



EASTERN VISAYAS
STATE UNIVERSITY

EVSU Research Ethics Standard Operations (SOP) Manual





OFFICE ORDER NO. 1 Series of 2026

To/For : All Members of the Faculty, Non-Teaching Personnel, and Students engaged in Research Activities across Campuses

From : Vice-President for Research, Innovation, and Extension Services

Date : August 17, 2026

Subject : Research Ethics Committee Manual

With the Eastern Visayas State University Board of Regents' approval of the institution's Research Ethics Committee manual (Board Resolution No. 2026-031), all members of the faculty, non-teaching personnel, and students engaged in research activities shall perform the following:

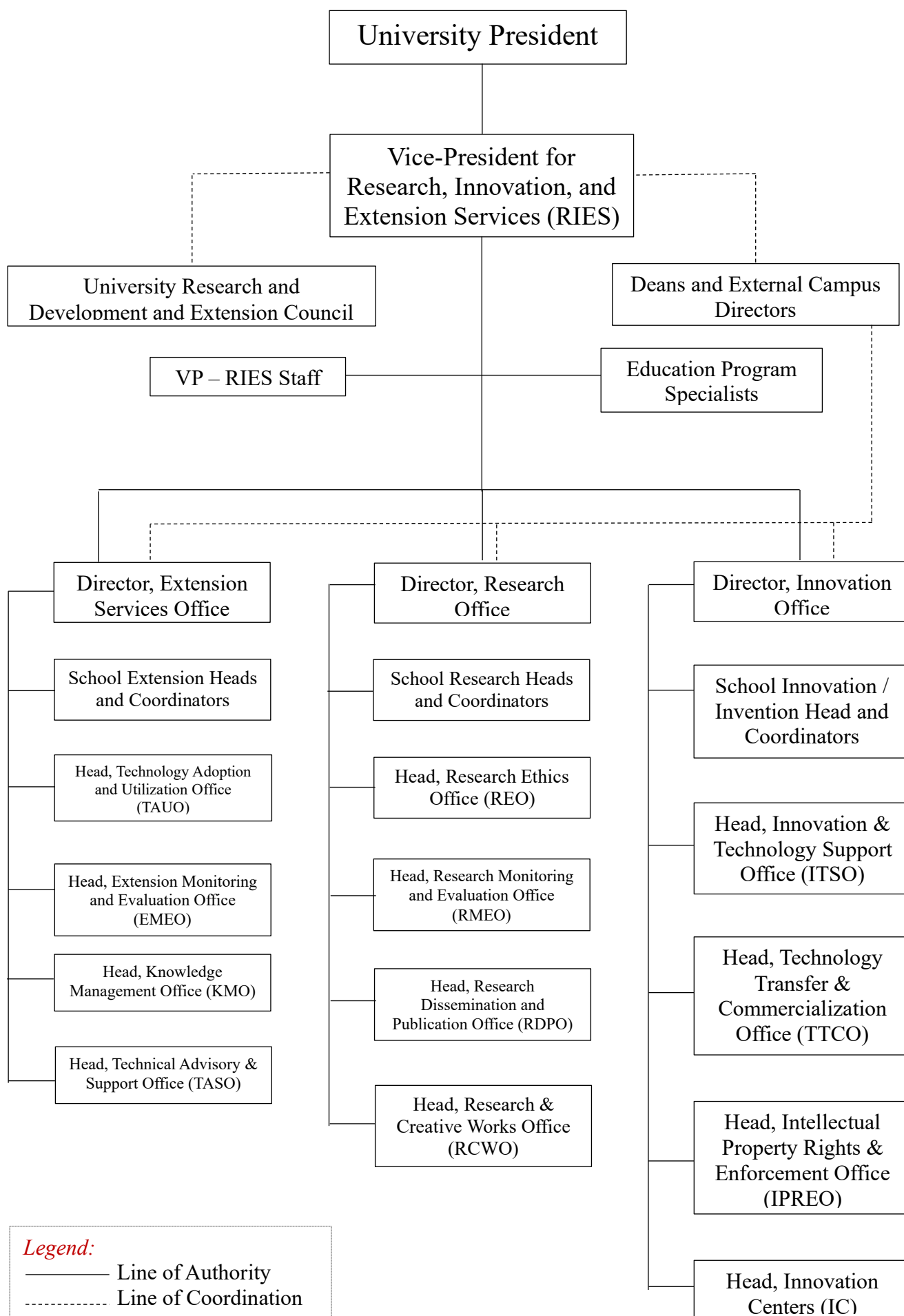
1. Secure a copy of the manual. It is available and downloadable via the institution's portal. The REC manual serves as the backbone and framework of any research endeavour that any aforementioned employee or student undertakes.
2. It is necessary that the aforementioned persons possess a copy of the document to ensure that ethical standards relative to research are complied. The essence of its publication at the EVSU portal ensures that all they are made aware of it, and that they observe the mandate of it. Ignorance of it and its contents is now avoidable.
3. All theses and dissertations from the undergraduate, graduate, to post graduate levels of the university shall undergo the review process of the Research Ethics Committee (REC). The REC clearance is free of charge and its issuance shall be at the sole discretion of the committee.
4. Research works of the members of the faculty as well as the non-teaching personnel, and students of the university who engage in research shall also undergo a mandatory review from the REC before its proceeds to the data gathering phase. REC clearance in this category shall also be free of charge. The necessity of this process stems from the reality that some journals require ethics clearance before an article is published. Working back to secure this document is a violation under the ethics code, hence securing it properly and in accordance with rules is a must.
5. To guarantee paperless submissions and in consonance to the university's aspiration of becoming a National University for Resiliency and Climate Action, all submissions shall be done electronically to the official email of the REC reo@evsu.edu.ph. After review, papers shall be returned to the author or authors electronically.

This is for your guidance and strict compliance.

SHELDON IVES G. AGATON, Ph.D.

Vice-President for Research, Innovation, and Extension Services

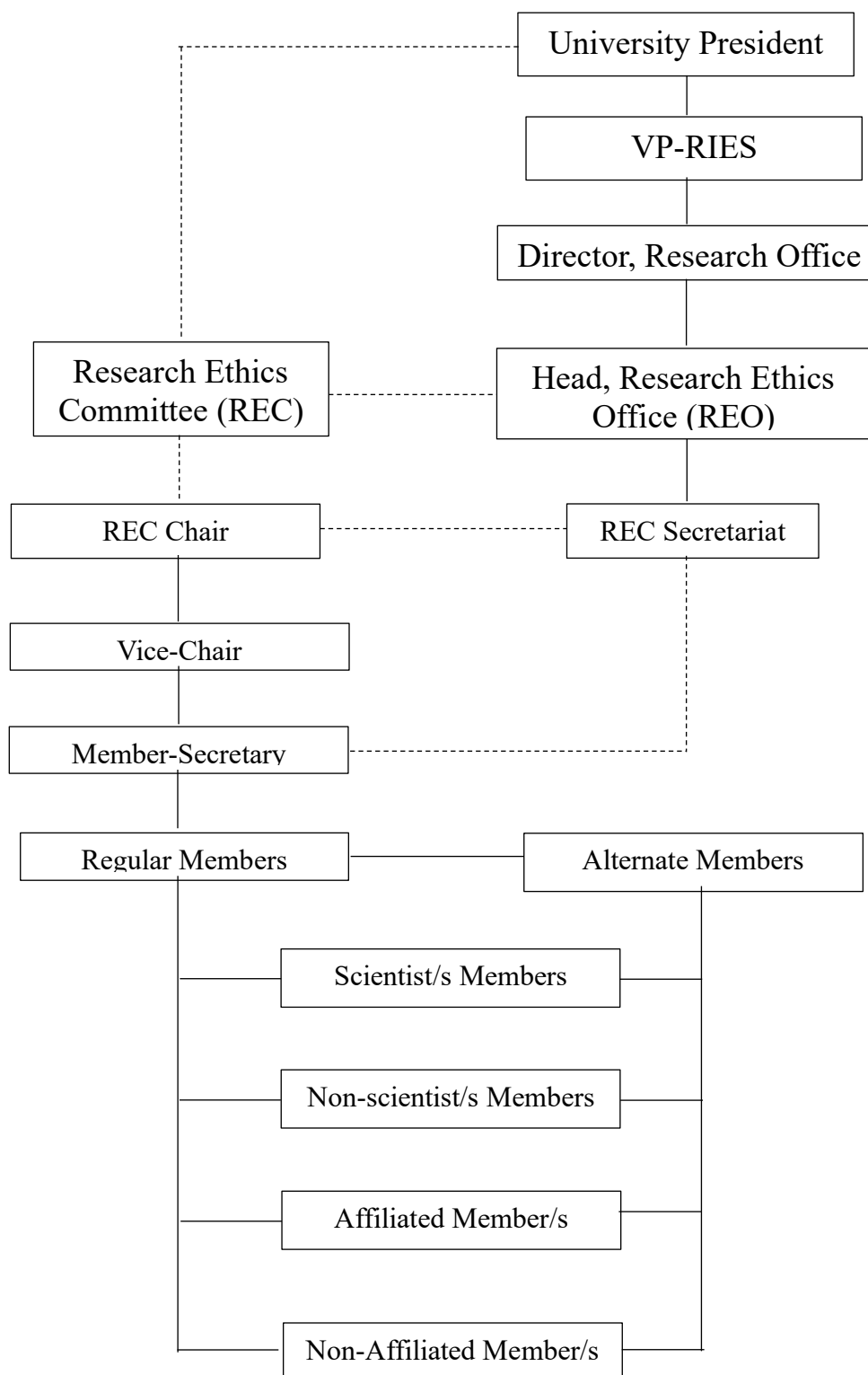






Research Ethics Office

ORGANIZATIONAL CHART



Legend:
—— Line of Authority
----- Line of Coordination

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List of Forms

Form Code	Form Title
<i>EVSU REC F-01</i>	Call for Nominations (Alternate/Regular)
<i>EVSU REC F-02</i>	Nomination Form
<i>EVSU REC F-03</i>	Curriculum Vitae
<i>EVSU REC F-04</i>	Recommendation and Endorsement for Regular REC Members
<i>EVSU REC F-05</i>	Recommendation and Endorsement for Alternate REC Members
<i>EVSU REC F-06</i>	REC Member Appointment and Conformity Form
<i>EVSU REC F-07</i>	Conflict of Interest and Confidentiality Agreement
<i>EVSU REC F-08</i>	Membership Database
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<i>EVSU REC F-11</i>	Confirmation Letter for REC Vice-Chairperson with Conformance
<i>EVSU REC F-12</i>	Confirmation Letter for REC Member-Secretary with Conformance
<i>EVSU REC F-13</i>	Invitation Letter for Independent Consultant
<i>EVSU REC F-14</i>	Appointment Letter for Independent Consultant
<i>EVSU REC F-15</i>	Confidentiality and Conflict of Interest Disclosure Agreement
<i>EVSU REC F-16</i>	Exemption Checklist
<i>EVSU REC F-17</i>	Exemption Notice
<i>EVSU REC F-18</i>	Study Protocol Evaluation Form – Expedited Review
<i>EVSU REC F-18B</i>	Study Protocol Evaluation Form – Full Review
<i>EVSU REC F-19</i>	Informed Consent Evaluation Form
<i>EVSU REC F-20</i>	Decision Letter / Ethics Clearance
<i>EVSU REC F-21</i>	Protocol Package Checklist
<i>EVSU REC F-22</i>	Protocol File Index Form
<i>EVSU REC F-23</i>	Application for Protocol Review
<i>EVSU REC F-24</i>	Submission Acknowledgment and Routing Form
<i>EVSU REC F-25</i>	Protocol Resubmission Form
<i>EVSU REC F-26</i>	Reminder Letter for Continuing Review
<i>EVSU REC F-27</i>	Progress Report Form
<i>EVSU REC F-28</i>	Protocol Amendment Form
<i>EVSU REC F-29</i>	Protocol Amendment Assessment Form
<i>EVSU REC F-30</i>	Deviation / Non-Compliance / Violation Report

Form Code	Form Title
<i>EVSU REC F-31</i>	Receipt and Recommendation for Further Action
<i>EVSU REC F-32</i>	Letter for Clarificatory Interview
<i>EVSU REC F-33</i>	Reportable Negative Event (RNE) Report
<i>EVSU REC F-34</i>	SAE / SUSAR Report Form
<i>EVSU REC F-35</i>	Evaluation of SAE / SUSAR Report Form
<i>EVSU REC F-36</i>	Application for Continuing Review
<i>EVSU REC F-37</i>	Final Report Form
<i>EVSU REC F-38</i>	Early Termination Report Form
<i>EVSU REC F-39</i>	Management of Appeals
<i>EVSU REC F-40</i>	Notice of Site Visit to Researcher(s)
<i>EVSU REC F-41</i>	Letter of Invitation to Members of Site Visit Team
<i>EVSU REC F-42</i>	Site Visit Report
<i>EVSU REC F-43</i>	Submission Log
<i>EVSU REC F-44</i>	Receipt and Recommendation for Further Action
<i>EVSU REC F-45</i>	Secret Ballot Form (REC Decision on Full Review)
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<i>EVSU REC F-47</i>	Minutes Template
<i>EVSU REC F-48</i>	Study Completion Report
<i>EVSU REC F-49</i>	Notice of EVSU REC Meeting
<i>EVSU REC F-50</i>	Summary of Reviewers' Comments and Suggestions
<i>EVSU REC F-51</i>	Summary of Actions Taken
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<i>EVSU REC F-54</i>	Archived File Request
<i>EVSU REC F-55</i>	Request for Access to Confidential Files Form
<i>EVSU REC F-56</i>	Query/Complaint Form

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	01 – Selection and Appointment of REC Members	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

1. Policy Statement

The selection of REC members shall be through a nomination process that ensures representation of different disciplines (scientists and non-scientists), sectors (male and female, older and younger age groups), and member/s who are not affiliated with the institution, including representation of community perspectives.

The committee shall have a maximum membership of thirty-five (35). The members are selected based on their: (1) disciplinary and sectoral representation; (2) relevant trainings attended; and (3) willingness to volunteer time and effort for EVSU-REC activities.

The EVSU REC shall have at least nine (9) regular members at all times, with provision for alternate members. The Committee must include: at least one (1) scientist member, one (1) non-scientist member, and one (1) non-affiliated member, representation of both sexes, and multidisciplinary expertise relevant to the types of research reviewed.

The maximum thirty-five (35) shall not supersede the required minimum composition. Failure to maintain the required minimum composition shall result in temporary suspension of review activities until compliance is restored.

Members shall be classified as regular or alternate members. The regular members shall serve for a period of three (3) years but may be renewed for several terms. The alternate members shall serve on a yearly basis and shall attend meetings whenever called to ensure that meetings are conducted with sufficient members.

Alternate members shall only be counted toward quorum when officially designated to replace an absent regular member.

Selection of members shall be through nominations from current committee members and other nominators identified by EVSU. Their appointments shall be issued by the EVSU President.

The REC members shall serve for a term of three (3) years, which shall begin on the first day of the academic year with option for renewal. Terms of REC members shall be staggered to ensure continuity of committee operations. The EVSU-REC shall function independently of institutional, political, or commercial influence in the performance of its ethical review and decision-making functions.

2. Objective of the Activity

This activity aims to ensure that the selection of members complies with international and national guidelines and that their appropriate expertise, independence, and diversity are taken into consideration.

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3. Scope

This Standard Operating Procedure (SOP) applies specifically to the selection of members of the Research Ethics Committee (REC). This SOP begins with the determination of vacancy and ends with the filing of appointment documents and CVs of new REC members in the membership file.

4. Roles and Responsibilities

A. Member (Scientist):

- review, discuss, and consider protocols in research involving human subjects according to the operational standard operating procedures (SOPs);
- attend regular and special meetings;
- participate in continuing education, trainings and seminars on research ethics as required by PHREB;
- do expedited reviews of certain study protocols;
- participate in full reviews of some study protocols;
- conduct site monitoring of approved proposals;
- monitor serious adverse event reports and recommend appropriate action/s
- review progress reports and monitor on-going studies as appropriate;
- evaluate final reports and outcomes;
- maintain confidentiality of the documents and deliberations regular and special meetings;
- conduct all other tasks specified in the SOPs;
- propose and follow set procedures for the writing, reviewing, distributing and amending the SOPs;
- disclose immediately any conflict of interest that may arise in the performance of duties and responsibilities, and inhibit from participation in review, deliberation, and decision-making when such conflict exists; and
- perform other tasks as may be assigned by the Chair.

B. Member (Non-scientist):

- represents the interests and concerns of the community, as well as serve as the voice of the patients, persons living with challenging health conditions, and their families;
- review, discuss, and consider protocols in research involving human subjects according to the operational standard operating procedures (SOPs);
- reviews the Informed Consent Form of research proposals involving human participants that are either for expedited or full reviews;
- attends regular and special meetings;
- participates in continuing education, trainings and seminars on research ethics as required by PHREB;
- participates in the conduct of protocol deliberations and approval during regular or special meetings;
- conducts site monitoring of approved proposals;

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- h. monitors serious adverse event reports and recommend appropriate action/s
- i. reviews progress reports and monitor on-going studies as appropriate;
- j. evaluate study completion reports and related manuscript;
- k. maintains confidentiality of the documents and deliberations regular and special meetings;
- l. proposes and follow set procedures for the writing, reviewing, distributing and amending the SOPs;
- m. discloses immediately any conflict of interest that may arise in the performance of duties and responsibilities, and inhibit from participation in review, deliberation, and decision-making when such conflict exists;
- n. conducts all other tasks specified in the SOPs; and
- o. performs other tasks as may be assigned by the Chair.

C.Non-Affiliated Member (Scientist):

- a. reviews, discusses, and considers protocols in research involving human subjects according to the operational standard operating procedures (SOPs);
- b. attends regular and special meetings;
- c. participates in continuing education, trainings and seminars on research ethics as required by PHREB;
- d. does expedited reviews of certain study protocols;
- e. participates in full reviews of some study protocols;
- f. conducts site monitoring of approved proposals;
- g. monitors serious adverse event reports and recommends appropriate action/s
- h. reviews progress reports and monitors on-going studies as appropriate;
- i. evaluates final reports and outcomes;
- j. maintains confidentiality of the documents and deliberations regular and special meetings;
- k. conducts all other tasks specified in the SOPs;
- l. proposes and follow set procedures for the writing, reviewing, distributing and amending the SOPs;
- m. discloses immediately any conflict of interest that may arise in the performance of duties and responsibilities, and inhibit from participation in review, deliberation, and decision-making when such conflict exists;
- n. conducts all other tasks specified in the SOPs; and
- o. performs other tasks as may be assigned by the Chair.

D.Non-Affiliated Member (Non-Scientist):

- a. represents the interests and concerns of the community, as well as serves as the voice of the patients, persons living with challenging health conditions, and their families;
- b. reviews, discusses, and considers protocols in research involving human subjects according to the operational standard operating procedures (SOPs);
- c. reviews the Informed Consent Form of research proposals involving human participants that are either for expedited or full reviews;
- d. attends regular and special meetings;

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- e. participates in continuing education, trainings and seminars on research ethics as required by PHREB;
- f. participates in the conduct of protocol deliberations and approval during regular or special meetings;
- g. conducts site monitoring of approved proposals;
- h. monitors serious adverse event reports and recommends appropriate action/s
- i. reviews progress reports and monitors on-going studies as appropriate;
- j. evaluates study completion reports and related manuscript;
- k. maintains confidentiality of the documents and deliberations regular and special meetings;
- l. proposes and follows set procedures for the writing, reviewing, distributing and amending the SOPs;
- m. discloses immediately any conflict of interest that may arise in the performance of duties and responsibilities, and inhibits from participation in review, deliberation, and decision-making when such conflict exists;
- n. ensures the independence of the REC;
- o. conducts all other tasks specified in the SOPs; and
- p. performs other tasks as may be assigned by the Chair.

5. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Call for nominations	<i>REC Chair</i>	<i>Within 10 working days after vacancy determination</i>
Step 2: Receipt of nominations	<i>REC Secretariat</i>	<i>Within 2 working days per submission</i>
Step 3: Shortlisting of nominees	<i>REC Chair</i>	<i>Within 5 working days after nomination deadline</i>
Step 4: Receipt of appointment papers of new members	<i>REC Chair</i>	<i>Within 20 working days from endorsement</i>
Step 5: Forwarding of appointment papers to the new members	<i>REC Secretariat</i>	<i>Within 5 working days</i>
Step 6: Signing of conforme, conflict of interest disclosure and confidentiality agreement	<i>REC New Member/s</i>	<i>Within 10 working days</i>
Step 7: Filing of appointment documents, CVs, and signed agreements in the membership file (SOP on managing active files)	<i>REC Secretariat</i>	<i>Within 5 working days</i>
Step 8: Entry into the membership database	<i>REC Secretariat</i>	<i>Within 5 working days</i>

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6. Description of Procedures

Step 1. Call for Nominations

- A. The Call for Nominations shall specify that nominations must be submitted within fifteen (15) working days from date of issuance. The nomination period shall remain open for fifteen (15) working days from issuance of the Call for Nominations. The REC Chair determines the specific vacancy for regular/alternate positions (i.e., scientist, non-affiliate, non-scientist);
- B. The REC Chair issues the Call for Nominations (**EVSU REC F-01**) to the entire EVSU community, which may be coursed through the Dean/Head of the different schools, departments, and other support units or by using other means that the EVSU-REC may find appropriate or useful.

The Call for Nominations (**EVSU REC F-01**) must specify the following:

- a. vacant position
- b. nomination process (as provided below)
- c. requirements to be prepared by the nominee/s:
 - i. completely filled Nomination Form (**EVSU REC F-02**):
 - 1) name of nominee
 - 2) specialization
 - 3) justification or reason for the nomination
 - 4) acceptance by the nominee (Conforme)
 - 5) name and signature of nominator/proponent
 - ii. latest version of the signed and dated Curriculum Vitae (**EVSU REC F-03**)
 - 1) deadline for submission of nominations
 - 2) office for submission

The nomination process shall be observed as follows:

- a. The REC Secretariat prepares the Nomination Form (**EVSU REC F-02**) and issues the same to the requesting nominator
- b. The REC Secretariat checks that the nominator:
 - i. provides a copy of the prescribed Nomination Form (**EVSU REC F-02**)
 - ii. submits the completely filled Nomination Form (**EVSU REC F-02**) and the required CV of the nominee (**EVSU REC F-03**)
 - iii. does the above on or before the deadline
- c. The REC Secretariat monitors those nominations from the non-affiliated member(s) are only done for the vacancies of such a position.

Step 2. Receipt of Nominations

- A. The REC Secretariat:
 - a. receives all submitted nominations and
 - b. checks the completeness of the submitted nominations for either physical or email submissions, incomplete submissions will be returned to the nominator for further completion:
 - i. for physical submissions, the REC Secretariat:
 - 1) date-stamps the submission nomination documents

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- 2) acknowledges receipt of nominations with complete requirements
- 3) scans the Nomination Form (**EVSU REC F-02**) and the Curriculum Vitae (**EVSU REC F-03**) into a single PDF file
- 4) saves the digital version into the appropriate folder in the REC Secretariat computer system unit using this filename format: Nomination_Vacancy_Initials for First and Middle Name and Family Name of Nominee (e.g., *Nomination_Non-Scientist_JSCruz*)
- ii. for email submissions, the REC Secretariat:
 - 1) sends an acknowledgement to the email source to indicate receipt of the submission
 - 2) prints the submitted document/s
 - 3) date-stamps the document/s
 - 4) saves the digital version in the appropriate folder in the REC Staff computer system unit using this filename format: Nomination_Vacancy_Initials for First and Middle Name and Family Name of Nominee (e.g., *Nomination_Non-Scientist_JSCruz*)
- c. records the submission in the Logbook of Incoming Communications (**EVSU REC F-53**) and indicate the following details:
 - i. date of submission
 - ii. name of nominee
 - iii. specialization
 - iv. justification or reason for the nomination
 - v. vacancy nominated for
 - vi. name of nominator

Step 3. Shortlisting of Nominees

- A. The REC Secretariat:
 - a. prepares a spreadsheet of the list of nominations with the following details:
 - i. date of submission
 - ii. name of nominee
 - iii. specialization
 - iv. justification or reason for the nomination
 - v. vacancy nominated for
 - vi. name of nominator
 - b. compiles submitted documents per nominee
 - c. forwards the compilation to the REC Chair for further deliberation by the committee
- B. The REC Chair:
 - a. prepares a shortlist of nominees for both regular and alternate members based on the requirements and qualifications.
 - b. includes in the agenda for a regular or special meeting the deliberation of the nominees
- C. The EVSU REC en banc evaluates the qualifications of the nominees and decides on the final list of members for appointment.
- D. The REC Chair forwards the list and documents of the REC-approved

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nominees to the Research Office Director for endorsement (**EVSU REC F-04 and F-05**).

- E. The Research Office Director endorses the REC-approved nominees for appointment by the EVSU President.

Step 4. Receipt of Appointment Papers of New Members

- A. The EVSU President issues the official appointments of regular and alternate members of the EVSU REC.
- B. The REC Secretariat receives the appointment papers from the University President and informs the REC Chair accordingly. The same specifies the conditions of the appointment including member's roles and responsibilities found in their respective Terms of Reference. Each member is appointed for a term of three (3) years with an option for renewal.

Step 5. Forwarding of Appointment papers to the new members. The REC Chair instructs the REC Secretariat to forward to the newly appointed members their appointment papers.

Step 6. Signing of Conforme, Conflict of Interest Disclosure and Confidentiality Agreement. Newly appointed EVSU REC members affix their full conformity to their appointment papers by signing on the appropriate space provided in the REC Member Appointment and Conformity Form (**EVSU REC F-06**) and Conflict of Interest Agreement Form (**EVSU REC F-07**).

Step 7. Filing of Appointment Documents, CVs, and Signed Agreements in the Membership File. The REC Secretariat keeps the conformed appointment, Confidentiality and Conflict of Interest Agreement Form (**EVSU REC F-07**) of EVSU REC Members for Regular Members in the physical folder labeled for such purpose. A digital copy shall also be uploaded to the EVSU REC Google Drive.

Step 8. Entry Into the Membership Database. The REC Secretariat encodes the details of the new member into the Membership Database of EVSU REC (**EVSU REC F-08**).

7. Glossary

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Alternate Member— Individuals who possess the qualifications of specified regular members. They are called to attend a meeting and substitute for regular members to comply with the quorum requirement when the latter cannot attend the meeting. Alternate members shall be asked to serve as observers in at least one (1) regular REC meeting so s/he will be oriented with the process. While being observers, the alternate members will be asked to comply with the needed Confidentiality Agreement.

Non-Affiliated Member — A professional who is not a member of the university system (i.e., *must not be in the roster of personnel or staff of the Institution, not an employee of the institution nor do they receive regular salary or stipend from the institution*), its research affiliates and of the community in the site where the research activities are to be conducted.

Non-Scientist — An individual, whose primary interest is not in any of the natural, physical and social sciences and whose highest formal education is a bachelor's degree, who will represent the interests and concerns of the community as well as serve as the voice of the patients, persons living with challenging health conditions, and their families.

Regular Member — Refers to someone who is appointed by the University President to serve the REC for a term of two (2) years and conducts review of protocols assigned by the REC Chair as well as other functions provided in the Terms of Reference.

Scientist — An individual whose formal education is at least a master's degree in a scientific discipline, e.g. biology, physics, social science, etc.

8. Forms

FORM CODE	FORM TITLE
<i>EVSU REC F-01</i>	Call For Nominations (Alternate/Regular)
<i>EVSU REC F-02</i>	Nomination Form
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<i>EVSU REC F-06</i>	REC Member Appointment and Conformity Form
<i>EVSU REC F-07</i>	Conflict of Interest Agreement Form
<i>EVSU REC F-08</i>	Membership Database of EVSU REC
<i>EVSU REC F-53</i>	Logbook of Incoming Communications

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9. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	April 2026	Dr. Brian John Sarno	Initial Version

10. References

- CIOMS. 2016. *International Ethical Guidelines for Health-related Research Involving Humans*.
- International Conference on Harmonization. 1996. *Guidance on Good Clinical Practice (ICH GCP)*.
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- UNESCO. 2017. *Code of Conduct Social Science Research*.
- World Health Organization (WHO). 2011. *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants*.
- World Medical Association (WMA). 2013. *Declaration of Helsinki -Ethical Principles for Medical Research Involving Human Subjects*.

Prepared by:	Reviewed and approved by:	Approved by:
Research Ethics Committee (REC)	sgd. GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	sgd. DENNIS C. DE PAZ, PhD <i>University President</i>

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	02 – Designation of REC Officers	Version No:	01-00
		Approval Date:	06/27/26
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1. Policy Statement

The EVSU REC Officers shall comprise a Chair, a Vice-Chair, and a Member-Secretary who shall be selected from among the voting REC members. The REC Member-Secretary is a voting member of the REC, while the REC Secretariat and support staff are non-voting personnel and shall not participate in deliberation or voting.

The EVSU REC Officers shall serve for a fixed term of three (3) years, beginning on the first day of the academic year. Officers may serve for a maximum of three (3) consecutive terms, after which a break of at least one (1) term is required before re-election to the same position.

The REC Secretariat shall provide administrative and technical support to the Committee and shall be composed of designated personnel from the Research Ethics Office (REO), including the REO Head and support staff, who shall serve in a non-voting capacity.

The designation of officers shall be conducted through a transparent election process by secret ballot during a properly convened meeting with quorum, free from coercion or external influence. The University President formally appoints the REC Officers as recommended by the Research Office Director.

The designation of REC officers shall uphold the independence of the REC and shall be free from institutional, political, or commercial influence.

Only REC members without conflict of interest in the election process shall participate in nomination and voting. Any member with a declared conflict shall inhibit from participation.

2. Objective of the Activity

This activity aims to ensure that the designation of EVSU REC officers conforms to EVSU's institutional practice, aligns with PHREB accreditation requirements, upholds independence, transparency, and accountability in REC governance, and ensures proper separation of voting authority and administrative support functions.

3. Scope

This SOP applies exclusively to the designation of officers of the EVSU Research Ethics Committee (REC). This SOP begins with the call for a special meeting for election and ends with the proper filing and archiving of confirmed appointment documents.

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	02 – Designation of REC Officers	Version No:	01-00
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4. Roles and Responsibilities

A. REC Chairperson

- a. head the REC and lead in the review and discussion of protocols in research involving human subjects according to the standard operating procedures (SOPs) adapted by the Committee;
- b. presides over REC meetings and directly reports to the REO (Research Ethics Office) Head for administration concerns ONLY;
- c. ensure that quorum requirements, including the presence of both scientist and non-scientist members when required, are met during officer designation;
- d. conduct initial review of submitted protocols and decide on the type of review for each protocol;
- e. designate primary reviewers for study protocols for either full or expedited reviews;
- f. ensure that the decision arrived at by the Committee towards a study protocol is a consensus of all the members of the committee, i.e., free of bias and external influence;
- g. disclose immediately any conflict of interest that may arise in the performance of duties and responsibilities, and inhibit from participation in related deliberation, nomination, or voting when such conflict exists;
- h. sign decision documents that are communicated to researcher(s)/proponent(s);
- i. grant access to REC files, especially those that are considered to be confidential;
- j. respond to queries and complaints;
- k. ensure that REC files are properly managed and curated;
- l. recommend the appointment of REC members and designation of officers;
- m. evaluate the performance of the REC Secretariat;
- n. submit mid-year and/or year-end reports to PHREB and REO of the REC's activities;
- o. invite independent consultants to provide special expertise to the Committee on proposed
- p. research protocols;
- q. initiate programs and activities that will enhance the effectiveness of the Committee in
- r. reviewing research protocols;
- s. ensures sufficient financial and administrative support for REC operation in coordination
- t. with the REO;
- u. represent the EVSU-REC in official functions both within and outside the university; and
- v. perform other tasks being a member of the EVSU-REC indicated in her/his Terms of Reference except as a primary reviewer of any protocol.

B. REC Vice-Chairperson

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- a. assist the REC Chair initiate programs and activities that will enhance the effectiveness of the Committee in performing its functions;
- b. assumes all authority of the Chair only in the Chair's documented absence or declared conflict of interest, exercises full voting authority, and perform any related duty;
- c. head the REC and lead in the review and discussion of protocols in research involving human subjects according to the standard operating procedures (SOPs) adapted by the Committee;
- d. presides over REC meetings and directly reports to the REO (Research Ethics Office) Head for administration concerns ONLY;
- e. conduct initial review of submitted protocols and decide on the type of review for each protocol;
- f. designate primary reviewers for study protocols for either full or expedited reviews;
- g. ensure that the decision arrived at by the Committee towards a study protocol is a consensus of all the members of the committee, i.e., free of bias and external influence;
- h. disclose immediately any conflict of interest that may arise in the performance of duties and responsibilities, and inhibit from participation in related deliberation, nomination, or voting when such conflict exists;
- i. sign decision documents that are communicated to researcher(s)/proponent(s);
- j. grant access to REC files, especially those that are considered to be confidential;
- k. respond to queries and complaints;
- l. ensure that REC files are properly managed and curated;
- m. recommend the appointment of REC members and designation of officers;
- n. evaluate the performance of the REC Secretariat;
- o. submit mid-year and/or year-end reports to PHREB and REO of the REC's activities;
- p. invite independent consultants to provide special expertise to the Committee on proposed research protocols;
- q. initiate programs and activities that will enhance the effectiveness of the Committee in reviewing research protocols;
- r. ensures sufficient financial and administrative support for REC operation in coordination with the REO;
- s. represent the EVSU-REC in official functions both within and outside the university; and
- t. perform other tasks being a member of the EVSU REC indicated in her/his Terms of Reference except as a primary reviewer of any protocol; and
- u. perform other tasks being a member of the EVSU REC indicated in her/his Terms of Reference.

C. Member-Secretary (Voting Member)

- a. coordinate and manage the activities of the Committee;
- b. ensures quorum is documented prior to meetings;

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- c. responsible for scheduling the meetings, describing the agenda, determining quorum and
- d. ensuring that the function of the Committee is conducted as per norms and policies described in this SOPs;
- e. review disclosures to determine whether a conflict of interest exists and to determine appropriate management for the conflict of interest;
- f. disclose immediately any conflict of interest that may arise in the performance of duties and responsibilities, and inhibit from participation in related deliberation, nomination, or voting when such conflict exists;
- g. ensures minutes accurately reflect attendance, quorum determination, and vote count;
- h. oversee the functions of the REC Secretariat pertinent to each SOP;
- i. assist the Chair and/or Vice-Chair in performing their tasks;
- j. perform the different assigned duties indicated in each SOP; and
- k. perform other tasks being a member of the EVSU REC indicated in her/his Terms of Reference.

5. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Call for meeting (SOP on Preparing for a Meeting - SOP No. 18)	<i>REC Chair</i>
Step 2: Nomination of officers	<i>REC Members</i>
Step 3: Election by secret ballot	<i>REC Members</i>
Step 4: Endorsement	<i>REC Chair</i>
Step 5: Confirmation of new officers	<i>University President</i>
Step 6: Filing of confirmation documents (SOP on Managing Active Files (SOP No. 24)	<i>REC Secretariat</i>

6. Description of Procedures

Step 1. Call for meeting. The EVSU-REC follows the procedures provided for in SOP No. 18 on Preparing for a Meeting.

Step 2. Nomination of Officers

- A. If there is no REC Chair yet, the Research Office Director will preside the meeting with the appointed REC Members (refer to Special Order issued by the Office of the University President).
- B. The Research Office director opens the floor for the nomination of REC Officers (Chair, Vice Chair, and Member-Secretary).
- C. Only voting REC members may nominate and vote.
- D. The REC Members nominate their preferences.
- E. The nominee will be asked to accept the nomination to be vetted for election. Should the nominee decline, one needs to provide an explanation for declining.

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- F. The REC Secretariat records the acceptance or rejection of the nominations done.
- G. The REC Members close the nomination process.
- H. Members with declared conflict of interest related to any nominee shall inhibit from nomination and voting processes.

Step 3. Election by Secret Ballot

- A. Voting shall be conducted by secret ballot.
- B. Only voting REC members present and counted in quorum may vote.
- C. The conduct of voting shall ensure that quorum is maintained throughout the election process.
- D. The presence of both scientist and non-scientist members shall be ensured in accordance with PHREB requirements.
- E. A simple majority determines the winner.
- F. In case of tie, a re-vote shall be conducted. If still tied, the REC shall decide through consensus or a neutral mechanism agreed upon by the committee to ensure impartiality.
- G. Vote count shall be documented in the minutes but ballots shall remain confidential.

Step 4. Endorsement

- A. The REC Secretariat prepares the following documents:
 - a. Letter Request for Endorsement by the Research Office Director for the confirmation of elected REC Officers to be signed by the REC Chair (**EVSU REC F-09**)
 - b. draft Confirmation Letters with Conforme (**EVSU REC F-10, -11, -12**) containing the terms of reference of each elected officer per his/her specific positions including his/her roles and responsibilities of his/her office.
- B. The REC Chair signs the letter request for Endorsement and forwards the same to the Research Office Director for action.
- C. The Research Office Director prepares the Endorsement Letter for the confirmation of the elected REC Officers and forwards it together with the draft Confirmation Letters to the Office of the University President for confirmation.

Step 5. Confirmation of new officers

- A. The EVSU President reviews the documents and ensures the regularity of the documents by conferring with the Research Office Director.
- B. The EVSU President signs the Confirmation Letters designating the elected REC Officers with the detailed list of their roles and responsibilities.
- C. Once done, the Office of the President forwards to the REC Office the signed Confirmation Letters.
- D. The REC Secretariat receives the Confirmation papers by duly recording their receipt in the REC Logbook of Incoming Communications (**EVSU REC F-53**) and informs the REC Chair about them.
- E. The REC Secretariat forwards to the REC Officers their respective Confirmation

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Letters and asks them to sign under Conforme.

- F. The REC Officer signs the Conforme within two (2) working days. Once done, s/he sends a copy of the signed document to the REC Secretariat.
- G. The REC Secretariat receives and scans the signed Confirmation Letter and forwards the digital copy to the Research Office Director and EVSU President for their record keeping.
- H. The REC Secretariat records the submission of the REC Officers of their Conforme in the REC Logbook of Incoming Communication (**EVSU REC F-53**).

Step 6. Filing of confirmation documents.

The REC Secretariat:

- A. generates a digital or scanned copy of the Confirmation Letter (**EVSU REC F-10, -11, -12**) to be saved in a Google folder labeled for such purpose under Active Files (SOP No. 24).
- B. places the printed copy of the Confirmation Letter in the appropriate folder labeled for such purpose.

Replacement of the REC Chair

The position of REC Chair shall be declared vacant upon: (1) expiration of term without renewal, (2) resignation (3) incapacity, (4) removal for just cause by the appointing authority, (5) permanent conflict of interest compromising leadership.

Procedure:

- A. The Vice-Chair shall assume the role of Acting Chair within three (3) working days.
- B. A special REC meeting shall be convened within fifteen (15) working days.
- C. The REC shall deliberate and nominate or elect a replacement Chair following the Steps on Nomination of Officers (SOP 1).
- D. The recommendation shall be forwarded to the Research Office Director within five (5) working days.
- E. The EVSU President shall issue the formal appointment within thirty (20) working days.
- F. The transition shall be recorded in the official minutes and membership file.
- G. No REC meeting shall proceed without an Acting or officially appointed Chair.
- H. The Member-Secretary will call the meeting if just in a special case that both Chair and Vice-Chair resign.
- I. The newly designated Chair shall complete the required trainings from NIH.

7. Glossary

Fixed Terms (Officers)

— Three (3) years.

