1. **Policy Statement**

The ISU-IREB SOP handbook will be evaluated on a regular basis to ensure efficiency, transparency, and consistency of IREB operations. It also aims to determine the necessity for amendment or the establishment of new SOPs in order to respond to the IREB's evolving operational concerns. The IREB shall establish a team to examine its set of SOPs on an annual basis to ensure their continued relevance and effectiveness in its operations.

1. **Objective of the Activity**

This Standard Operating Procedure (SOP) defines the process for reviewing, revisiting, amending, and storing SOPs and Guidelines to ensure continuing quality assurance of IREB functions and systemic operation of the ISU-IREB.

1. **Scope**

This SOP applies to all ISU-IREB activities involved in the development of its SOPs and their revisions as published and distributed by the institution. This SOP begins with the proposal and approval for revision or writing of a new SOP and ends with the inclusion of the new or revised SOP in the SOP Manual and its dissemination.

1. **Workflow**

What are the different steps involved in the process of writing, reviewing, approving and disseminating SOPs of the IREB? Who are the persons responsible in each of these steps?

For example:

|  |  |
| --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** |
| 1.Proposal and approval for revision or writing of a new SOP | Assigned IREB SOP Team |
| 2. Designation of the SOP Team | IREB Chair |
| 3. Drafting of the revision or new SOP | IREB SOP Team |
| 4. Review and finalization of SOP | IREB Members |
| 5. Submission of finalized SOP to  the institutional authority | Chair |
| 6. Inclusion of the new or revised SOP in the SOP Manual and its dissemination | IREB member Secretary and Secretariat |

1. **Description of Procedures**

**5.1 - Proposal for a revision of an SOP or a new SOP and its approval**:

The IREB members can propose a new SOP or revision of a new SOP. The request for new SOPs and amendments to existing ones can be initiated based on the emerging needs and concerns in conducting review of documents. The proposal shall be presented to the IREB chairperson and members on a special meeting designed solely to deliberate and/or evaluate the substance of the proposal and to determine the need for revision or the inclusion of a new SOP. The recommendation of the revision or inclusion of the SOP will be based on the consensus of the IREB members and approved by the IREB chairperson.

**5.2 - Designation of the SOP Team**:

The SOP team is composed of at least five(5) members and are selected by the IREB Chair. Regular IREB members who are actively involved in paper review are given priority. The designation is supported by an appointment paper issued by the ISU.

**5.3 - Drafting of the revision or new SOP**:

To harmonize the writing of SOPs, a standard SOP template shall be adapted by the SOP Team which include the following details:

1. Title, which is descriptive of contents
2. Policy statement
3. Objective/s of the activity, which defines the purpose and intended outcome
4. Scope, which defines the extent of coverage of the SOP and its limitations
5. Workflow provides a graphic representation of the essential steps to implement the SOP and the responsible person for each step.
6. Detailed instructions, which elaborates the steps listed in workflow
7. Glossary – acronyms and terms which need to be defined
8. Forms, documents to be accomplished by different parties as required by the SOP,
9. Document history which tabulates the different versions (from draft to final versions) of the document by author, version, date, and description of main changes
10. References, which lists the instruments use to draft the Guideline such as other SOPs, guidelines, or policies

The SOPS shall be  alphanumerically coded **I,V,X or Y** where “I, V,X or Y” can refer to the SOP number (starting from I).

**4 - Review and approval of SOP**:

The draft version of the proposal for revision or inclusion of new SOP shall be forwarded to the IREB chair for approval of the draft using Form\_\_\_ Request for Creation/Revision of an SOP and Form \_\_\_ SOP Template. Once the draft is approved by the IREB Chairperson, the draft of the proposal will be presented thru a ISU assembly for consultation deliberation and collection of comments with other ISU committee. After which, the draft shall be forwarded to the ISU Executive Director for further review and recommendation will be made by the ISU Executive Director to the DOST RO2 Regional Director for final approval. The review and approval of the proposal will be processed within(four(4) weeks or twenty (20) working days.

Once the proposal for revision of SOP and inclusion of new SOP is approved by the DOST RO2 Regional Director, the revised or new SOP will be made effective two weeks from the date of signing of its approval.

**5 – Submission of the SOP to the institutional authority**

The approved revised and/or new SOP shall be submitted to the Office of the Philippine Health Ethics Board for final implementation. A copy shall be forwarded to the office of the Regional Director of the Department of Science and Technology and to the ISU Executive Director.

**6 - Inclusion of the new or revised SOP in the SOP Manual and its dissemination**:

The new or revised SOP will be made available in Hard copy and E-copy. The timeline from approval to dissemination will be done within thirty (30) days from approval by the head of institution. The original and official copy shall be kept under the custody of the IREB Secretariat. The new or revised SOP shall be integrated in the SOP manual and reproduction of the new and,/or approved SOP will be under the responsibility of the IREB secretariat under the supervision of the IREB Member secretary.  A notice of revision shall also be disseminated to stakeholders informing them that old version is superseded by the revised SOP manual. The old SOP manual will be stored separately from the new version. The Revised SOP manual and communications related to its revision shall be properly filed by the IREB secretariat. The Secretariat archives the superseded version of the SOP in the historical file maintained by the ISU-IREB. Superseded SOPs are clearly marked “superseded" with the year of archiving stamped in the cover page while Outdated SOPs are considered a permanent file.

