1. **Policy Statement**

The IREB shall communicate its decisions to the researcher/s within six (6) weeks after the receipt of complete set of sub missed documents. The communication document is written on an official stationery of the IREB signed by the chair and provides the details of the decision including clear instructions/recommendations for guidance of the researcher. The result of decision will be disseminated within two weeks or ten (10) working days after the IREB monthly meeting.

1. **Objective of the Activity**

The IREB decisions shall be properly communicated to ensure that all stakeholders are properly, accurately, and promptly informed of the outcomes of the IREB's deliberation.

1. **Scope**

This SOP addresses IREB actions related to communicating IREB decisions.  As a matter of procedure, it starts with the finalization of recommendations of the decision by the committee or the reviewers. After which, dissemination of the decision will be made using the Form 5C or the Decision Letter Template to summarize required modifications in the protocol or to its approval respectively. Finally, this SOP ends with the filing of document in the protocol file by the IREB secretariat.

|  |  |
| --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** |
| 1. Finalization of recommendations of the committee (in case of full review) (SOP 05 Full Review) or Finalization of recommendations of reviewers (in case of expedited review) (SOP 04 Expedited Review) | IREB Chair and Members |
| 2. Transfer of information from meeting minutes or reports to IREB decision forms or templates | IREB Member Secretary and secretariat. |
| 1. Approval of the IREB decision document | Chair |
| 1. Transmittal of IREB decision to researcher | IREB Secretariat |
| 1. Filing of the decision document in the protocol file (SOP 23 Managing Active Files) and Update of Protocol Database | IREB Secretariat |

1. **Workflow**
2. **Description of Procedures**

**1 - Finalization of recommendations of the committee:** Finalization of Committee’s and Reviewers‘ Recommendationsshall be based on the consensus of the IREB  members during the IREB monthly meeting**.** In case of full review, the procedure for SOP 05 on Full Review will be followed (see SOP 05). In case of expedited review, the procedures for SOP 04 on Expedited Review will be followed (see SOP 04).

After which, Finally, this SOP ends with the filing of document in the protocol file by the IREB secretariat.

**2 - Transfer of information from meeting minutes to IREB decision forms or templates**: The draft of minutes, shall be prepared by the IREB secretariat based on the reviewers’ recommendations and IREB decision during the IREB monthly meeting. The document shall be properly reviewed by the REC member secretary for approval by the IREB Chairperson. This process is given three (3) working days processing until it is forwarded for approval.

**3 - Approval of the IREB decision document**:

The member secretary reviews the final draft of the IREB decision document and approved by the IREB Chairperson.  The draft is transcripted in final form using the Decision Letter Template (Form 5C) to summarize required modifications in the protocol or its approval respectively. The Decision Letter is communicated and is written on an official stationery of the IREB and signed by the chair. This process takes atleast two (2) working days.

**4 - Transmittal of IREB decision to researcher**:

The results of the review shall be sent within five (5) working days after the approval of the IREB chair. The decision document will be disseminated through email, hand-delivered or can be picked-up at the IREB office or maybe sent thru mail.

**5 - Filing of the decision document in the protocol file and Update of the Protocol Database**:

The IREB will maintain proper record keeping of all protocol related decisions or actions in the protocol folder to facilitate retrieval. The action should also be noted in the protocol database.  Record keeping and storage system will be made in hard and digital/soft copies which include protocol index and database. The filing of document is managed by the IREB secretariat and supervised by the member secretary.  See SOP on Managing Active Files (SOP# 23).

1. **Glossary**

***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.*

***Protocol Index –*** *is a chronological record of the documents in the protocol file.  The*

*protocol index is in table form indicating the date of filing, the nature of the document filed, the name and signature of the person who filed and an extra column to record any movement of the document.  The index is pasted inside the cover page of the protocol file/folder for easy reference and checking,*

***Protocol Database -*** *a collection of information about protocols that is structured and*

*organized for easy access, management, interpretation, analysis and updating. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.*

***Decision Letter*** *– communication document written on an official stationery of the IREB*

*signed by the chair and provides the details of the decision including clear*

*instructions/recommendations for guidance of the researcher.*

***Active Files –*** *are documents pertaining to protocols which are currently being assessed,*

*managed or monitored by the IREB.*

1. **Forms**

**FORM 5C - DECISION LETTER TEMPLATE**

**ISABELA STATE UNIVERSITY**

**Institutional Ethics Review Board**

(ISU-IREB

(Date)

**(NAME OF PROPONENT)**

(Designation)

(Institution)

(Address)

**RE:     (Title of project/study)**

**REC code:**

**Subject: (Nature of action requested, e.g. ethical clearance extension, acceptance of report, etc.)**

Dear ***(Name of proponent)***:

This is to acknowledge receipt of your request and the following supporting documents dated\_\_\_\_\_\_\_\_.

* \_
* \_

The above documents underwent full/expedited review which generated the following:

(List of findings)

(List of recommendations)

(Specific instructions to the proponent, if any)

Very truly yours,

(Signature)

(Name)

  Chair

1. **History of SOP**

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

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

Prepared by:

**IREB Members**

Recommending Approval:

Approved by:

**Approval Date:   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**