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REC Member Qualifications	—	The EVSU REC Chair should be a highly respected individual from any EVSU current member institutions, fully capable of managing the EVSU REC and the matters brought before it, with fairness and impartiality. The EVSU REC must be perceived to be fair and impartial, immune from pressure by the researchers/proponents whose protocols are brought before it or by other professional and non-professional sources.
REC Member Secretary	—	A voting REC member designated to coordinate committee operations and ensure procedural compliance.
REC Secretariat	—	An administrative support staff in the REO responsible for documentation, communication, and file management. Does not deliberate or vote.
Secret Ballot	—	A voting method that ensures confidentiality and freedom from coercion.
Tenure	—	Term of holding office.

8. Forms

FORM CODE	FORM TITLE
<i>EVSU REC F-09</i>	Endorsement Letter for EVSU REC Officers
<i>EVSU REC F-10</i>	Confirmation Letter for REC Chair with Conforme
<i>EVSU REC F-11</i>	Confirmation Letter for REC Vice-Chair with Conforme
<i>EVSU REC F-12</i>	Confirmation Letter for REC Member-Secretary with Conforme
<i>EVSU REC F-53</i>	Logbook of Incoming Communication

9. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	April 2026	Dr. Brian John Sarno	Initial Version

10. References

- CIOMS. 2016. *International Ethical Guidelines for Health-related Research Involving Humans*.
- Philippine Health Research Ethics Board (PHREB). 2015. *A Workbook for Developing Standard Operating Procedures*.
- Philippine Health Research Ethics Board (PHREB). 2017. *National Ethical Guidelines for Health and Health-Related Research*.
- Philippine Health Research Ethics Board (PHREB). 2020. *2020 PHREB Standard Operating Procedures*.

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UNESCO. 2017. *Code of Conduct Social Science Research*.

World Health Organization (WHO). 2011. *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants*.

World Medical Association (WMA). 2013. *Declaration of Helsinki -Ethical Principles for Medical Research Involving Human Subjects*.

Prepared by:	Reviewed and approved by:	Approved by:
Research Ethics Committee (REC)	sgd. GILBERT ANTHONY O. ABAÑO, MAN, RN REC Chairperson	sgd. DENNIS C. DE PAZ, PhD University President

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	03 – Appointment of Independent Consultants	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

1. Policy Statement

The EVSU-REC shall maintain a list of independent consultants who may be requested for specialized input on specific study protocols as needed, even if they are not affiliated with the university.

The REC Chairperson is responsible for identifying necessary external expertise from professionals with unique scientific backgrounds to complement the current EVSU-REC team's capabilities. This list of independent consultants is submitted for approval by the University President upon endorsement by the Research Ethics Office (REO).

Additionally, the University President may extend invitations to previous EVSU-REC members to act as independent consultants, providing institutional knowledge and continuity for the current REC team. These experienced consultants may also contribute to special projects or other roles as circumstances require, ensuring consistency in REC practices and facilitating effective transitions.

Independent consultants shall serve in an advisory capacity only and shall not participate in deliberation, quorum determination, or voting. All independent consultants must disclose any conflict of interest and shall inhibit from participation in the review of protocols where such conflict exists. Engagement of independent consultants shall be based solely on expertise and shall be free from institutional, political, or commercial influence.

2. Objective of the Activity

This activity aims to establish a systematic approach for identifying, evaluating, and appointing external experts who can contribute specialized knowledge essential to the ethical review of complex study protocols. This SOP ensures that the REC can efficiently access diverse expertise beyond its in-house capabilities, strengthening the ethical rigor of its reviews. Independent Consultants, drawn from varied scientific fields and selected by the REC Chairperson based on specific expertise requirements, play a pivotal role in supplementing the REC's expertise for studies requiring additional insights. This process also includes provisions for former REC members to be appointed as consultants by the University President to promote knowledge continuity and provide historical perspective to the REC team.

3. Scope

This activity encompasses the structured process for identifying, evaluating, and appointing experts from outside the institution who possess specialized skills and knowledge essential for the ethical review of complex research protocols. This SOP applies to all activities related to the selection, invitation, and official engagement of

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Independent Consultants whose expertise may not be available within the current REC membership. It includes the roles of the REC Chairperson in identifying necessary external expertise, the REO in endorsing potential consultants, and the University President in approving and formally appointing these consultants. This SOP also extends to the selection of previous EVSU-REC members who may be invited by the University President to contribute historical knowledge, ensure REC continuity, and participate in special projects as needed.

4. Roles and Responsibilities

A. REC Chairperson

- Proposes the list of potential independent consultants to the REC Members.
- Determines the need for external expertise based on protocol requirements;
- Ensures that the selection of consultants is based on expertise and free from conflict of interest; and
- Ensures that consultants are properly oriented on their advisory role and confidentiality obligations.

B. Independent Consultants

- Provides expert evaluation on scientific, ethical, or methodological aspects of the study;
- Assesses scientific rigor, appropriateness of methodology, and risk-benefit considerations;
- Submits a written assessment report to the REC;
- May attend REC meetings upon invitation to provide clarification;
- Does not participate in quorum determination, deliberation, or voting;
- Signs confidentiality and conflict of interest disclosure agreements prior to engagement;
- Inhibits from participation when a conflict of interest exists.

C. REC Secretariat

- Facilitates documentation, communication, and processing of consultant engagement;
- Ensures completeness of required documents prior to engagement;
- Maintains consultant records and roster;
- Files consultant reports as part of the protocol documentation.

5. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Identify the need for an Independent Consultant based on specific protocol needs	<i>REC Chair</i>
Step 2: Determine the required expertise and consult the roster of potential consultants	<i>REC Chair</i>

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Step 3: Endorse the identified Independent Consultant to the REO for review and recommendation	<i>REC Chair, REO</i>
Step 4: Review and endorse the recommended consultant to the University President for approval	<i>REO</i>
Step 5: Issue the appointment letter upon approval and include the terms of reference	<i>University President, REO</i>
Step 6: Provide the consultant with necessary study protocol documents and Confidentiality and Conflict of Interest Disclosure Agreement	<i>REC Secretariat, REO</i>
Step 7: Obtain signed confidentiality and conflict of interest agreement and add consultant to official roster	<i>REC Secretariat</i>
Step 8: Integrate consultant's assessment and input into protocol review process, ensuring inclusion in study file	<i>Independent Consultant, REC Chairperson, Primary Reviewer</i>
Step 9: Update the consultant roster and maintain relevant documents in consultant records	<i>REC Secretariat, REO</i>

6. Description of Procedures

Step 1. Identify the need for an Independent Consultant based on specific protocol needs. The REC Chairperson initially reviews the study protocol and identifies specific areas where additional expertise is required. This may be due to the complexity of the study or specialized scientific, ethical, or cultural considerations that the current EVSU-REC members may not fully cover. The need for an independent consultant shall be justified based on lack of expertise within the REC.

Step 2. Determine the required expertise and consult the roster of potential consultants. The REC Chairperson determines the precise expertise needed, such as expertise in a specific scientific field, cultural knowledge, or ethical perspective. The Chairperson then reviews the EVSU-REC's roster of consultants or identifies potential candidates externally if the required expertise is not already listed. An invitation letter for Independent Consultants (**EVSU REC F-13**) will be sent to the chosen consultants.

Step 3. Endorse the identified Independent Consultant to the REO for review and recommendation. The REC Chairperson formally recommends the identified consultant to the Research Ethics Office (REO). The endorsement includes the consultant's qualifications, relevant expertise, and justification for their selection based on protocol requirements.

Step 4. Review and endorse the recommended consultant to the University President for approval. The REO evaluate the consultant's qualifications and appropriateness for the specific protocol. Upon agreement, they forward the

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endorsement to the University President with a recommendation for approval, ensuring alignment with institutional standards and PHREB SOP guidelines.

Step 5. Issue the appointment letter upon approval and include the terms of reference. Upon the University President’s approval, an official appointment letter is issued to the consultant (**EVSU REC F-14**), including the terms of reference, roles, responsibilities, and any expected deliverables. This step formalizes the consultant’s engagement and clarifies the scope of their input for the EVSU-REC.

Step 6. Provide the consultant with necessary study protocol documents and Confidentiality and Conflict of Interest Disclosure Agreement. The REC Secretariat provides the consultant with relevant study protocol documents to review, along with a Confidentiality and Conflict of Interest Disclosure Agreement. This agreement must be signed before the consultant can access sensitive information, ensuring compliance with ethical standards. Access to protocol documents shall only be granted upon submission of signed confidentiality and conflict of interest disclosure agreements.

Step 7. Obtain signed confidentiality and conflict of interest agreement and add consultant to official roster. The consultant signs and returns the Confidentiality and Conflict of Interest Disclosure Agreement (**EVSU REC F-15**) to the REC Secretariat, who then files the document and updates the EVSU-REC’s official roster of active Independent Consultants.

Step 8. Integrate consultant’s assessment and input into protocol review process, ensuring inclusion in study file. The consultant reviews the protocol based on their expertise, focusing on areas specified in the terms of reference. They may submit a written assessment or attend the REC meeting to present findings. Their input is documented and added to the protocol study file, strengthening the ethical and scientific review process. The consultant’s written assessment shall form part of the official protocol file and shall be considered during REC deliberation.

Step 9. Update the consultant roster and maintain relevant documents in consultant records. The REC Secretariat updates the EVSU-REC’s consultant roster to reflect current active consultants and maintains records of their engagement, including the appointment letter, agreement forms, and completed assessments. This ensures up-to-date documentation and easy retrieval for future reference or audit

7. Glossary

Advisory Role — A non-voting function limited to providing expert input without participation in REC decisions.

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Conflict of Interest	—	A situation in which personal, professional, or financial interests may affect objectivity.
Confidentiality Agreement	—	A document ensuring protection of sensitive research information accessed during review.
Independent Consultant	—	An external expert engaged by the REC to provide specialized advice on specific aspects of a research protocol.

8. Forms

FORM CODE	FORM TITLE
<i>EVSU REC F-13</i>	Invitation Letter for Independent Consultant
<i>EVSU REC F-14</i>	Appointment Letter for Independent Consultant
<i>EVSU REC F-15</i>	Confidentiality and Conflict of Interest Disclosure Agreement

9. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	April 2026	Engr. Juvyneil E. Cartel	Initial version

10. References

- Leyte Normal University. (2023). *Research Ethics Manual (REM)*. Leyte Normal University.
- Philippine Health Research Ethics Board. (2020). Standard operating procedure: Appointment of independent consultants (SOP No. 03). *In A workbook for developing standard operating procedures. Philippine Health Research Ethics Board.*
- Philippine Health Research Ethics Board. (2022). *National ethical guidelines for health and health-related research*. Department of Science and Technology.
- World Health Organization. (2011). *Standards and operational guidance for ethics review of health-related research with human participants*

Prepared by:	Reviewed and approved by:	Approved by:
<i>Research Ethics Committee (REC)</i>	sgd. GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	sgd. DENNIS C. DE PAZ, PhD <i>University President</i>

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		Effective Date:	08/17/26

1. Policy Statement

Research protocols with no human participants and those that involve no to less than minimal risk or impact on the physical, biological, and spatial environment of research participants are exempt from review. These include:

- A. Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g. meta-analysis protocols)
- B. Protocols do not involve more than minimal harm:
 - 1. Protocols for institutional quality assurance purposes
 - 2. Evaluation of public service programs
 - 3. Public health surveillance;
 - 4. Educational evaluation activities;
 - 5. Consumer acceptability tests;
- C. Research studies that only include interactions involving:
 - 1. Survey procedures;
 - 2. Interview procedures; or
 - 3. Observation of public behavior (including visual or auditory recording) if:
 - a) There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation
 - b) The researcher records the information obtained in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.
- D. Protocols that involve the use of publicly available data or information

Exemption is not self-determined by the researcher. Only the REC has authority to classify a study as exempt. Exemption determination must be documented using an approved Exemption Checklist. If uncertainty exists regarding risk level, the protocol shall be elevated to expedited or full review. Exempt studies remain subject to: (1) Data Privacy Act compliance; (2) Institutional research integrity policies; and (3) Reporting requirements if modifications introduce risk.

The assigned Primary Reviewer evaluates the exemption category. Final confirmation is approved by the REC Chair. The REC Secretariat shall issue the Exemption Notice within 10 working days, provided all documents are complete. The assigned Primary Reviewer is responsible for granting an exemption signed by the REC Chair while the REC Secretariat is responsible for communicating the exemption and furnishing the exemption notice within 10 working days from the date of the application submission.

Exempt review shall be conducted by at least one (1) designated REC reviewer. Independent consultants, if engaged, shall be non-voting and advisory only.

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All exemption determinations shall be reported in the next Full Board meeting for transparency and documentation.

2. Objective of the Activity

This SOP intends to ensure exemption of research protocols for review which satisfy the criteria listed in the policy statement and the immediate communication and issuance of exemption notice.

3. Scope

This SOP applies to initial submissions for ethical review and covers the application to the presentation of research protocols exempted from review to the Full Review and Expedited Review.

4. Roles and Responsibilities

A. REC Chairperson

- a. screens submissions for exemption eligibility, approves exemption classification, and ensures proper escalation when necessary.

B. Primary Reviewer

- a. evaluates exemption eligibility using approved checklist, and recommends exemption or escalation.

C. REC Secretariat

- a. checks completeness of submission, facilitates review process, communicates decisions, and files and records documents.

5. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Receipt and completeness check of submission	<i>REC Secretariat</i>
Step 2: Screening for exemption eligibility	<i>REC Chair</i>
Step 3: Assignment of reviewer and provision of checklist	<i>REC Chair / REC Secretariat</i>
Step 4: Review and completion of exemption checklist	<i>Primary Reviewer</i>
Step 5: Approval and preparation of exemption notice	<i>REC Secretariat / REC Chair</i>
Step 6: Communication of decision	<i>REC Secretariat</i>

6. Description of Procedures

Step 1. Receipt and Completeness Check of Submission.

- A. Follow and refer to SOP 06 “*Managing Initial Submission*”

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- B. Only complete submissions shall be processed. Incomplete submissions shall be returned without review.
- C. The REC Secretariat receives and screens the submission for completeness

Step 2. Screening for Exemption Eligibility

- A. The REC Chair initially review for possible exemption eligibility.
- B. If clearly outside exemption criteria, the protocol is immediately routed to expedited or full review.

Step 3. Assignment of Reviewer and Provision of Checklist. The REC Chair assigns primary reviewer and the REC Secretariat shall provide the approved Exemption Checklist (**EVSU REC F-16**) together with the submitted protocol to the assigned reviewer.

Step 4. Review and Completion of Exemption Checklist.

- A. The conduct of all the assigned reviews shall be completed within **5 working days** of receiving the checklists and protocols.
- B. When deemed necessary by the reviewers, they may contact the researcher(s) or representative to clarify or solicit additional documents or information. All the transpired conversations must be documented in the “Remarks” section of the form(s).
- C. The completed checklists shall then be submitted electronically via the official email of the research ethics committee or handed over to the office.
- D. All forms must be signed and dated before turning over to the REC Secretariat.
- E. The assigned reviewer evaluates exemption eligibility.

Step 5. Approval and Preparation of Exemption Notice. An Exemption Notice (**EVSU REC F-17**) which also serves as the ethical clearance, shall be drafted by the REC Secretariat and forwarded to the REC Chairperson for approval.

Step 6. Communication of Decision.

- A. The approved Exemption Notice (**EVSU REC F-17**) shall be communicated to the researcher(s) electronically via their email address(es). A hard copy could also be given once requested.
- B. Refer to SOP 22 “Management of Incoming/Outgoing Communications” and SOP 21 “Communicating REC Decisions”
- C. The Exemption Notice shall be issued **within three (3) working** days after final approval.

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7. Glossary

Exempt Research	—	Research determined by the REC to fall under NEGRIHP exemption categories and involving no more than minimal risk.
Minimal Risk	—	Probability and magnitude of harm not greater than those ordinarily encountered in daily life or routine examinations.
Exemption Notice	—	Official REC-issued document certifying exemption from review.
Assigned Reviewer	—	REC member designated to evaluate exemption eligibility.
Escalation	—	Process of elevating a protocol to expedited or full review.
Full Board Oversight	—	Reporting of exempt protocols to REC for transparency.
Misclassification	—	Incorrect assignment of review category.

8. Forms

FORM CODE	FORM TITLE
<i>EVSU REC F-16</i>	Exemption Checklist
<i>EVSU REC F-17</i>	Exemption Notice

9. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	October 2024	Ms. Jennilou C. Patindol	First Draft of SOP
	April 2026	Dr. Cara Luz Buar	Policy Statement, Workflow/Description of Procedures, Forms

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	04A – Exempt Review	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

10. References

Eastern Visayas Health Research and Development Consortium-Ethics Review
 Committee Standard Operating Procedure (SOP) Manual version 4 2022
 National Ethical Guidelines for Health and Health-related Research 2022
 Philippine Health Research Ethics Board. 2022 *National Ethical Guidelines for
 Research Involving Human Participants 2022 NEGRIHP*
 Philippine Health Research Ethics Board. 2020 *PHREB Standard Operating
 Procedures Workbook 2020 PHREB SOP Workbook- PDF*
 Philippine Health Research Ethics Board Standard Operating Procedures 2020

Prepared by:	Reviewed and approved by:	Approved by:
<i>Research Ethics Committee (REC)</i>	sgd. GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	sgd. DENNIS C. DE PAZ, PhD <i>University President</i>

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	04B – Expedited Review	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

1. Policy Statement

Research protocols for expedited review involve not more than minimal risk or impact on the physical, biological, and spatial environment of research participants, do not have study participants belonging to a vulnerable group, and the study procedures do not generate vulnerability. These include:

- A. Anonymous surveys of non-sensitive nature;
- B. Chart review;
- C. Use of non-identifiable specimens/samples, data, documents, or records;
- D. Revised proposals previously approved through expedited review or full review with no changes in the degree of the risk(s);
- E. Minor deviations and amendments during the period of submission:
 - 1. Typographical errors;
 - 2. Change (removal and addition) in researcher(s);
 - 3. Change in researcher(s) contact details;
 - 4. Minor modifications in the technical aspect;
 - 5. Minor alterations in the ethical considerations
- F. Research during emergencies and disasters

There shall be exactly two (2) primary reviewers assigned for expedited review. The reviewers must be voting REC members with relevant expertise. Expedited review shall include one (1) scientist member and one (1) non-scientist member. Independent consultants may be invited for technical advice but are strictly non-voting and shall not determine the final decision. Expedited review shall not apply to: (1) Studies involving vulnerable populations; (2) Studies involving more than minimal risk; and (3) Studies generating new vulnerability. Final approval rests with the REC Chair upon concurrence of reviewers. All expedited approvals shall be reported in the next Full Review meeting. The expedited review process shall be completed by the primary reviewers before the Expedited Review Meeting scheduled on every **fourth (4th) Friday of the month**, 10 working days after the cutoff date of protocol submission (every 15th of the month) unless rescheduled due to declared non-working Holidays, weekends, etc.

2. Objective of the Activity

This SOP intends to ensure expedited review of research protocols which satisfy the criteria listed in the policy statement and the immediate communication and issuance of ethical clearance.

3. Scope

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	04B – Expedited Review	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

This SOP applies to initial submissions and resubmissions for ethical review and covers the application to the inclusion of the Expedited Reviews in Full Review meeting.

4. Roles and Responsibilities

- A. **REC Chairperson** - determines eligibility, assigns reviewers, and finalizes decisions.
- B. **Primary Reviewers** - conducts ethical review, and submit evaluation forms.
- C. **REC Secretariat** - checks completeness, facilitates review, communicates decisions, and files records.

5. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Receipt and completeness check of submission	<i>REC Secretariat</i>
Step 2: Assignment of primary reviewers	<i>REC Chair</i>
Step 3: Conduct of review	<i>Primary Reviewers</i>
Step 4: Consolidation and decision	<i>REC Chair</i>
Step 5: Communication of decision	<i>REC Secretariat</i>

6. Description of Procedures

Step 1. Receipt and Completeness Check of Submission.

- A. Follow and refer to SOP 06 “*Managing Initial Submission*”
- B. Only complete submissions shall be processed. Incomplete submissions shall be returned without review.
- C. The REC Secretariat receives and screens the submission for completeness and provide the REC Chair with the Study Protocol Evaluation Form (**EVSU REC F-18**).

