form 6? Protocol Assessment Form

Form 6? ICF Assessment Form

Form 5C REC Decision Form

1. **History of SOP**

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| --- | --- | --- | --- |
| **Version No.** | **Date** | **Authors** | **Main Change** |
| 0 |  |  | First draft |

1. **References**

*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 2022*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

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