1. **Glossary**

**Standard Operating Procedures** - are the step-by-step description of the different procedures done to accomplish the objective of an activity. They consist of clear, unambiguous instructions for ethical review to ensure quality and **consistency.**

**Coding** – unique number assigned to a particular SOP that reflects its serial position among the SOPs and version number to indicate the number of times it has been revised.

**Format**- general style or layout of the document

**Date of Effectivity** – date when the guidelines shall be enforced.

1. **Forms**

This SOP shall utilize the following forms:

1. Form \_\_\_ Request for Creation/Revision of an SOP

|  |  |  |
| --- | --- | --- |
|  | **ISABELA STATE UNIVERSITY**  **Institutional Ethics Review Board**  **(ISU-IREB)** | **For New SOP**  Date of Creation of SOP:\_\_\_\_\_\_\_\_\_\_\_  **For SOP Revision**  Change Control No:\_\_\_\_\_\_\_\_\_\_\_\_\_\_  SOP Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date of Previous Revision:\_\_\_\_\_\_\_\_\_  Revision Number : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date of New Revision:\_\_\_\_\_\_\_\_\_\_\_\_  Revision Number: |
| **Request for Creation / Revision of an SOP** |
| **SOP Title or Name : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Requested by : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Designation : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Date : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Purpose of Creation / Revision  of SOP:** | | |
| **Scope :** | | |
| **Responsibility :** | | |
| **Items requiring change :** | | |
| **Other documents affected :** | | |
| Actual Changes made:    By :         \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_    Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_         \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_    Date : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_         \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_    Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **Print Name** | **Designation** | **Signature** | **Date** | | Reviewed by | Dr. Daisy Duunuan | CVHRDC REC Chairperson |  |  | | Recommending Approval | Dr. Julius T. Capili | CVHRDC  Executive Director |  |  | | Approved | Dr.VIRGINIA G. BILGERA | CVHRDC Chairperson |  |  | | | |

1. Form \_\_\_ SOP Template

|  |  |  |
| --- | --- | --- |
|  | **ISABELA STATE UNIVERSITY**  **Institutional Ethics Review Board**  **(ISU-IREB)** | Version No:\_\_\_\_\_\_\_\_\_  Page Number: \_\_\_\_\_\_\_  Date of Approval:\_\_\_\_\_  Effectivity Date:\_\_\_\_\_\_\_ |
| SOP No. \_\_\_\_\_  SOP TITLE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| **1.** **Policy Statement**  (consists of institutional or committee policies upon which the activity and procedures are based. This section may also include specific provisions from international and national guidelines pertinent to the activity)  **2.**  **Objective**  (refers to the purpose of the activity (e.g. for SOP **Preparing for a Meeting**, the objective may be stated as “Preparing for a meeting aims to ensure that all meeting documents and necessary logistics are available during the meeting.”).  **3.** **Scope**  (is based on the Workflow (Section 5) and includes the initial and final steps involved in the activity.)  **4.**  **Workflow**  (section is a diagram or a matrix briefly showing the different steps involved in the activity and the responsible persons. It may be illustrated as a flowchart using standard symbols like circles (denoting the start and end steps), rectangles (denoting the specific steps), and diamonds (for decision points). The person/s doing the action in each step is identified. Usually, verb-nouns like “receipt of”, “submission of”, “conduct of “, “distribution of”, “filing of”, “approval of” are used)  **5.** **Detailed** **Description** **of** **Procedures**  (describes the performance of each step in the Workflow. The person/s responsible and the forms to be used are mentioned and cited. The active forms of verbs are used.  It is important to ensure that the number of steps in the Workflow (Section 4) is the same number of steps described in Section 5. )  **6.** **Glossary**  (a list of terms, including acronyms and abbreviations used in the SOP that need to be defined or explained. (Note: the glossaries of the different SOPs may be put together in one list and included as an annex or appendix of the whole SOP Manual).  **7**. **Forms**  (section lists the specific forms (and corresponding codes) used in the activity (e.g. application form, checklist, review guide, communication templates).  **8.** **History**  (section is a tabulation of the version dates and number, authors, and the enumeration of major changes that the SOP has undergone. For example, the history section of **SOP Designation of REC Officers** may be represented as follows:   |  |  |  |  | | --- | --- | --- | --- | | **Version Number** | **Date** | **Authors** | **Change/s** | | 1 | 2023 October 24 | REC Members | Initial version | | 2 | 2024 December 10 | REC Members | Added the determination of type of review as a responsibility of the member secretary | | 3 | 2024 December 5 | REC Chair & Co Chair | Included a co-chair as an officer. |   **9.** **References**            (section is a list of guidelines, other institutional SOPs, manuals used in the development of the SOP) | | |

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| --- | --- | --- | --- |
| ***Version No.*** | ***Date*** | ***Authors*** | ***Main Change*** |
| *1* | *2023 October 25* | *CVHRDC REC Members* | *First draft* |

1. **History of SOP**
2. **References**

1. WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
2. CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
3. Philippine Health Research Ethics Board Standard Operating Procedures 2020
4. National Ethical Guidelines for Research Involving Human Participants 2022

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