Step 2. Assignment of Primary Reviewers. The REC Chair assigns two (2) primary reviewers that include a scientist and non-scientist member. The non-scientist member reviews the informed consent form (ICF) and fill out the ICF Evaluation Form (**EVSU REC F-19**).

Step 3. Conduct of Review. The conduct of all the assigned reviews by the primary reviewers shall be completed before the scheduled Expedited Review Meeting every **fourth (4th) Friday of the month**.

Step 4. Consolidation and Decision. The REC Chair shall finalize the review results and make objective decision on opposing views about the reviewed research protocol.

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Step 5. Communication of Decision. The approved Research Protocol shall be communicated by the REC Secretariat to the researcher(s) electronically via their email address(es). A hard copy could also be given once requested. The Decision Letter containing the approval of the protocol also serve as the Ethics Clearance which is valid for one (1) year (**EVSU REC F-20**). Minor modification decisions require submission of revised documents prior to clearance issuance. Disapproved protocols shall automatically be elevated to Full Review. Expedited review of modifications shall remain under expedited pathway if no risk increase occurs.

7. Glossary

Expedited Review	–	Ethical review conducted by two (2) designated Primary Reviewers for minimal-risk research.
Minimal Risk	–	Risk not greater than those encountered in daily life or routine exams.
Primary Reviewers	–	Scientist and non-scientist members assigned to conduct ethical evaluation
Independent Consultant	–	Subject matter expert invited for advice; non-voting.
Escalation	–	Formal elevation of protocol to Full Review.
Decision Letter (Ethical Clearance)	–	Official written REC approval to implement the protocol.
Resubmission	–	Revised protocol responding to REC comments.

8. Forms

FORM CODE	FORM TITLE
<i>EVSU REC F-18</i>	Study Protocol Evaluation Form
<i>EVSU REC F-19</i>	Informed Consent Evaluation Form
<i>EVSU REC F-20</i>	Decision Letter (Ethics Clearance)

9. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	October 2024	Ms. Jennilou C. Patindol	First Draft of SOP
	April 2026	Dr. Cara Luz Buar	Policy Statement, Workflow/Description of

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	04B – Expedited Review	Version No:	01-00
		Approval Date:	06/27/26
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			Procedures, Forms
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10. References

Eastern Visayas Health Research and Development Consortium-Ethics Review
 Committee Standard Operating Procedure (SOP) Manual version 4 2022
 National Ethical Guidelines for Health and Health-related Research 2022
 Philippine Health Research Ethics Board. 2022 *National Ethical Guidelines for
 Research Involving Human Participants 2022 NEGRIHP*
 Philippine Health Research Ethics Board. 2020 *PHREB Standard Operating
 Procedures Workbook 2020 PHREB SOP Workbook- PDF*
 Philippine Health Research Ethics Board Standard Operating Procedures 2020

Prepared by:	Reviewed and approved by:	Approved by:
Research Ethics Committee (REC)	sgd. GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	sgd. DENNIS C. DE PAZ, PhD <i>University President</i>

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	05 – Full Review	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

1. Policy Statement

All research protocols that do not qualify for exemption or expedited review, carry more than minimal risk to study participants, and involvement of vulnerable populations and special groups shall be subjected to Full Review by the REC en banc during a convened meeting with quorum on **every first (1st) Friday of the month**. These include:

- A. Research involving bio-hazardous materials that may cause harm to humans, animals, or the environment.
- B. Research involving genetically modified organisms or crops.
- C. Research involving pathogenic organisms affecting humans or animals.
- D. Research involving radiation exposure.
- E. Research involving vulnerable populations, even when risk is minimal.
- F. Research involving psychological or social harm.
- G. Studies involving deception of participants.
- H. Research with greater than minimal risk;
 - a. Amendments of proposals/related documents (including but not limited to informed consent documents, recruitment methods, etc.) involving an altered risk;
 - b. Made deviations and violations in the protocol;
 - c. Any new information that emerges during the research to decide whether or not to terminate the study because of the altered benefit-risk assessment;
- I. Research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee;
- J. Research during emergencies and disasters through unscheduled Full Review meetings as determined by the REC Chair based on urgency;
- K. Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs;
- L. Any other research the REC Chair determines that requires a full committee review.

Only protocols submitted on or before the cutoff date **every 15th of the month** (unless rescheduled due to holidays or institutional circumstances) shall be included in the Full Review Meeting agenda.

Each protocol undergoing Full Review shall have one (1) Primary Reviewer, and two (2) additional REC members serving as Secondary Reviewers that must involve one (1) scientist and one (1) non-scientist member. All REC members present during the meeting may participate in deliberation. Independent consultants may be invited to

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provide technical expertise but are non-voting. All decisions shall be made during a convened Full Review meeting with quorum and shall not be delegated outside the Full Board. Assigned reviewers shall be given at most fifteen (15) working days prior to the scheduled Full Review meeting to conduct their review.

2. Objective of the Activity

This SOP intends to ensure a full review of research protocols that satisfy the criteria listed in the policy statement and the immediate communication and issuance of ethical clearance.

3. Scope

This SOP applies to initial, resubmissions, and post-approval submissions for ethical review and covers the evaluation of primary reviewers and the filing of protocol-related documents.

4. Roles and Responsibilities

A. REC Chair

- determines review classification;
- assigns Primary and additional reviewers;
- presides over Full Board meetings;
- ensures quorum and proper deliberation;
- facilitates consensus or voting;
- confirms REC decisions.

B. Primary Reviewer

- conducts in-depth ethical and technical review;
- prepares and submits evaluation;
- presents findings during Full Board meeting;
- inhibits from deliberation and voting when conflicted.

C. Additional Reviewers

- review assigned protocol;
- provide comments during deliberation;
- contribute to decision-making.

D. REC Members

- participate in deliberation and decision-making;
- declare conflicts of interest and inhibit when necessary;
- ensure participant protection and ethical compliance.

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E. REC Secretariat

- checks completeness of submission;
- facilitates review process;
- prepares agenda and documentation;
- communicates REC decisions;
- files protocol records.

5. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Provision of Evaluation Forms	<i>REC Secretariat</i>
Step 2: Accomplishment of Evaluation Forms	<i>Primary Reviewer / Additional Reviewers</i>
Step 3: Scheduling and Agenda Inclusion	<i>Member-Secretary</i>
Step 4: Presentation of Review Findings	<i>Primary Reviewer</i>
Step 5: Deliberation and Decision	<i>REC Members</i>
Step 6: Decision Communication	<i>REC Secretariat</i>
Step 7: Filing of Protocol-related Documents	<i>REC Secretariat</i>

6. Description of Procedures

Step 1. Provision of Evaluation Forms

- The identified review type should be communicated to the researcher(s) with the scheduled review and expected decision date before handing out the evaluation forms. Refer to **SOP 22** “*Management of Incoming/Outgoing Communications*”.
- The REC Chair assigns one (1) Primary Reviewer and two (2) additional reviewers that must include one (1) scientist and one (1) non-scientist member.
- The REC Secretariat shall provide the reviewers with the Protocol Evaluation Form (**EVSU REC F-18B**) and Informed Consent Evaluation Form (**EVSU REC F-19**) together with the complete protocol package.

Step 2. Accomplishment of Evaluation Forms.

- The REC Chair assigns one (1) Primary Reviewer, and two (2) Secondary Reviewers that include a scientist and non-scientist member. The non-scientist member reviews the informed consent form (ICF) and fill out the ICF Evaluation Form (**EVSU REC F-19**).
- The conduct of all the assigned reviews by the reviewers shall be completed before the scheduled Full Review Meeting **every first (1st) Friday** of the month.

Step 3. Scheduling and Agenda Inclusion

- Full Review meetings are conducted monthly.

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- B. Only protocols with completed primary reviewer assessments prior to the meeting shall be included in the meeting agenda. Refer to SOP 18 “*Preparing the Meeting Agenda*”.

Step 4. Presentation of Review Findings. The Primary Reviewer shall present their findings and recommendations to the REC during the Full Review meeting. The Primary Reviewer presents findings. If absent, the additional reviewer may present the findings.

Step 5. Deliberation and Decision

- A. The Chair facilitates discussion of ethical and technical issues.
- B. REC members deliberate on the protocol considering scientific validity, participant protection, and risk-benefit balance.
- C. Decisions may be reached through **voting**. Possible decisions include: (1) Approval, (2) Approval with Minor Modifications, (3) Major Modifications Required, and (4) Disapproval.
- D. Members with conflict of interest shall inhibit from deliberation and voting.

Step 6. Decision Communication

- A. The approved Research Protocol shall be communicated to the researcher(s) electronically via their email address(es). A hard copy could also be given once requested. The decision letter will serve as the Ethical Clearance (**EVSU REC F-20**).
- B. The REC Secretariat communicates the decision within five (5) working days after the Full Review Meeting.
 - a. Major Modifications → Full Board Review upon resubmission
 - b. Minor Modifications → Expedited Review
 - c. Disapproved → with justification and will undergo Full Review.
- C. Refer to SOP 22 “*Management of Incoming/Outgoing Communications*” and SOP 21 “*Communicating REC Decisions*”

Step 8. Filing of Protocol-related Documents

- A. All documents are filed and recorded in accordance with SOP 23 on Managing Active Files.
- B. Refer to SOP 23 “*Managing Active Files*” for the access, maintenance, recording, storage, retention and disposal of archived files and documents
- C. An Annual Report with the lists of all proposals or protocols that were subjected to full reviews shall be prepared and recorded by the REC Secretariat.

7. Glossary

Full Review	–	Ethical evaluation conducted by the REC en banc during a convened meeting with quorum.
Vulnerable Groups	–	Individuals with limited capacity to protect their interests or at increased risk of exploitation.

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- Major Modification** – Revision affecting study design, participant protection, or risk–benefit balance.
- Minor Modification** – Revision that does not affect participant safety or research integrity.
- Voting** – Formal decision-making process where majority vote determines the outcome.
- Inhibition** – Withdrawal of a REC member from discussion and voting due to conflict of interest or involvement in the research.

8. Forms

FORM CODE	FORM TITLE
<i>EVSU REC F-18B</i>	Study Protocol Evaluation Form
<i>EVSU REC F-19</i>	Informed Consent Evaluation Form
<i>EVSU REC F-20</i>	Decision Letter (Ethics Clearance)

9. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	October 2024	Ms. Jennilou C. Patindol	First Draft of SOP
	April 2026	Dr. Cara Luz Buar	Policy Statement, Workflow/Description of Procedures, Forms

10. References

Eastern Visayas Health Research and Development Consortium-Ethics Review Committee Standard Operating Procedure (SOP) Manual version 4 2022

National Ethical Guidelines for Health and Health-related Research 2022

Philippine Health Research Ethics Board. National Ethical Guidelines for Research Involving Human Participants (2022).

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Prepared by:	Reviewed and approved by:	Approved by:
<i>Research Ethics Committee (REC)</i>	sgd.	sgd.
	GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	DENNIS C. DE PAZ, PhD <i>University President</i>

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	06 – Management of Initial Submissions	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

1. Policy Statement

This SOP outlines the institutional procedure for managing initial research protocol submissions to the EVSU-REC. It ensures that all submissions are processed efficiently, fairly, and transparently, consistent with institutional policies and national ethical standards for research involving human participants.

This procedure applies to all initial submissions from undergraduate and graduate students, researchers, faculty, and external researchers seeking ethical review from the EVSU-REC.

Only complete submissions on or before the cutoff date **every 15th of the month** shall be accepted for processing. Incomplete submissions shall be returned to the researcher without review, with notification of missing requirements.

All submissions shall be recorded in the protocol logbook and assigned a unique protocol code for tracking and documentation.

2. Objective of the Activity

The objective of this activity is to ensure that all initial research submissions undergo a standardized process for ethical review, screening, and routing to the appropriate review pathway, while ensuring protection of participants' rights, privacy, and safety.

3. Scope

This SOP applies to all researchers submitting proposals for ethical review, whether students, faculty, researchers, or external researchers affiliated with the institution. This SOP begins with the receipt and completeness check of submissions and ends with the routing of protocols to the appropriate review pathway and communication to the researcher.

4. Roles and Responsibilities

A. Researcher(s)

- prepare and submit complete, accurate documentation, ensure compliance with submission requirements, and respond to requests for clarification.

B. REC Secretariat

- receives and logs submissions in the protocol logbook;
- checks completeness of submitted documents;
- returns incomplete submissions;
- prepares protocol review package;

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- e. facilitates routing and communication;
- f. maintains protocol records.

C. Member-Secretary

- a. oversees protocol coding and documentation, and ensures accuracy of records and databases entries.

D. REC Chairperson

- a. determines the appropriate type of review (Exempt, Expedited, or Full Review), and ensures proper classification based on risk and study characteristics.

5. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Submission of all required documents	<i>Researcher(s)</i>
Step 2: Receipt and completeness check	<i>REC Secretariat</i>
Step 3: Assignment of permanent protocol code	<i>REC Secretariat</i>
Step 4: Recording of protocol in REC database	<i>REC Secretariat</i>
Step 5: Determination of type of review	<i>REC Chair</i>
Step 6: Preparation of protocol review package	<i>REC Secretariat</i>
Step 7: Filing of protocol in protocol file folder	<i>REC Secretariat</i>
Step 8: Routing to appropriate review process	<i>REC Secretariat</i>
Step 9: Communication to researcher	<i>REC Secretariat</i>

6. Description of Procedures

Step 1. Submission of All Required Documents. The researchers shall be responsible for preparing and submitting complete, accurate documentation, to the Research Ethics Office (REO) including the research proposal, informed consent forms, and other required attachments, through email in between 8:00am to 5:00pm. They must ensure completeness and accuracy to avoid delays. The documents must be sent to the official email of REO, reo@evsu.edu.ph.

Step 2. Receipt and Completeness Check. The REC Secretariat shall receive the submission and check completeness of all required forms using the Protocol Package Checklist (**EVSU REC F-21**), and only accept the submission only if all required forms and documents are complete. The REC Secretariat shall also record the submission in the REC Protocol Submission Logbook, indicating: (1) Date received, (2) Title of protocol, (3) Researcher(s), and Institutional affiliation. Incomplete submissions shall be returned to the researcher without processing.

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Step 3. Assignment of Permanent Protocol Code. The REC Secretariat assigns a permanent protocol identification code to the submission package for tracking and future reference. Example coding format: EVSU-REC-2026-06; where EVSU-REC is Institution/Committee, 2026 is the Year received, and 06 is the Sequential Protocol Number. This code must appear on all documents and communications related to the protocol.

Step 4. Recording of Protocol in REC Database. The REC Secretariat logs the protocol into the EVSU-REC database with the assigned permanent protocol code. It must include: (1) Protocol code, (2) Protocol title, (3) Researcher(s), (4) Date received, and (5) Type of review (to be determined).

Step 5. Determination of Type of Review. The REC Chair determines whether the submission qualifies for an exempt, expedited, or full review, based on risk level, participant population, and study procedures.

Step 6. Preparation of Protocol Review Package. The REC Secretariat prepares the protocol review package, which includes the submitted documents, and distributes them to the assigned reviewers for evaluation.

Step 7. Filing of Protocol in Protocol File Folder. The REC Secretariat creates a Protocol File Folder using the Protocol File Index Form (**EVSU REC F-22**). Each protocol file shall contain: (1) Application for Protocol Review Form (**EVSU REC F-23**), (2) Protocol Package Checklist (**EVSU REC F-21**), (3) Submitted Research Protocol, (4) Supporting documents, (5) REC Communications, and (6) Review Reports. Files shall be labeled with the assigned protocol code and stored in the Active Protocol File Cabinet.

Step 8. Routing to Appropriate Review Process. Once complete, the protocol shall be routed to the appropriate review pathway: Exempt Review SOP, Expedited Review SOP, or Full Review SOP.

Step 9. Communication to Researcher. The REC Secretariat communicates the assigned review category using the Submission Acknowledgment and Routing Form (**EVSU REC F-24**) to the researcher.

7. Glossary

Initial Submission	–	First submission of a research protocol to the REC for ethical review.
Protocol Code	–	Unique identifier assigned to a research submission for tracking.

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- Protocol File** – Official REC record containing all documents related to a research protocol.
- Protocol Package** – Complete set of submitted research documents for ethical review.
- Protocol Submission Logbook** – Official record of protocol submissions received by the REC.
- Completeness Check** – Administrative verification that all required submission forms and documents are present.

8. Forms

FORM CODE	FORM TITLE
<i>EVSU REC F-21</i>	Protocol Package Checklist
<i>EVSU REC F-22</i>	Protocol File Index
<i>EVSU REC F-23</i>	Application for Protocol Review
<i>EVSU REC F-24</i>	Submission Acknowledgment and Routing Form

9. History of SOP

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01	May 2025	Arch. Charlotte B. Montañó	First draft of SOP
	April 2026	Dr. Cara Luz Buar	Policy Statement, Workflow/Description of Procedures, Forms

10. References

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		Effective Date:	08/17/26

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Prepared by:	Reviewed and approved by:	Approved by:
<i>Research Ethics Committee (REC)</i>	sgd.	sgd.
	GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	DENNIS C. DE PAZ, PhD <i>University President</i>

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	07 – Management of Resubmissions	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

1. Policy Statement

The REC shall require resubmission of a protocol when modifications are required based on the REC Decision Letter (Ethics Clearance). Resubmissions shall be submitted not later than twenty (20) working days after receipt of the Decision Letter (Ethics Clearance).

- A. Minor Modifications shall undergo Expedited Review (SOP 04B)
- B. Major Modifications shall undergo Full Review (SOP 05)

Only complete resubmissions shall be accepted for processing. Incomplete resubmissions shall be returned without review.

Resubmitted protocols shall retain the original protocol code and shall be tracked under the same protocol file.

2. Objective of the Activity

The activity aims to ensure that all required modifications identified during REC review are adequately addressed prior to approval, and that resubmissions undergo appropriate ethical review.

3. Scope

This SOP applies to the resubmission of revised or modified protocols that have been previously reviewed by the REC. The procedure begins with the receipt of the revised protocol documents. It ends with the filing of the documents in the protocol file and the entry of the submission in the protocol database.

4. Roles and Responsibilities

A. Researchers

- a. submits revised protocol addressing REC comments;
- b. ensures completeness of resubmission documents;
- c. provides clarifications when required.

B. REC Secretariat

- a. receives and records resubmissions in the protocol logbook;
- b. checks completeness of submitted documents;
- c. returns incomplete submissions;
- d. facilitates review and communication;

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- e. files and updates protocol records.

C. REC Chairperson

- assigns reviewers;
- determines appropriate review pathway;
- ensures consistency with prior REC decisions.

D. Assigned Reviewers

- evaluate resubmitted protocol against prior Decision Letter (Ethics Clearance) (**EVSU REC F-20**);
- determine adequacy of revisions;
- recommend appropriate decision.

5. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Receipt and logbook entry	<i>REC Secretariat</i>
Step 2: Assignment of primary reviewers	<i>REC Chair</i>
Step 3: Determination and confirmation of review pathway	<i>Assigned Reviewers / REC Chair</i>
Step 4: Review of the resubmission	<i>Assigned Reviewers</i>
Step 5: Communication of decision	<i>REC Secretariat</i>
Step 6: Filing of documents and database update	<i>REC Secretariat</i>

6. Description of Procedures

Step 1. Receipt and Logbook Entry. The REC Secretariat receives the revised protocol documents and records the submission in the Protocol Submission Logbook, including: (1) Protocol code, (2) Date received, (3) Title of study, and the (4) Name of researcher(s). The resubmitted protocol retains the original protocol code assigned during the initial submission. Protocol Resubmission Form (**EVSU REC F-25**) must be used upon resubmission of the protocol containing the comments and suggestions of the reviewers and how are these addressed by the researchers.

Step 2. Assignment of Primary Reviewers. The REC Chair assigns the Primary Reviewer and additional reviewers (if necessary) who participated in the initial review whenever possible.

Step 3. Determination of Review Pathway. The REC Chair confirms the appropriate review pathway and routes the resubmission to either: Expedited Review or Full Review.

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Step 4. Review of the Resubmission. The assigned reviewers evaluate the resubmitted protocol (**EVSU REC F-25**) by reviewing the required modifications from the previous review. The reviewers determine whether the requested revisions have been adequately addressed. Depending on the level of modification: Minor Modifications - Expedited Review (SOP 04B), and Major Modifications - Full Review (SOP 05).

Step 5. Communication of Decision. The REC Secretariat communicates the REC decision to the researcher through the Decision Letter (Ethics Clearance) (**EVSU REC F-20**).

Step 6. Filing of Documents and Database Update. The REC Secretariat compiles all documents related to the resubmission including: (1) Revised protocol, (2) Decision Letter (Ethics Clearance), (3) Reviewer assessment, and (4) Approval letter (if applicable). These documents are filed in the protocol folder and recorded in the protocol database.

7. Glossary

Resubmission	–	A revised research protocol submitted in response to recommendations made during the initial REC review.
Decision Letter (Ethics Clearance)	–	Official communication issued by the REC indicating the outcome of the review and required modifications.
Protocol Code	–	Unique identification number assigned to each protocol during initial submission.
Protocol Database	–	Electronic system used to track protocol status and study monitoring.
Logbook	–	Chronological record of incoming protocol documents maintained by the REC Secretariat.

8. Forms

FORM CODE	FORM TITLE
<i>EVSU REC F-25</i>	Protocol Resubmission Form

9. History of SOP

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NO.			
01	May 2025	Dr. Gerry B. De Cadiz	Frist draft of SOP
02	April 2026	Dr. Cara Luz Buar	Policy Statement, Workflow/Description of Procedures, Forms

10. References

- CIOMS. 2016. *International Ethical Guidelines for Health-related Research Involving Humans*.
- Philippine Health Research Ethics Board (PHREB). 2020. *2020 PHREB Standard Operating Procedures*.
- Philippine Health Research Ethics Board (PHREB). 2022. *National Ethical Guidelines for Research Involving Human Participants*.
- World Health Organization (WHO). 2011. *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants*.

Prepared by:	Reviewed and approved by:	Approved by:
Research Ethics Committee (REC)	sgd.	sgd.
	GILBERT ANTHONY O. ABAÑO, MAN, RN REC Chairperson	DENNIS C. DE PAZ, PhD University President

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	08 – Review of Progress Reports	Version No:	01-00
		Approval Date:	06/27/26
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1. Policy Statement

The EVSU Research Ethics Committee (EVSU-REC) shall require the submission of Progress Reports from the researcher during the implementation of the approved research protocol. The frequency of submission shall be explicitly stated in the Decision Letter (Ethics Clearance) (**EVSU REC F-20**), depending on the level of risk of the study. Typical reporting schedules include: (1) Bi-annually – for higher-risk studies, (2) Quarterly – for moderate-risk studies, and (3) Annual – for minimal-risk studies. The REC Secretariat will send a Reminder Letter (**EVSU REC F-26**) to the researchers, twenty (20) working days before the cutoff date, to remind them on the submission of progress reports.

The review of Progress Reports shall follow the initial type of review:

- A. Protocols initially reviewed through Expedited Review shall undergo Expedited Review for progress report evaluation.
- B. Protocols initially reviewed through Full Review shall undergo Full Review for progress report evaluation.

If the Progress Report reveals major modifications, safety concerns, or significant deviations, the protocol shall be elevated to Full Review.

Approved decisions during Expedited Review shall be reported in the next Full Review meeting for transparency and documentation.

2. Objective of the Activity

This activity aims to ensure that the conduct of the study is in compliance with the approved protocol and that the safety and welfare of study participant(s) are promoted.

3. Scope

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

4. Roles and Responsibilities

A. Researcher(s)

- a. submit Progress Reports according to the frequency stated in the Decision Letter (**EVSU REC F-20**).

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- b. provide accurate information regarding the status of the study.
- c. report any protocol deviations, amendments, or safety issues encountered during the study.

B. REC Chairperson

- a. determines whether the Progress Report will undergo Expedited Review or Full Review.
- b. assigns the Primary Reviewer(s) when applicable.
- c. finalize the committee decision based on reviewer recommendations.

C. Primary Reviewer(s)

- a. reviews the Progress Report in relation to the approved protocol.
- b. evaluates the implementation status of the research.
- c. recommends an appropriate decision regarding the continuation of the study.

D. REC Secretariat

- a. receives the Progress Report submissions.
- b. checks the Protocol Logbook and recording the submission.
- c. retrieves the relevant protocol file.
- d. notifies the REC Chair and assigned reviewers.
- e. communicates the REC decision to the researcher.
- f. files the Progress Report and updating the protocol database.

5. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Receipt and logbook entry of the Progress Report	<i>REC Secretariat</i>
Step 2: Retrieval of the protocol file	<i>REC Secretariat</i>
Step 3: Notification of REC Chair and Primary Reviewer(s)	<i>REC Secretariat</i>
Step 4: Determination of review type (Expedited or Full Review)	<i>REC Chair</i>
Step 5: Conduct of review of the Progress Report	<i>Primary Reviewer(s)</i>
Step 6: Communication of committee action	<i>REC Secretariat</i>
Step 7: Filing of documents and database update	<i>REC Secretariat</i>

6. Description of Procedures

Step 1. Receipt and Logbook Entry of the Progress Report. The REC Secretariat receives the submitted Progress Report Form (**EVSU REC F-27**), verifies

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completeness of submission, and records it in the Protocol Submission Logbook, ensuring that:

- A. The protocol code is verified.
- B. The date of submission is recorded.
- C. The type of report submitted is identified.
- D. The submission shall also be entered into the protocol database.
- E. Incomplete reports shall be returned without processing

Step 2. Retrieval of Protocol file. The REC Secretariat retrieves the previously approved protocol file, including: (1) Approved protocol documents, (2) Decision Letter (Ethics Clearance), (3) Previous review reports. The submitted Progress Report is added to the protocol file.

Step 3. Notification of REC Chair and Primary Reviewer. Within three (3) working days after receipt of the submission (cutoff date is every 15th of the month), the REC Secretariat shall notify the REC Chair, and the Primary Reviewers, or Independent Consultants (when applicable).

Step 4. Determination of type of reviews, expedited or full review. The REC Chair determines whether the Progress Report shall undergo Expedited Review (refer to SOP 04B – Expedited Review), or Full Review (refer to SOP 05 – Full Review). The decision is based on the initial review type, and whether significant issues are identified in the Progress Report.

Step 5. Conduct of Review of the Progress Report. The Primary Reviewer review the submitted Progress Report in relation to the approved research protocol, covering the following:

- A. Participant enrollment (accrual) and participant status.
- B. Progress of the research project, including percentage of completion relative to objectives.
- C. Protocol amendments introduced during implementation.
- D. Protocol deviations from the approved protocol.
- E. New safety information or literature affecting the risk-benefit assessment.
- F. Issues or problems encountered during the conduct of the study.
- G. Actions taken by the researcher to address these issues.
- H. If necessary, the Primary Reviewer may request clarification from the researcher through the REC Secretariat.
- I. The reviewer shall then recommend a decision regarding the continuation of the study.

Step 6. Communication of committee action. The REC Chair and/or Primary Reviewer has at most 10-15 working days to review prior to the review meeting and grant any of the applicable decision. Possible decisions include:

- A. approval (indicate frequency of progress reporting)

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- B. request for additional information or specific action(s) from the researcher(s)/proponent(s)
- C. suspension of the study
- D. termination of the study

Once a decision has been reached, the REC Chair informs the REC Secretariat about it within 2-3 working days from date of decision.

Following the process on communicating REC decisions found in SOP No. 22, the REC Secretariat communicates to the researcher(s) the decision within five (5) working days from the date of receipt from the REC Chair.

Step 7. Filing of Progress Report and Decision. The REC Secretariat files the following documents in the protocol folder: Progress Report Form, Review Evaluation, Decision Letter (Ethics Clearance), and the protocol database is updated accordingly.

7. Glossary

Progress Report	–	A report submitted by the researcher describing the progress of the study relative to the approved protocol.
Primary Reviewer(s)	–	REC member assigned to conduct detailed evaluation of submitted reports or protocols.
Independent Consultant	–	External expert invited to provide technical advice; non-voting.
Protocol Deviation	–	A departure from the approved protocol during study implementation.

8. Forms

FORM CODE	FORM TITLE
<i>EVSU REC F-26</i>	Reminder Letter
<i>EVSU REC F-27</i>	Progress Report Form

9. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
	May 2025	Dr. Brian John Sarno	First draft of SOP

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01	April 2026	Dr. Cara Luz Buar	Policy Statement, Workflow/Description of Procedures, Forms
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10. References

Eastern Visayas Health Research and Development Consortium-Ethics Review
 Committee Standard Operating Procedure (SOP) Manual version 4 2022
 National Ethical Guidelines for Health and Health-related Research 2022
 Philippine Health Research Ethics Board. 2022 *National Ethical Guidelines for
 Research Involving Human Participants 2022 NEGRIHP*
 Philippine Health Research Ethics Board. 2020 *PHREB Standard Operating
 Procedures Workbook 2020 PHREB SOP Workbook- PDF*
 Philippine Health Research Ethics Board Standard Operating Procedures 2020

Prepared by:	Reviewed and approved by:	Approved by:
<i>Research Ethics Committee (REC)</i>	sgd. GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	sgd. DENNIS C. DE PAZ, PhD <i>University President</i>

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1. Policy Statement

The EVSU Research Ethics Committee (EVSU-REC) shall require the submission of proposed protocol amendments for review and approval prior to their implementation. This requirement shall be clearly stated in the Decision Letter (Ethics Clearance).

Protocol amendments shall be reviewed according to their level of impact on the study:

- A. Minor amendments (e.g., typographical corrections, minor administrative updates, or changes not affecting participant safety) shall undergo Expedited Review.
- B. Major amendments (e.g., changes affecting study design, participant risk, eligibility criteria, or research procedures) shall undergo Full Review.

The review of protocol amendments shall be completed during the earliest Expedited Review meeting or the next scheduled Full Review meeting for amendments requiring full review.

Only complete amendment submissions shall be accepted for processing. Incomplete submissions shall be returned without review.

All amendment approvals conducted through Expedited Review shall be reported in the next Full Review meeting for transparency and documentation.

2. Objective of the Activity

This activity aims to ensure that any modification to an approved research protocol is reviewed and approved by the EVSU-REC prior to implementation, thereby safeguarding the rights, safety, and welfare of research participants.

3. Scope

This SOP applies to the management and review of protocol amendment(s) submitted by the researcher(s) while the study is on-going. This SOP begins with the receipt and logbook entry of amendment submissions and ends with filing of documents and updating of the protocol database.

4. Roles and Responsibilities

A. REC Secretariat

- a. acknowledge receipt of the report;

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- b. retrieve the Logbook of Protocols;
- c. notify the REC Chair;
- d. notify the identified primary reviewer(s);
- e. forward the protocol amendment documents to the assigned primary reviewer(s); and
- f. communicate to the researcher(s)/proponent(s) the result of the review.

B. The REC Chairperson

- a. determine the type of review: expedited or full review;
- b. review and grant decision on the submitted protocol; and
- c. inform the REC Staff about the decision.

C. The Primary Reviewer(s) review of protocol amendment(s).

5. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Receipt and logbook entry	<i>REC Secretariat</i>
Step 2: Retrieval of the protocol file	<i>REC Secretariat</i>
Step 3: Notification of REC Chair and Primary Reviewer(s)	<i>REC Secretariat</i>
Step 4: Determination of review type (Expedited or Full Review)	<i>REC Chair</i>
Step 5: Conduct of review of the Progress Report	<i>Primary Reviewers</i>
Step 6: Communication of committee action	<i>REC Secretariat</i>
Step 7: Filing of documents and database update	<i>REC Secretariat</i>

6. Description of Procedures

Step 1. Receipt and Logbook Entry. The REC Secretariat receives the Protocol Amendment Form (**EVSU REC F-28**) submission and records the following details in the Protocol Logbook: (1) Protocol code, (2) Date received, (3) Title of the protocol, (4) Researcher(s), and (5) Type of submission (amendment). The submission shall also be entered into the protocol database.

Step 2. Retrieval of protocol file. The REC Secretariat retrieves the approved protocol file, including the original protocol documents and Decision Letter (**EVSU REC F-20**). The submitted amendment documents are added to the protocol information package.

Step 3. Notification of REC Chair and Primary Reviewer: Within **three (3)** working days after receipt of the submission, the REC Secretariat forwards the protocol amendment package to the REC Chair.

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Step 4. Determination of Type of Review. In cases of Protocol Amendments, which need further review...

- A. The REC Chair determines the appropriate type of review, whether expedited or full review guided by the following criteria:
 - a. for Expedited Review: if the amendments introduced are minor in nature like typo errors or any minor administrative change or those that entail minimal risks
 - b. for Full Review: if the amendments introduced entail more than minimal risk or harm or those that include major changes in the protocol design, number of samples, increase or decrease in dose or exposure to risk/harm, changes in the inclusion/exclusion criteria, significant change in the number of subjects/participants
- B. The REC Chair forwards the protocol amendment(s) documents to the assigned primary reviewer(s).
- C. Accordingly, the assigned primary reviewers conduct the review based on applicable SOPs: SOP No. 04 for Expedited Review and SOP No. 05 for Full Review.
- D. The EVSU REC or the designated primary reviewers accomplish the Protocol Amendment(s) Assessment Form (**EVSU REC F-29**) to reflect their recommended action on the application.

Step 5. Conduct of Review. The Primary Reviewer evaluate the amendment by reviewing:

- A. The proposed amendment and justification
- B. The approved protocol
- C. Potential impact on participant safety
- D. Impact on the scientific integrity of the study
- E. The reviewer(s) document their assessment using the Protocol Amendment Assessment Form.

Possible recommendations include:

- A. Approval of the amendment
- B. Request for additional information
- C. Disapproval of the amendment

Step 6. Communication of Committee Decision. The REC Secretariat prepares the Decision Letter (**EVSU REC F-20**) and communicates the committee decision to the researcher within **five (5) working days** after receiving the final decision. If the amendment is approved, the researcher shall submit the revised protocol incorporating the approved amendment.

Step 7. Filing of Documents. The REC Secretariat files the following documents in the protocol folder:

- A. Amendment submission documents

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- B. Reviewer assessment forms
 - C. Decision letter (Ethics Clearance)
- The protocol database is updated accordingly.

7. Glossary

Protocol Amendment	Proposed modification to an approved research protocol.
Minor Amendment	Modification that does not affect participant safety or study risk.
Major Amendment	Modification that may affect study procedures, risk level, or participant protection.
Decision Letter (Ethics Clearance)	Official REC communication indicating the decision on the amendment.

8. Forms

FORM CODE	FORM TITLE
<i>EVSU REC F-28</i>	Protocol Amendment Form
<i>EVSU REC F-29</i>	Protocol Amendment Assessment Form
<i>EVSU REC F-20</i>	Decision Letter (Ethics Clearance)

9. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	May 2025	Dr. Brian John Sarno	First draft of SOP
	April 2026	Dr. Cara Luz Buar	Policy Statement, Workflow/Description of Procedures, Forms

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10. References

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- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). 2016. *Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)*.
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- UCI Office of Research. “Modifications to Approved Research.” Available in <https://www.research.uci.edu/compliance/human-research-protections/researchers/modifications-to-approved-research.html#Level>.
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- World Health Organization (WHO). 2011. *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants*.
- World Medical Association (WMA). 2013. *Declaration of Helsinki -Ethical Principles for Medical Research Involving Human Subjects*.

Prepared by:	Reviewed and approved by:	Approved by:
Research Ethics Committee (REC)	sgd. GILBERT ANTHONY O. ABAÑO, MAN, RN REC Chairperson	sgd. DENNIS C. DE PAZ, PhD University President

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	10 – Management of Protocol Deviation and Violations Report	Version No:	01-00
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1. Policy Statement

Protocol deviations and violations refer to non-compliance with the approved research protocol during the conduct of a study.

A protocol deviation refers to a minor or administrative departure from the approved protocol that does not significantly affect the safety and welfare of participants or the integrity of the research data.

A protocol violation refers to serious or significant non-compliance with the approved protocol that may affect participant safety, rights, welfare, or the scientific integrity of the study.

Protocol deviations and violations diminish the integrity of the research and may pose risks to the safety and well-being of research participants. They may also lead to legal or regulatory consequences whether the deviation or violation is intentional or accidental. Thus, researchers must report protocol deviations and violations occurring during the conduct of an approved research study.

Protocol deviations and violations are mainly classified into major and minor categories unless otherwise amended. Major deviations or violations shall undergo Full Review. Minor deviations or violations shall undergo Expedited Review by the original Primary Reviewers.

- A. The Researcher(s) shall document, explain, and report to the assigned reviewer any minor or major deviation or violation from the approved protocol. The report must be submitted not later than twenty (20) working days after the occurrence or discovery of the protocol deviation or violation.
- B. The Researcher(s) may implement a deviation from the approved protocol without prior EVSU-REC approval only when necessary to eliminate an immediate hazard to study participants. However, the deviation shall be reported to the EVSU-REC immediately or within five (5) working days, together with a written explanation of the reasons and corresponding corrective actions.
- C. Reporting of study protocol non-compliance shall be done through the submission of a Deviation/Non-Compliance/Violation Report, together with documents deemed necessary by the Researcher(s) to clarify the information indicated in the report. These documents constitute the study protocol non-compliance report package.
- D. Study protocol non-compliance report packages subject to Full Review, received within the cut-off period every 4th Monday of the preceding month, are forwarded to the Primary Reviewers and included in the agenda of the Full Review Meeting for discussion and decision.
- E. Study protocol non-compliance under Expedited Review shall be evaluated by

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the Primary Reviewers and the resolution shall be reported during the Full Review Meeting.

- F. The Primary Reviewers accomplish and return the signed Deviation/Non-Compliance/Violation Report to the REC Secretariat on the day of the REC meeting together with the study protocol non-compliance report package.
- G. Only complete reports shall be accepted for processing. Incomplete submissions shall be returned without review.
- H. All actions taken through Expedited Review shall be reported in the next Full Review meeting for transparency and documentation.
- I. Serious or continuing non-compliance may result in suspension or termination of the study.

2. Objective of the Activity

The purpose of this activity is to describe the EVSU-REC review procedures for protocol violation/deviation. Review of protocol deviations aims to ensure that the safety and welfare of human participants in the study are safeguarded and that the credibility and integrity data are maintained.

3. Scope

This SOP applies to the review of reports of protocol deviations or violations in the conduct of previously approved studies. This begins with the receipt and documentation of the report of protocol violations and deviations in the logbook and ends with the filing of all related documents and updating of the database.

This SOP provides instructions for taking and maintaining records of various type of protocol deviation of violations which include any of the following:

- a. Failure of the researcher/s to comply with the procedures in the approved protocol.
- b. Failure of researcher/s to comply with national/international guidelines for the conduct of human research, including those who fail to respond to the EVSU-REC requests.
- c. It also covers action taken by the EVSU-REC related to protocol violation/deviation reports submitted by the Researcher(s) related to any event at the site that is not in compliance with the previously approved protocols documents.

4. Roles and Responsibilities

A. Researcher(s)

- a. reports deviations/violations within required timeframe;
- b. provides complete documentation and justification;
- c. implements corrective actions as required.

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B. REC Secretariat

- receives and logs reports;
- checks completeness of submissions;
- retrieves protocol file;
- notifies REC Chair and reviewers;
- communicates REC decision;
- files documents and updates database.

C. REC Chairperson

- classifies deviation/violation (minor or major);
- determines appropriate review pathway;
- assigns Primary Reviewer(s);
- finalizes REC decision.

D. Primary Reviewer(s)

- evaluate deviation/violation report;
- assess impact on participant safety and study integrity;
- recommend corrective actions and decisions.

5. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Submission and receipt of report on protocol deviation or violation	<i>Researcher(s) & REC Secretariat</i>	<i>During the 20-day deadline</i>
Step 2: Retrieval of the approved protocol file	<i>REC Secretariat</i>	<i>Within 1-2 day/s</i>
Step 3: Notification of REC Chairperson and Primary Reviewers	<i>REC Secretariat</i>	<i>Within 1-3 day/s</i>
Step 4: Determination of the type of deviation and/or violation and review	<i>REC Chairperson, Primary Reviewers</i>	<i>Within 1-2 day/s</i>
Step 5: Setting of protocol deviation and violation report as an agenda in next regular meeting	<i>REC Chairperson, REC Secretariat</i>	<i>Within 1-2 day/s</i>
Step 6: Communication of Research Ethics Committee Decision	<i>REC Secretariat</i>	<i>1-2 day/s after the REC meeting</i>
Step 7: Filing of protocol-related documents and updating of the protocol database	<i>REC Secretariat</i>	<i>Within 2-3 days</i>
Note: <i>In cases that the preceding step fall during holidays and weekends, the subsequent step shall be observed in the coming weekdays.</i>		

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6. Description of Procedures

Step 1. Submission and receipt of report on protocol deviation or violation. The Researcher(s) submits Deviation/Non-Compliance/Violation Report (**EVSU REC F-30**) to the REC Secretariat together with the documentary attachments in relation to the research protocol.

Step 2. Retrieval of the approved protocol file. The REC Secretariat checks the compliance with the necessary documents and attachment and, thereafter retrieves the original protocol file.

Step 3. Notification of Chairperson and Primary Reviewers. The REC Secretariat notifies and sends in writing or email the protocol deviation or violation report together with the retrieved pertinent documents to the REC Chair and the Primary Reviewers within three (3) working days.

Step 4. Determination of the type of deviation and/or violation and review. The REC Chairperson shall initially classify the protocol deviations/violations whether as major or minor according to the following conditions:

- A. Minor deviation/violation are non-systematic protocol noncompliance with minor effects to the participant's safety and well-being, or integrity of the research which include but not limited to deviation from administrative protocol of the concerned research locale. All minor deviations require an Expedited Review by the previous Primary Reviewers.
- B. Major Deviation/Violation are significant protocol noncompliance in major activities or since the beginning of the study with actual or potential serious consequence on the data analysis procedure and place the subject's safety and well-being at risk either physical, psychological, cultural, and any other relevant changes that are detrimental to the person. All major violations require a Full Review.

Step 5. Setting of protocol deviation and violation report as an agenda in next regular meeting. The REC Chairperson shall set the report of protocol deviation and violation as an agenda in the next regular meeting. In the Expedited Reviews, the original primary reviewers shall evaluate the nature of minor deviation or violation and agree on a set of course of actions that the researcher should follow in lieu of the deviation or violation. In the Full Review, the original primary reviewers deliberate on the degree of non-compliance and take the appropriate action.

The REC can recommend any of the following:

- A. submission of additional information
- B. requesting any of corrective actions but not limited to:
 - a. invitation to a clarificatory interview
 - b. submission of an amended study protocol
 - c. deferment of the study until REC recommendations are implemented

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- d. withdrawal of ethical clearance due to repeated violation
- C. termination of the study on the basis of one or more of the following:
 - a. SAE reports indicate harm to participants
 - b. breach of a previously approved conduct of research
 - c. major changes, deviations or amendments of the approved protocol without approval by the REC
 - d. revision in the Informed Consent form without approval by the REC
 - e. Repeated violation
 - f. Fraud

Step 6. Communication of REC Decision. The REC Member-Secretary prepares the draft decision based on the report of the Expedited Review or Minutes of the Meeting in the Full Review. The REC Secretariat collates and files the retrieved protocol documents, the report on protocol deviation and violation, and the decision letter signed by the REC Chair in the appropriate protocol file and updates the protocol database with the relevant information.

The Researcher(s) is notified of the REC decision (**EVSU REC F-20**) on the study protocol noncompliance report. The REC may also issue the Receipt and Recommendation for Further Action (**EVSU REC F-31**) or may send a Letter for Clarificatory Interview (**EVSU REC F-32**), if needed.

For submissions under Full Review and Expedited Review, the REC decision will be sent to Researcher(s) within five (5) working days after the meeting.

The Researcher(s) may be requested to provide additional information, submit additional documents, or implement corrective action.

The Researcher(s) may file an appeal within twenty (20) working days after the official decision letter of the REC is sent.

Step 7. Filing of protocol-related documents and updating of the protocol database. The REC Secretary stores the signed study protocol deviation and violations report package in the study protocol file folder. Files are managed in accordance with SOP 30 on Management of Active Files (Administrative and Study Files).

7. Glossary

Protocol Deviation	Departure from the approved protocol that does not significantly affect participant safety or study integrity
Protocol Violation	Serious non-compliance with the approved protocol that may affect participant safety or research integrity
Non-Compliance	Failure to adhere to approved research procedures or ethical standards

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	10 – Management of Protocol Deviation and Violations Report	Version No:	01-00
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Corrective Action

Measures implemented to address protocol deviations or violations

8. Forms

<i>FORM CODE</i>	<i>FORM TITLE</i>
<i>EVSU REC F-30</i>	Deviation/Non-Compliance/Violation Report
<i>EVSU REC F-31</i>	Receipt and Recommendation for Further Action
<i>EVSU REC F-32</i>	Letter for Clarificatory Interview

9. History of SOP

<i>VERSION NO.</i>	<i>DATE</i>	<i>AUTHORS</i>	<i>MAIN CHANGE</i>
01	May 2025	Prof. Niñoval A. Pacaol	Initial Version

10. References

- Philippine Health Research Ethics Board. National Ethical Guidelines for Research Involving Human Participants (2022)
- Philippine Health Research Ethics Board. PHREB Standard Operating Procedures Workbook (2020)
- WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants

Prepared by:	Reviewed and approved by:	Approved by:
Research Ethics Committee (REC)	sgd. GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	sgd. DENNIS C. DE PAZ, PhD <i>University President</i>

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	11A – Review of Reportable Negative Events (RNE) Reports	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

1. Policy Statement

The EVSU-REC shall require the submission of Reportable Negative Event (RNE) reports **within three (3) working days** after the event has come to the attention of the researcher. A special meeting shall be considered depending on the level of the risk involved.

A Reportable Negative Event (RNE) refers to an adverse event or incident that may be classified by the REC as an unanticipated problem posing risks to participants or others. An event is considered reportable to the REC when it is probably or definitely related to participation in the research and occurs during the implementation of a research study that may affect:

- A. the safety and well-being of participants,
- B. the dignity of participants,
- C. the safety of the research team, or
- D. the integrity of the research data.

Such events must be reported by the Researcher(s) to ensure that the balance of risks and benefits of the study remains acceptable.

Only complete RNE reports shall be accepted for processing. Incomplete submissions shall be returned without review.

All actions taken through Expedited Review shall be reported in the next Full Review meeting for transparency and documentation.

2. Objective of the Activity

The review of RNE report aims to ensure the safety and welfare of human participants and the research team are safeguarded and the information on RNEs are properly documented and evaluated by the team.

3. Scope

This SOP applies to the review of RNE reports. The SOP begins with the receipt and documentation of submission of RNE report in the logbook/database and ends with the filing of all related documents and updating the protocol database by the REC Secretary.

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	11A – Review of Reportable Negative Events (RNE) Reports	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

4. Roles and Responsibilities

A. Researcher(s)

- report any Reportable Negative Event within three (3) working days after the event becomes known;
- submit the Report of Negative Event (RNE) together with supporting documentation;
- implement immediate measures necessary to protect research participants; and
- cooperate with the REC during review and providing additional information when requested.

B. REC Secretariat

- receive the RNE report (EVSU REC F-33) and recording the submission in the protocol logbook and protocol database;
- retrieve the relevant protocol file;
- forward the RNE report and related documents to the REC Chairperson;
- coordinate the scheduling and documentation of any special meeting;
- communicate the REC decision to the researcher and relevant institutional authority; and
- file the RNE report and related documents in the protocol file and updating the protocol database.

C. REC Chairperson

- review the RNE report upon notification;
- determine whether the reported event requires a special meeting or Full Review;
- preside over the meeting and guiding the deliberation of the REC members; and
- confirm the committee's final decision regarding the RNE report.

D. REC Members

- review the RNE report and related documents;
- evaluate the risks posed by the event to research participants and study personnel; and
- recommend appropriate actions to address the reported event.

5. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Receipt and documentation of RNE report submission	REC Secretariat	Within 3 days after the event occurred

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	11A – Review of Reportable Negative Events (RNE) Reports	Version No:	01-00
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		Effective Date:	08/17/26

Step 2: Retrieval of pertinent protocol file	<i>REC Secretariat</i>	<i>Within 1-2 day/s</i>
Step 3: Notification of REC Chairperson	<i>REC Secretariat</i>	<i>Within 1-3 day/s</i>
Step 4: Call for a special meeting (if necessary)	<i>REC Chairperson</i>	<i>Within 1-2 day/s</i>
Step 5: Conduct of the special meeting	<i>REC Members</i>	<i>Within 1-3 day/s</i>
Step 6: Communication of REC action to the researcher and institutional authority	<i>REC Chairperson / REC Secretariat</i>	<i>1-2 day/s after the REC meeting</i>
Step 7: Filing of documents and updating of the protocol database	<i>REC Secretariat</i>	<i>Within 2-3 days</i>

6. Description of Procedures

Step 1. Receipt and documentation of RNE report submission. The REC Secretariat receives the accomplished Reportable Negative Event (RNE) report (**EVSU REC F-33**) and records the submission in the protocol logbook. The Secretariat verifies whether the report was submitted within the required three (3)-day reporting period.

Step 2. Retrieval of pertinent protocol file. The REC Secretariat retrieves the approved protocol file and verifies the identity of the assigned primary reviewers and other relevant study documents.

Step 3. Notification of REC Chairperson. The REC Secretariat forwards the RNE report and relevant documents to the REC Chairperson for review.

Step 4. Call for a special meeting. If the reported event involves significant risk, the REC Chairperson may convene a special meeting of the REC. The REC Secretariat prepares the meeting documents and may invite the Researcher(s) for a clarificatory meeting through a letter for clarificatory interview (**EVSU REC F-32**).

Step 5. Conduct of the special meeting. During the meeting, the REC Chairperson presents the details of the RNE report and leads the discussion among REC members. The committee evaluates:

- A. risks to participants or research personnel,
- B. adequacy of actions taken to address the event,
- C. impact on research data integrity, and
- D. implications for continuation of the study.

Possible REC actions include:

- A. suspension of the study until the risk is addressed;

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- B. withdrawal of ethical clearance;
- C. submission of a risk mitigation or corrective action plan;
- D. submission of an amendment to the approved protocol.

Step 6. Communication of REC action to the researcher and to the institutional authority. The decision of the REC is communicated to the Researcher(s) by sending the decision letter (**EVSU REC F-20**) and relevant institutional authority within **five (5) working days** after the final deliberation.

Step 7. Filing of all related documents and updating of the protocol database: The REC Secretariat records the decision and files all related documents in the protocol file folder, including: RNE report, meeting documentation, decision letter, and related correspondence. The protocol database is updated accordingly.

7. Glossary

Reportable Negative Event (RNE)	Event related to research posing risk to participants or others.
Unanticipated Problem	Event not previously expected that affects risk-benefit balance.
Corrective Action	Measures taken to address identified risk or issue.
Special Meeting	REC meeting convened for urgent review.

8. Forms

FORM CODE	FORM TITLE
<i>EVSU REC F-32</i>	Letter for Clarificatory Interview
<i>EVSU REC F-33</i>	Reportable Negative Event (RNE) Report
<i>EVSU REC F-20</i>	Decision Letter

9. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	May 2025	Dr. Jeffry V. Ocay	Initial version

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	11A – Review of Reportable Negative Events (RNE) Reports	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

10. References

- Eastern Visayas Health Research and Development Consortium (EVHRDC) SOP Manual (2022)
- Leyte Normal University REC SOP Manual (2023)
- Philippine Health Research Ethics Board. National Ethical Guidelines for Research Involving Human Participants (2022)
- Philippine Health Research Ethics Board. PHREB Standard Operating Procedures (2020)

Prepared by:	Reviewed and approved by:	Approved by:
<i>Research Ethics Committee (REC)</i>	sgd.	sgd.
	GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	DENNIS C. DE PAZ, PhD <i>University President</i>

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	11B – Review of SAEs and SUSARs Reports	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

1. Policy Statement

Serious Adverse Events (**SAEs**) and Suspected Unexpected Serious Adverse Reactions (**SUSARs**) are critical safety concerns that may arise during the conduct of clinical trials and other research involving human participants. Monitoring and reviewing such events is an essential function of the Research Ethics Committee (REC) to ensure the protection of research participants and the ethical conduct of research. The REC shall require the submission of reports of SAEs and SUSARs **within fifteen (15) working days** after the event has come to the attention of the researcher

In sponsored clinical trials, the study sponsor is responsible for collecting and reporting SAE and SUSAR information from all participating study sites. These reports are forwarded to the Lead Researcher, who then submits them to the institutional Research Ethics Committee (REC).

The EVSU-REC shall review SAE and SUSAR reports to determine whether the reported events affect the risk-benefit balance of the study and whether appropriate actions are required.

Only complete SAE/SUSAR reports shall be accepted for processing. Incomplete submissions shall be returned without review.

The REC Chair shall determine the urgency and appropriate review pathway. Urgent cases may require immediate action or a special meeting.

All SAE/SUSAR reports and actions taken shall be reported in the next Full Review meeting for transparency and documentation.

2. Objective of the Activity

The objective of reviewing SAE and SUSAR reports is to safeguard the safety, rights, and well-being of human research participants; ensure that SAE and SUSAR information is properly documented, evaluated, and acted upon; and determine whether modifications to the research protocol or study procedures are necessary.

3. Scope

This SOP applies to the review of Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARs) reported during the implementation of clinical trials or other applicable research studies. The procedure begins with the receipt and documentation of SAE/SUSAR reports and ends with the communication

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	11B – Review of SAEs and SUSARs Reports	Version No:	01-00
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of REC decisions and filing of documents in the protocol database and active protocol files.

4. Roles and Responsibilities

A. Researcher(s)

- report SAE and SUSAR events to the REC in accordance with regulatory timelines;
- submit the SAE/SUSAR report and supporting documentation;
- provide clarifications and additional information requested by the REC.

B. Sponsor (for sponsored clinical trials)

- collect safety information from participating study sites;
- forward SAE/SUSAR reports to researcher/s and regulatory authorities when required.

C. REC Secretariat

- receive SAE/SUSAR reports;
- record the submission in the protocol logbook and protocol database;
- retrieve the relevant protocol file;
- notify the REC Chair;
- forward the report to the SAE Subcommittee or designated reviewers;
- prepare documents for REC review and meetings;
- file all related documents and updating the protocol database.

D. REC Chairperson

- determine the urgency and appropriate review pathway for the SAE/SUSAR report;
- refer the report to the SAE Subcommittee or designated reviewers when applicable;
- convene a REC meeting if required;
- confirm the REC decision.

E. SAE Subcommittee / Designated Reviewer(s)

- review SAE/SUSAR reports;
- evaluate the seriousness, causality, and implications of the event;
- recommend appropriate actions to the REC.

5. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Receiving and recording SAE/SUSAR report submission	<i>REC Secretariat</i>
Step 2: Retrieval of relevant protocol file	<i>REC Secretariat</i>

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Step 3: Notification of REC Chair	<i>REC Secretariat</i>
Step 4: Submission of report to SAE Subcommittee / designated reviewers	<i>REC Secretariat</i>
Step 5: Inclusion of SAE/SUSAR report in REC meeting agenda	<i>REC Secretariat</i>
Step 6: Communication of REC decision to the Researcher/s	<i>REC Secretariat / REC Chair</i>
Step 7: Filing of documents and updating protocol database	<i>REC Secretariat</i>

6. Description of Procedure

Step 1. Receipt and Documentation of SAE/SUSAR Report. The REC Secretariat receives the completed SAE/SUSAR report form (**EVSU REC F-34**) and records the submission in the protocol logbook and protocol database, noting the date of submission and whether the report was submitted within the required reporting timeline.

Step 2. Retrieval of Pertinent Protocol File. The REC Secretariat retrieves the relevant protocol file and related documents, including: protocol information, researcher details, previous SAE/SUSAR reports, reviewer assignments.

Step 3. Notification of REC Chair. The REC Secretariat notifies the REC Chairperson regarding the receipt of the SAE/SUSAR report and forwards the retrieved documents for preliminary review.

Step 4. Submission to SAE Subcommittee or Designated Reviewer. The REC Secretariat forwards the SAE/SUSAR report and related documents to the SAE Subcommittee or designated reviewer(s) for evaluation prior to the REC meeting.

Step 5. Inclusion in REC Meeting Agenda. The SAE Subcommittee's report in the Evaluation of SAE/SUSAR Report Form (**EVSU REC F-35**) and recommendations are included in the agenda of the next REC meeting for discussion and decision.

Possible actions of the REC may include:

- A. requesting additional information from the investigator or sponsor;
- B. requiring protocol amendments;
- C. suspending recruitment or study procedures;
- D. suspending or terminating the study if necessary.

Step 6. Communication of REC Decision. The REC Secretariat communicates the REC's decision and recommendations (**EVSU REC F-20**) to the Researcher(s) in accordance with the SOP on communication of REC decisions.

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Step 7. Filing and Documentation. The REC Secretariat files all related documents in the Active Protocol Files and updates the protocol database.

7. Glossary

Serious Adverse Event (SAE)	–	Any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, results in congenital anomaly or birth defect, or requires intervention to prevent permanent impairment or damage.
Suspected Unexpected Serious Adverse Reaction (SUSAR)	–	A serious adverse reaction that is both unexpected and suspected to be related to the investigational product or research intervention, and whose nature or severity is not consistent with the available safety information (e.g., Investigator's Brochure or product label).
Lead Researcher	–	The individual responsible for the overall conduct, implementation, and reporting of a research study at a specific study site.
Researcher-Initiated Studies	–	Research studies conceptualized and conducted by an investigator or group of investigators, which may or may not receive external funding support.
Sponsor	–	An individual, company, institution, or organization responsible for initiating, managing, and financing a clinical trial.
SAE Subcommittee	–	A group of REC members or designated experts assigned by the REC to review Serious Adverse Events and Suspected Unexpected Serious Adverse Reactions and provide recommendations to the REC.

8. Forms

FORM CODE	FORM TITLE
<i>EVSU REC F-34</i>	SAE/SUSAR report form
<i>EVSU REC F-35</i>	Evaluation of SAE/SUSAR Report Form
<i>EVSU REC F-20</i>	Decision Letter

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	11B – Review of SAEs and SUSARs Reports	Version No:	01-00
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9. History of SOP

<i>VERSION NO.</i>	<i>DATE</i>	<i>AUTHORS</i>	<i>MAIN CHANGE</i>
01	May 2025	Prof. Gilbert Anthony O. Abaño	Initial Version

10. References

ICH-GCP Guideline E2A
 Philippine FDA Guidelines on Safety Reporting
 National Ethical Guidelines for Health and Health-Related Research (NEGRIHP 2022)
 PHREB Standard Operating Procedures (2020) Philippine Health Research Ethics Board. PHREB Standard Operating Procedures (2020)

Prepared by:	Reviewed and approved by:	Approved by:
<i>Research Ethics Committee (REC)</i>	sgd. GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	sgd. DENNIS C. DE PAZ, PhD <i>University President</i>

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	12 – Management of Application for Continuing Review	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

1. Policy Statement

The EVSU Research Ethics Committee (EVSU-REC) shall require the submission of an Application for Continuing Review **at least 40 working days prior to the expiration** of the protocol's ethical clearance.

Protocols that are still active or ongoing must undergo continuing review to ensure that the safety, rights, and well-being of research participants are protected, and that the research is conducted in accordance with the approved protocol.

Applications for continuing review shall undergo Expedited Review, unless issues identified during the review require Full Review.

Only complete applications for continuing review shall be accepted for processing. Incomplete submissions shall be returned without review.

All actions taken through Expedited Review shall be reported in the next Full Board meeting for transparency and documentation.

Failure to submit continuing review prior to expiration shall result in automatic suspension of study activities until REC approval is renewed.

2. Objective of the Activity

The activity aims to ensure that the study is conducted in an accordance with approved protocol, that the safety and well-being of study participants are promoted and that the integrity of the data is protected from the initial ethical clearance until the end of the study.

3. Scope

This SOP governs the processing of an application for continuing review submitted by a proponent whose research study is still ongoing but whose ethical clearance is about to expire. The procedure begins with the receipt of the application for continuing review and ends with the documentation and filing of the REC decision and updating of the protocol database.

4. Roles and Responsibilities

A. Researcher(s)

- a. submit the Application for Continuing Review before the expiration of ethical clearance;

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- b. provide accurate information regarding the progress of the study;
- c. submit required reports including:
 - i. progress reports
 - ii. protocol deviations/violations
 - iii. reportable negative events
 - iv. SAE/SUSAR reports if applicable.

B. REC Secretariat

- a. send a reminder letter to the researcher(s) (EVSU REC F-26);
- b. receive the application for continuing review (EVSU REC F-36);
- c. record the submission in the protocol logbook and database;
- d. retrieve the protocol file and related reports;
- e. notify the REC Chair and assigned reviewers;
- f. prepare documents for review;
- g. file documents and updating the protocol database.

C. REC Chairperson

- a. determine the appropriate review pathway (expedited or full board);
- b. assign Primary Reviewers when necessary;
- c. confirm the final REC decision.

D. Primary Reviewer(s)

- a. evaluate the continuing review application;
- b. review study progress and safety reports;
- c. recommend appropriate actions to the REC.

5. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Receipt of the application for continuing review and entry into logbook	<i>REC Secretariat</i>
Step 2: Retrieval of pertinent protocol files	<i>REC Secretariat</i>
Step 3: Notification of REC Chair and Primary Reviewers	<i>REC Secretariat</i>
Step 4: Determination of type of review (Expedited Review or Full Board Review)	<i>REC Chair</i>
Step 5: Conduct of Review	<i>Primary Reviewers</i>
Step 6: Communication of committee action (REC decision)	<i>REC Secretariat</i>
Step 7: Filing of documents and updating of protocol database	<i>REC Secretariat</i>

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	12 – Management of Application for Continuing Review	Version No:	01-00
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		Effective Date:	08/17/26

6. Description of Procedure

Step 1. Receipt of the Application for Continuing Review and entry into logbook.

After sending a Reminder Letter (**EVSU REC F-26**) to the researcher(s), the REC Secretariat receives the Application for Continuing Review (**EVSU REC F-36**) and records the submission in the protocol logbook and database.

Step 2. Retrieval of Pertinent Protocol Files. The REC Secretariat retrieves the approved protocol file and compiles relevant documents including:

- i. progress reports
- ii. protocol deviation/violation reports
- iii. Reportable Negative Events (RNEs)
- iv. SAE/SUSAR reports.

Step 3. Notification of REC Chair and Primary Reviewers. The REC Secretariat informs the REC Chair and Primary Reviewers regarding the application and forwards the relevant documents for review.

Step 4. Determination of Review Type. The REC Chair determines the appropriate review pathway. Continuing review applications shall normally undergo Expedited Review.

However, Full Board Review may be required when:

- i. serious safety issues are reported,
- ii. significant protocol deviations occurred,
- iii. major amendments are proposed.

Step 5. Conduct of Review. The Primary Reviewer(s) conduct their review and report to the REC Chair their decision on the application for continuing review.

Step 6. Communication of Committee Action. The REC Secretariat prepares the REC Decision Letter (**EVSU REC F-20**) based on the recommendations of the reviewers or the REC meeting.

Possible decisions include:

- i. approval for continuation of the study
- ii. request for additional information
- iii. suspension of the study
- iv. disapproval of continuing review.

Step 7. Filing of Documents. All relevant documents including the continuing review application, reviewer recommendations, and decision letter shall be filed in the protocol folder, and the protocol database shall be updated.

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		Effective Date:	08/17/26

7. Glossary

Continuing Review	– Periodic review conducted by the REC to ensure that an approved research study continues to meet ethical standards during its implementation.
Researcher(s)	– The individual(s) responsible for the overall conduct of a research study.
Expedited Review	– A review procedure used for research involving minimal risk or minor protocol changes.
Full Board Review	– Review conducted during a convened REC meeting with quorum.
Researcher-Initiated Study	– A study conceptualized and conducted by a researcher or research team.

8. Forms

FORM CODE	FORM TITLE
<i>EVSU REC F-36</i>	Application for Continuing Review
<i>EVSU REC F-26</i>	Reminder Letter
<i>EVSU REC F-20</i>	Decision Letter (Ethics Clearance)

9. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	May 2025	Dr. Mary Jean P. Yanger	First Draft of SOP
	April 2026	Dr. Cara Luz Buar	Revised Policy Statement, Workflow/Description of Procedures, Forms

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	12 – Management of Application for Continuing Review	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

10. 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 (2017/2022 update)
- Philippine Health Research Ethics Board Standard Operating Procedures (2020)

Prepared by:	Reviewed and approved by:	Approved by:
Research Ethics Committee (REC)	sgd. GILBERT ANTHONY O. ABAÑO, MAN, RN REC Chairperson	sgd. DENNIS C. DE PAZ, PhD University President

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	13 – Review of Final Report	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

1. Policy Statement

The EVSU Research Ethics Committee (EVSU-REC) shall require the submission of the Final Report not later than twenty (20) working days after completion of the study.

For EVSU-initiated protocols, the end of the study refers to the date of dissemination of the final report by the unit. For non-EVSU-initiated protocols, it shall be based on the approved study timeline (e.g., Gantt Chart) submitted by the Researcher(s).

The review pathway shall not be automatic and shall be determined by the REC Chair based on risk, compliance, and ethical issues.

Only complete Final Reports shall be accepted for processing. Incomplete submissions shall be returned without review.

Submission and review of the Final Report signify the completion of the study and closure of REC oversight.

2. Objective of the Activity

This activity primarily aims to ensure that the conduct of the study was in compliance with the approved protocol and that the safety and welfare of study participants were promoted and the integrity of data protected until the end of the study.

3. Scope

This policy applies to the management and review of final report submitted by the investigators at the end of the study. This SOP begins with the receipt and entry of the final report into the logbook and ends with an update of the protocol database.

4. Roles and Responsibilities

A. Researcher(s)

- submitting the Final Report within twenty (20) working days after study completion;
- ensuring that the report accurately reflects study conduct and outcomes;
- submitting required supporting documents (e.g., approval sheets for theses/dissertations);
- responding to REC requests for clarification.

B. REC Secretariat

- receiving the Final Report and recording it in the protocol logbook and database;

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- b. retrieving the relevant protocol file;
- c. notifying the REC Chair and Primary Reviewers;
- d. preparing documents for review;
- e. communicating REC decisions;
- f. filing documents and updating the protocol database.

C. REC Chairperson

- a. determining the appropriate review pathway (Expedited or Full Board);
- b. ensuring proper review of the Final Report;
- c. confirming and signing the REC decision.

D. Primary Reviewer(s)

- a. reviewing the Final Report in relation to the approved protocol;
- b. evaluating whether the study complied with REC approvals;
- c. recommending appropriate action.

5. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Receipt of final report and entry into logbook	<i>REC Secretariat</i>
Step 2: Retrieval of pertinent protocol file	<i>REC Secretariat</i>
Step 3: Notification of REC Chair and Primary Reviewers	<i>REC Secretariat</i>
Step 4: Determination and conduct of review (Expedited or Full Review)	<i>REC Chair / Primary Reviewers</i>
Step 5: Communication of committee action	<i>REC Secretariat / REC Chair</i>
Step 6: Filing of documents and updating of protocol database	<i>REC Secretariat</i>

6. Description of Procedure

Step 1. Receipt of final report and entry into logbook. The REC Secretariat receives and enters the date of receipt of the Final Report Form (**EVSU REC F-37**) in the logbook. For thesis and dissertations, the Final Report will only be accepted when submitted together with a certification of approval/Approval Sheet and/or clearance from the Department's Research and Technical Review Committee/ or Panel of Examiners.

Step 2. Retrieval of pertinent protocol file: The REC Secretary retrieves the corresponding protocol file as reference in the review of the final report.

Step 3. Notification of REC Chair and Primary Reviewers: The REC Secretary notifies the REC Chairperson and the Primary Reviewers regarding the submission

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and the summary of the reports submitted and decisions made during the period of effectively of initial ethical clearance.

Step 4. Determination and Conduct of Review

The REC Chair determines the appropriate review pathway based on:

- i. nature of the study (student, faculty, researcher or sponsored);
- ii. level of risk;
- iii. presence of deviations, violations, or safety concerns.

Expedited Review:

- i. Typically applied to student research and minimal-risk studies.
- ii. Conducted by Primary Reviewers
- iii. Confirms compliance with the approved protocol
- iv. Recommends approval if no issues are identified

Full Review:

- i. Typically applied to faculty research, externally funded, or higher-risk studies.
- ii. Conducted during a convened REC meeting
- iii. Required when:
 - a. deviations or violations are identified;
 - b. safety concerns exist;
 - c. ethical issues remain unresolved

Primary Reviewer(s) may recommend:

- i. Approval of Final Report
- ii. Request for clarification
- iii. Submission of deviation/violation report
- iv. Elevation to Full Board Review

Step 5. Communication of committee action. The REC Chairperson finalizes the decision and signs the Decision Letter (**EVSU REC F-20**) forwarded by the REC Secretariat to the Researcher(s) within five (5) working days after final decision.

Step 6. Filing of Documents and Updating of Protocol Database. The REC Secretariat files the Final Report (**EVSU REC F-37**) and related documents including reviewer recommendations and decision letter in the appropriate folder and updates the protocol database.

7. Glossary

Final Report

A comprehensive report submitted by the researcher at the completion of the study.

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Study Completion	The point at which all study procedures and participant involvement have ended.
Expedited Review	Review conducted by designated REC reviewers for minimal-risk research.
Full Board Review	Review conducted during a convened REC meeting with quorum.
Protocol Closure	Formal completion of REC oversight after acceptance of the Final Report.

8. Forms

FORM CODE	FORM TITLE
<i>EVSU REC F-37</i>	Final Report Form
<i>EVSU REC F-20</i>	Decision Letter

9. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	May 2025	Prof. Christopher Bacungan	First Draft of SOP
	April 2026	Dr. Cara Luz Buar	Revised Policy Statement, Workflow/Description of Procedures, Forms

10. References

- EVHRDC (2022). Eastern Visayas Health Research and Development Consortium- Ethics Review Committee Standard Operating Procedure (SOP) Manual
- LNU (2023). Leyte Normal University Research Ethics Review Committee SOP Manual
- PHREB (2022). National Ethical Guidelines for Research Involving Human Participants.
- PHREB (2020). Philippine Health Research Ethics Board Standard Operating Procedures.

Prepared by:	Reviewed and approved by:	Approved by:
<i>Research Ethics Committee (REC)</i>	sgd. GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	sgd. DENNIS C. DE PAZ, PhD <i>University President</i>

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	14 – Review of Early Termination Report	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

1. Policy Statement

The EVSU REC shall require submission of an early termination report when the researcher(s), or sponsor decides to end the implementation of a study before its completion to ensure the adequate protection and welfare of study participants that have already been recruited. The researcher(s) shall submit a written and detailed explanation of the early termination. Early termination reports shall be reviewed and the appropriate course of action shall be agreed upon by the REC, based on the nature of the termination, risks to participants, and compliance with REC approvals. REC shall not approve deletion of official protocol records to ensure compliance with regulatory, audit, and documentation requirements. When justified, the REC may approve alternative measures such as anonymization, restricted access, or secure archiving.

Only complete reports shall be accepted. Incomplete submissions shall be returned.

The REC Chair shall determine whether review shall be Expedited or Full Board based on risk and issues identified.

2. Objective of the Activity

This activity aims to ensure that the conduct of the study is in compliance with the approved protocol and that the safety and welfare of study participant(s) are promoted.

3. Scope

This SOP applies to the management and review of early termination reports submitted by the researcher(s)/proponent(s) while the study is on-going or has ended. This SOP begins with the receipt and entry to the logbook and database of the early termination report and ends with the communication of committee action.

4. Roles and Responsibilities

A. Researcher(s)

- submit the Early Termination Report with complete justification;
- ensure that participant safety measures are implemented upon termination;
- provide additional information when requested by the REC.

B. REC Secretariat

- receiving the report and recording it in the protocol logbook and database;
- retrieving the protocol file;
- notifying the REC Chair and Primary Reviewers;

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- d. communicating REC decisions;
- e. filing documents and updating the protocol database.

C. REC Chairperson

- a. reviewing the Early Termination Report upon notification;
- b. determining the appropriate level of review and action;
- c. coordinating with Primary Reviewers;
- d. confirming the final REC decision.

D. Primary Reviewer(s)

- a. evaluating the Early Termination Report;
- b. assessing implications for participant safety and data integrity;
- c. recommending appropriate actions.

5. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Receipt and entry into logbook of Early Termination Report	<i>REC Secretariat</i>
Step 2: Retrieval of pertinent protocol file	<i>REC Secretariat</i>
Step 3: Notification of REC Chair and Primary Reviewers	<i>REC Secretariat</i>
Step 4: Review and determination of appropriate action	<i>REC Chair / Primary Reviewers</i>
Step 5: Communication of committee action	<i>REC Secretariat</i>

6. Description of Procedure

Step 1. Receipt and entry into logbook of Early Termination Report. The REC Secretariat acknowledges receipt of the Early Termination Report Form (**EVSU REC F-38**) by indicating the date on the duplicate copy of the report submitted.

Step 2. Retrieval of pertinent protocol file. The REC Secretariat retrieves the previously approved protocol package, then adds to the protocol information package the early termination report for review.

Step 3. Notification of REC Chair and Primary Reviewers. The REC Secretariat notifies the REC Chair, within two (2) working days after the receipt of the aforementioned submissions. Then, the REC Chair informs the Primary Reviewer(s), of the submissions, at most, two (2) working days after the receipt of the documents.

Step 4. Review and determination of appropriate action. The REC Chair and Primary Reviewer(s) evaluate the Early Termination Report, considering:

- A. reasons for early termination;

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- B. risks to participants;
- C. actions taken to protect participants;
- D. compliance with REC approvals.

The REC shall determine and agree upon appropriate actions, which may include:

- A. Acceptance of the Early Termination Report
- B. Request for clarification or additional information
- C. Requirement for corrective actions
- D. Referral to other relevant SOPs (e.g., deviations, SAE, or RNE) if applicable

Step 5. Communication of committee action. The REC Chair and/or Primary Reviewer review(s) grant any of the applicable decision option within ten (10) working days after receipt of the document: (a) acceptance of report and (b) require submission of report with corrections. Once a decision has been reached, the REC Chair informs the REC Secretariat about it within one (1) working day from date of decision (**EVSU REC F-20**). Following the process on communicating REC decisions, the REC Secretary communicates to the researcher(s) the decision within five (5) working days from date of receipt from the REC Chair.

7. Glossary

Early Termination	–	Premature discontinuation of a research study before its planned completion.
Early Termination Report	–	A report submitted by the researcher explaining the reasons and circumstances for ending a study early.
Researcher	–	The individual responsible for the conduct of the study.
Protocol Closure	–	Formal conclusion of REC oversight of a study.

8. Forms

FORM CODE	FORM TITLE
<i>EVSU REC F-38</i>	Early Termination Report Form
<i>EVSU REC F-20</i>	Decision Letter (Ethics Clearance)

9. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	May 2025	Prof. Christopher Bacungan	First Draft of SOP
	April 2026	Dr. Cara Luz Buar	Revised Policy Statement, Workflow/Description of Procedures, Forms

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
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		Approval Date:	06/27/26
		Effective Date:	08/17/26

10. References

- EVHRDC (2022). Eastern Visayas Health Research and Development Consortium- Ethics Review Committee Standard Operating Procedure (SOP) Manual
- PHREB (2022). National Ethical Guidelines for Research Involving Human Participants.
- PHREB (2020). Philippine Health Research Ethics Board Standard Operating Procedures.
- USC (2022). University of San Carlos Research Ethics Review Committee SOP Manual.

Prepared by:	Reviewed and approved by:	Approved by:
Research Ethics Committee (REC)	sgd. GILBERT ANTHONY O. ABAÑO, MAN, RN REC Chairperson	sgd. DENNIS C. DE PAZ, PhD University President

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	15 – Management of Appeals	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

1. Policy Statement

An appeal is any request by researcher(s) or, by extension, by sponsors and/or funding agencies, for reconsideration of the REC's decision or recommendation with regard the protocol or related documents. The admission of appeals in the observance of research ethics reflects the open-mindedness of REC members and their adherence to the principles of transparency, fairness, and due process.

The REC shall consider the perspective of the researcher regarding the feasibility and acceptability of REC recommendations including its disapproval.

All appeals shall undergo Full Review (REC en banc) to ensure independent, fair, and comprehensive evaluation.

Appeals must be submitted using the official REC Appeal Form, together with a written justification and supporting documents.

Only complete appeal submissions shall be accepted.

Members with conflict of interest shall inhibit from deliberation and voting.

2. Objective of the Activity

The objective specifies the intended outcome/s of management of appeals. Management of appeals ensures fairness, transparency and comprehensiveness of ethics review that takes into consideration the perspective of the researcher.

3. Scope

The SOP on Management of Appeals covers procedures that begin with the receipt of the appeal and ends with communicating the committee's action to the researcher and updating of the protocol.

4. Roles and Responsibilities

A. Researcher(s)

- submit a duly accomplished Appeal Form (EVSU REC F-39);
- provide a written justification and supporting documents;
- respond to clarifications requested by the REC.

B. REC Secretariat

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- receive the appeal and verifying completeness of documents;
- record the appeal in the protocol logbook and database;
- retrieve the protocol file;
- notify the REC Chair and members;
- prepare documents for Full review;
- communicate the REC decision;
- file documents and updating the protocol database.

C. REC Chairperson

- ensure that the appeal is included in the Full Review meeting agenda;
- facilitate fair and unbiased deliberation;
- ensure that conflicted members inhibit from discussion and voting;
- confirm and sign the final REC decision.

D. REC Members

- review the appeal independently;
- participate in deliberation during the Full Review meeting;
- decide on the appeal through consensus or voting.

5. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Receipt of appeal and logbook entry	<i>REC Secretariat</i>
Step 2: Retrieval of pertinent protocol file	<i>REC Secretariat</i>
Step 3: Notification of REC Chair and members	<i>REC Secretariat</i>
Step 4: Inclusion in Full Review Agenda	<i>REC Chair</i>
Step 5: Full Review deliberation	<i>REC Chair / REC Members</i>
Step 6: Communication of committee action	<i>REC Secretariat</i>
Step 7: Filing of documents and updating of protocol database	<i>REC Secretariat</i>

6. Description of Procedure

Step 1. Receipt of an Appeal and Logbook Entry. The REC Secretariat receives the Appeal Form (**EVSU REC F-39**), written justification, and supporting documents. The submission is recorded in the protocol logbook and database. Only complete appeal submissions shall be accepted for processing.

Step 2. Retrieval of Pertinent Protocol file. The REC Secretariat retrieves the pertinent file for reference in the review. The file includes the initially submitted protocol, ICF, research tools and other related documents.

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Step 3. Notification of Chair and Members. The REC Secretariat notifies the REC Chair and the primary reviewers about the letter of appeal and awaits further instructions.

Step 4. Inclusion in the Full Review Agenda. The REC Chair instructs the REC Secretariat to include the appeal in the agenda of the full review meeting, to ensure that the retrieved protocol and related documents are available during the meeting and to inform the researcher to be available on the scheduled meeting in case there is a need for further clarification.

Step 5. Full Review Deliberation. The primary reviewer(s) summarize(s) the protocol and the previous discussion of the issues in the protocol as background to the appeal. The REC Chair presents the contents of the appeal and leads discussion. The researcher may be called in for further clarification of issues. The researcher is asked to step out after the committee has taken up the issues for clarification. The committee then decides (by voting) whether to accept any or all of the points raised in the appeal.

Step 6. Communication of Committee Action. Based on the deliberations, the Chair summarizes the decision points and instructs the REC Secretariat to prepare the draft decision letter for his/her finalization and forwarding to the researcher.

Step 7. Filing of Documents and Update of Protocol Database. The REC Secretariat files all the documents into the appropriate folder and updates the protocol database accordingly.

7. Glossary

Appeal	- A formal request for reconsideration of an REC decision.
Full Board Review	- Review conducted by the REC during a convened meeting with quorum.
Researcher(s)	- The individual(s) responsible for the conduct of the study.
REC Decision	- Official action taken by the REC after review or deliberation.

8. Forms

<i>FORM CODE</i>	<i>FORM TITLE</i>
<i>EVSU REC F-39</i>	Appeal Form
<i>EVSU REC F-20</i>	Decision Letter

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	15 – Management of Appeals	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

9. History of SOP

<i>VERSION NO.</i>	<i>DATE</i>	<i>AUTHORS</i>	<i>MAIN CHANGE</i>
01	May 2025	Prof. Niñoval F. Pacaol	First Draft of SOP
	April 2026	Dr. Cara Luz Buar	Revised Policy Statement, Workflow/Description of Procedures, Forms

10. References

EVHRDC SOP Manual (2022)
PHREB National Ethical Guidelines (2022)
PHREB SOP Workbook (2020)

Prepared by:	Reviewed and approved by:	Approved by:
<i>Research Ethics Committee (REC)</i>	sgd.	sgd.
	GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	DENNIS C. DE PAZ, PhD <i>University President</i>

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	16 – Conduct of Site Visits	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

1. Policy Statement

The EVSU-REC shall designate a team to conduct visits of selected sites of approved protocols. Moreover, site visits are part of the EVSU-REC OVERSIGHT functions in the following conditions: (a) high risk studies, (b) receipt of significant number of protocol violations, (c) receipt of complaints from participants and families, (d) non-receipt of required after-approval reports, and € if with multiple studies conducted by a researcher.

All site visit findings and actions shall be reviewed and confirmed by the REC and reported in the next Full Review meeting.

Only authorized REC members shall conduct site visits, and conflict of interest must be declared prior to participation.

2. Objective of the Activity

Site visits are mechanisms within which the EVSU-REC monitors compliance with approved protocols, ICF process and continuing protection and promotion of participant's dignity, rights and well-being. Site visits may be initiated for an onsite evaluation of a study site for a routine audit.

3. Scope

This SOP includes the steps in conducting visits to study sites for reasons set by the EVSU-REC. This begins with the selection of the site to be visited and ends with the draft of Site Visit Report, presentation of report during the meeting, discussion of the recommendations, filing of Site-Visit Reports in the protocol folder and updating of the protocol database.

4. Roles and Responsibilities

A. REC Chair

- select site and approves visit, and
- assign site visit team

B. REC Secretariat

- coordinate logistics,
- issue notices, and
- document and file reports.

C. Site Visit Team

- conduct visit,

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- b. evaluate compliance, and
- c. prepare report.

5. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Selection of site to visit	<i>REC Chair</i>
Step 2: Notification of Researcher	<i>REC Secretariat</i>
Step 3: Creation of Site Visit team	<i>REC Chair</i>
Step 4: Conduct of site visit	<i>Site Visit Team</i>
Step 5: Draft of report and presentation of report during meeting and discussion for recommendations	<i>Site Visit Team</i>
Step 6: Transmittal of Site Visit Report and Recommendations to the Researcher(s)	<i>REC</i>
Step 7: Filing of Site-Visit Reports in the protocol folder and update of Protocol database	<i>REC Secretariat</i>

6. Description of Procedure

Step 1. Selection of site to visit. The EVSU-REC Chairperson designates members to perform on sites of relevant projects. Once selected, The REC Secretary checks protocol files and prepares all relevant documents needed for adequate and comprehensive site visit by the team. Moreover, the REC Chairperson may take into account the following criteria in deciding which research site to visit.

- A. high risk studies;
- B. consistent non-submission of failure to submit after-approval submission requirements;
- C. reports of major protocol noncompliance;
- D. significant number of serious adverse events; and
- E. reports of complaints form study participants.

Step 2. Notification of Researcher. The REC Chairperson, through the REC Secretariat informs the Researcher(s) at least **10 working days** before the scheduled visit through a Notice of Site Visit to Researcher(s) (**EVSU REC F-40**). The letter provides site visit schedule details and instructions on what the Researcher(s) need(s) to prepare that will be used for the site visit. The documents to be prepared include the complete protocol document, informed consent forms being used, and all post-approval documents.

Step 3. Creation of Site Visit Team. A site visit team is created for each site visit. The REC Chairperson assigns members of the site visit team. The team should be composed of at least three (3) people: two (2) Primary Reviewers of the protocol and the REC Chairperson/Vice-Chairperson or Member-Secretary, or one (1)

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Primary Reviewer and two (2) REC Officers. The site visit team members are informed of their assignment through the issuance of a Letter of Invitation to Members of Site Visit Team (EVSU REC F-41). The REC Secretariat prepares a Study Visit Package for each member of the Site Visit Team, inclusive of the Site Visit Report (EVSU REC F-42) and a copy of the approved study protocol and related documents.

Step 4. Conduct of Site Visit. During the visit the designated site visit team shall:

- A. Review the study protocol;
- B. Review the informed consent documents and verify if the site is using the most recently approved versions;
- C. Ask the lead researcher or any member of the team to explain the informed consent process;
- D. Review the post-approval documents and verify if the site is using the most recently approved version;
- E. Ensure that the documents are being filed properly securely, and with confidentiality at the study site;
- F. Make an overall resolution of the protection of the rights, safety and welfare of human participants in the study; and
- G. At the end of the visit the Site Visit Team will discuss the findings with the research team and solicit feedback.
- H. All actions and decisions made through this procedure shall be included in the agenda of the next Full Board meeting for reporting and documentation.

Step 5. Draft of report and presentation of report during meeting and discussion for recommendations. The site visit team completes the Site Visit Report (EVSU REC F-42) and submits it to REC Secretariat **not later than five (5) working days** after the Site Visit. The REC Secretariat logs the date of submission in the Submission Log (EVSU REC F-43). The REC Secretariat files a copy of the report in the study file and places the Site Visit Report in the agenda for the next Full Review meeting. During the meeting the REC Secretariat distributes the completed Site Visit Report to REC Members along with the meeting agenda. The REC deliberates on the results of the Site Visit based on the rights, safety, and welfare of the study participants and makes an overall conclusion of protocol compliance.

Step 6. Transmittal of the Site Visit Report and Recommendations to the Researcher/s. The REC Secretariat notifies the Researcher(s) of the REC actions or recommendations through the form Receipt and Recommendation for Further Action (EVSU REC F-44). The REC decision will be sent to the Researcher(s) **within five (5) working days** after the REC Full Review

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Meeting. The Researcher(s) may be requested to provide additional information, submit additional documents, or implement corrective action.

Step 7. Filing of the Site Visit documents and updating of the Protocol database. The REC Secretary files the accomplished Site Visit Report and the recommendations in the appropriate folder and updates the protocol database accordingly. (See SOP 23 on Management of Active Files).

7. Glossary

After-approval reports	- Reports required by the REC for submission by the researcher/investigator after the study has been approved for implementation. These include, but are not limited to, progress reports, protocol deviation/violation reports, amendments, early termination reports, final reports, and applications for continuing review.
Decision	- The result of the deliberations of the REC in the review of a protocol or other submissions.
Full Review	- The ethical evaluation of a research proposal and other protocol-related documents, including resubmissions and after-approval submissions, conducted by the Research Ethics Committee en banc, in the presence of a quorum, using established technical and ethical criteria.
High-Risk Studies	- Research where harm or danger resulting from the study intervention is very likely for participants.
Primary Reviewer	- A member of the Research Ethics Committee assigned to conduct an in-depth evaluation of research-related documents using established technical and ethical criteria.
Protocol Database	- A collection of information regarding protocols that is structured and organized to allow efficient access, management, interpretation, analysis, and updating.
Protocol File/Folder	- An organized compilation of all documents (physical or electronic) related to a study.
Protocol Violation	- Non-compliance with the approved protocol that may result in increased risk or decreased benefit to participants, or significantly affects their rights, safety, welfare, or the integrity of data (e.g., incorrect treatment, non-compliance with inclusion/exclusion criteria).

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Site Visit

- A REC oversight activity in which an assigned team visits the research site or office for monitoring and evaluation purposes based on established criteria.

8. Forms

FORM CODE	FORM TITLE
<i>EVSU REC F-40</i>	Notice of Site Visit to Researcher(s)
<i>EVSU REC F-41</i>	Letter of Invitation to Members of Site Visit Team
<i>EVSU REC F-42</i>	Site Visit Report
<i>EVSU REC F-43</i>	Submission Log
<i>EVSU REC F-44</i>	Receipt and Recommendation for Further Action

9. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	May 2025	Dr. Ma. Windie C. Velarde	Initial Version

10. References

- LNU (2023). Leyte Normal University Research Ethics Manual SOP Initial Version
- BatMC (2021). Batangas Medical Center Research Review Committee SOP Manual version 5.7.
- EVHRDC (2022). Eastern Visayas Health Research and Development Consortium-Ethics Review Committee Standard Operating Procedure (SOP) Manual version 4.
- PHREB (2020). Philippine Health Research Ethics Board Standard Operating Procedures.
- PHREB (2022). National Ethical Guidelines for Research Involving Human Participants.

Prepared by:	Reviewed and approved by:	Approved by:
<i>Research Ethics Committee (REC)</i>	sgd. GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	sgd. DENNIS C. DE PAZ, PhD <i>University President</i>

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	17 – Preparing for a Meeting	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

1. Policy Statement

Full Review meeting shall be conducted every first (1st) Friday of the month, and Expedited Review meeting shall be conducted every fourth (4th) Friday of the month. If the scheduled meeting falls on a holiday, weekend, or when circumstances prevent convening, the meeting shall be rescheduled to the nearest appropriate working day as determined by the REC Chair. As much as practicable, all meetings shall be held within the premises of the institution and shall be coordinated with physical plan division. Special meetings may be held to resolve issues which require immediate attention or action and which issues must be specifically mentioned in the notice. However, when conducting face-to-face meetings become impossible for legitimate reasons provided either by legal authorities or by the institutional leadership or as determined by the EVSU REC members, an online meeting may be organized.

2. Objective of the Activity

The preparation for a meeting aims to contribute to a smooth, orderly, inclusive, and efficient conduct of meetings.

3. Scope

This SOP covers all activities prior to the conduct of a regular or special EVSU REC meeting. This SOP begins with the preparation of the agenda and ends with the notification of REC Members and confirmation of attendance.

4. Roles and Responsibilities

A. REC Secretariat

- coordinate with the Member-Secretary in the preparation of the agenda for the EVSU REC Meeting;
- prepare for the set-up of the meeting;
- assemble the materials and documents to be used in the meeting;
- prepare the logistics needed for the meeting; and
- notify REC members and secure their confirmation to attend.

B. Member-Secretary assist in the preparation of the meeting agenda.

C. REC Members signify their attendance to the scheduled meeting.

5. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Preparation of the agenda (SOP No. 18 Preparing the Meeting Agenda)	REC Secretariat and Member-Secretary

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Step 2: Preparation for the meeting set-up	<i>REC Secretariat</i>
Step 3: Assembly of materials and documents needed for the meeting	<i>REC Secretariat</i>
Step 4: Preparation of logistics for the meeting	<i>REC Secretariat</i>
Step 5: Notification of REC Members and confirmation of attendance	<i>REC Secretariat</i>

6. Description of Procedures

Step 1. Preparation of the agenda. The REC Secretariat shall follow the procedures set in SOP No. 18 on Preparing the Meeting Agenda.

Step 2. Preparation of the meeting set-up.

- A. For face-to-face meetings, the REC Secretariat:
 - a. books the ORIES conference room for the conduct of the REC meeting (Full Review or Expedited Review Meeting scheduled every month
 - b. should the conference room be not available, searches any available space within the university premises
 - c. ensures that all the needed equipment mentioned in Step 4 are readily available or are viable in the reserved space for the meeting.
- B. For online meetings, the REC Secretariat:
 - a. sets the meeting schedule in the Google Calendar account of the EVSU REC
 - b. generates the Google Meet code for said meeting
 - c. invites the REC members through their institutional or their registered email accounts.

Step 3. Assembly of materials and documents needed for the meeting. Whichever is practicable, the REC Secretariat prepares the following:

- A. For face-to-face meetings:
 - a. copies of the following documents for the REC members
 - i. Meeting agenda
 - ii. Minutes of the previous regular meeting
 - iii. Protocol folders (in electronic format)
 - iv. Letters and invitations, if available
 - b. administrative documents and references
 - i. Attendance Sheet for the meeting
 - ii. EVSU REC SOP
 - iii. National Ethical Guidelines for Health-Related Research
 - iv. Other pertinent references (e.g., documents for Honorarium of Reviewers)

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B. For online meetings: Sends the specific link to the Google Folder containing the following documents to be used in the meeting:

- i. House Rules for the online meeting
- ii. Meeting agenda
- iii. Minutes of the previous regular meeting
- iv. Protocol folders
- v. Letters and invitations, if available
- vi. EVSU REC SOP
- vii. National Ethical Guidelines for Health-Related Research
- viii. Other pertinent references

C. The Member Secretary oversees that these documents and materials are in place for the scheduled meeting.

Step 4. Preparation of Logistics for the Meeting.

Whichever is practicable, the REC Secretariat prepares the following at least one (1) hour before the actual meeting:

A. For face-to-face meetings:

- a. Equipment:
 - i. LCD projector
 - ii. Office laptop
 - iii. VGA cable(s)
 - iv. HDMI adapter
 - v. Extension wires, if needed
 - vi. Digital recorder
- b. Conference room set-up:
 - i. Cleaning the conference table
 - ii. The number of chairs must be enough to accommodate those who confirmed their attendance
- c. Attendance sheet placed at a conspicuous place that can be easily accessed by the REC members
Different reference materials on the conference table where the REC members can easily access them should they need to
- d. Refreshments and meals enough for those who confirmed their attendance to the meeting

B. For online meetings:

- a. Reliable internet connection of each REC member especially of the REC Staff who takes charge of recording the minutes of the meeting
- b. Audio and camera functions of the attendees
- c. House Rules to be observed during the meeting
- d. Attendance to be taken via *viva voce* so it can be duly recorded
- e. Specific link to the Google Folder containing all important documents to be used in the meeting

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Step 5 – Notification of REC Members and confirmation of attendance:

- A. The REC Chair coordinates with the REC Secretariat for the sending of meeting notification details, i.e. venue and other logistics pertinent to the meeting, as well as the copy of the provisional agenda and the minutes of the previous meeting.
- B. Once cleared by the REC Chair, the REC Secretariat sets the meeting schedule via Google Calendar using the official account of the EVSU REC at least **five (5) working days** before the schedule and send Notice of EVSU REC Meeting (**EVSU REC F-49**). The REC Members and/or resource persons are invited via the Google Calendar using their institutional or any registered email accounts. Said invitation shall include the following details:
 - a. Actual date of the meeting
 - b. Time of the meeting
 - c. Venue
 - d. Provisional meeting agenda
 - e. Google Meet code for said meeting
 - f. Prompt for verification
 - g. Note for the invitee to confirm up to at least 3 working days before the schedule
- C. The REC Secretariat updates the REC Chair re the confirmation of the REC members and/or resource persons at least two (2) working days from the date of the meeting schedule. Quorum must be assured from the confirmation of attendance by the REC Members. However, should the required quorum be not achieved via the responses, the following must be observed:

The REC Chair asks the REC Secretariat to inquire from the REC members about their preferred time so the meeting may be properly reset. Once a viable schedule is agreed, the notification and confirmation process as stated in item 2 of Step 5 shall be observed to properly document the confirmation from the REC Members

- a. If the same is still not feasible, the REC Chair inquiries from the REC members if their alternate members may be invited in their stead so the meeting may push through. Once the regular members agree, the notification and confirmation process as stated in item 2 of Step 5 shall be observed with invites sent to the alternate members.

7. Glossary

Administrative Documents - Refer to the attendance sheets that REC members sign when attending meetings or sessions as well as acknowledge receipts for the non-affiliated members who receive their transportation allowance and/or honoraria.

Alternate Members - Individuals who possess the qualifications of specified regular members. They are called to

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attend a meeting and substitute for regular members to comply with the quorum requirement when the latter cannot attend the meeting. Alternate members shall be asked to serve as observers in at least one (1) regular REC meeting so s/he will be oriented with the process. While being observers, the alternate members will be asked to comply with the needed Confidentiality Agreement.

Logistics

- Refers to the different resources that are needed by the REC in the conduct of meetings. They are specified as follows, among others: equipment, space set-up, internet connectivity, reference materials, and meals.

Meeting Agenda

- Refers to the document containing the items that will be covered during a particular meeting. Among others, the preliminary details of the protocols that will be presented must also be found in the agenda. These protocols must be grouped accordingly: *Submitted Protocols for Full Review; Submitted Protocols for Expedited Review; Exempted Applications; Resubmitted Protocols; Revised and Amended Protocols; Continued Review Reports; Study Completion Reports; Protocol Violations.*

Quorum

- Refers to the required number of present regular REC members so that the committee deliberations and decisions are legally carried out. The committee requires the presence of majority (i.e. 50% plus 1) of its regular members with the following composition: a) meeting presider (REC Chair or designated member); b) at least one (1) scientist(s); c) at least one (1) non-scientist(s); and d) at least one (1) non-affiliated member. In addition, the quorum must be composed of more than one profession /discipline and gender.

Special Meeting

- Refers to a meeting called for by the REC Chair in order to tackle very specific protocols or matters and because of its urgent nature that

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they cannot anymore wait to be calendared for the regular meeting. Strictly, only those items found in the notice of a special meeting that was communicated will be covered. No other items may be added to the agenda. Also, a quorum must be maintained throughout the entire discussion. Special meetings may be held via teleconference, if applicable.

8. Forms

FORM CODE	FORM TITLE
<i>EVSU REC F-49</i>	Notice of EVSU REC Meeting

9. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	May 2025	Dr. Brian John Sarno	Initial Version

10. References

- LNU (2023). Leyte Normal University Research Ethics Manual SOP Initial Version
- BatMC (2021). Batangas Medical Center Research Review Committee SOP Manual version 5.7.
- EVHRDC (2022). Eastern Visayas Health Research and Development Consortium-Ethics Review Committee Standard Operating Procedure (SOP) Manual version 4.
- PHREB (2020). Philippine Health Research Ethics Board Standard Operating Procedures.
- PHREB (2022). National Ethical Guidelines for Research Involving Human Participants.

Prepared by:	Reviewed and approved by:	Approved by:
<i>Research Ethics Committee (REC)</i>	sgd. GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	sgd. DENNIS C. DE PAZ, PhD <i>University President</i>

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1. Policy Statement

The meeting agenda shall be based on the submissions received on or before the cutoff date every 15th of the month. It shall follow the established template for the meeting agenda.

2. Objective of the Activity

The preparation of the meeting agenda aims to ensure a smooth, orderly, inclusive, and efficient conduct of meetings.

3. Scope

This SOP describes how the EVSU REC determines what items are included in the agenda of the regular and special meetings. This SOP begins with the preparation of the draft meeting agenda and ends with the filing of the final meeting agenda.

4. Roles and Responsibilities

A. REC Secretariat

- prepare the draft meeting agenda;
- distribute the provisional meeting agenda; and
- file the approved meeting agenda.

B. REC Chair

- approve the provisional meeting agenda.

C. REC Members

- approve the final meeting agenda

5. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Preparation of the draft meeting agenda	<i>REC Secretariat and Member-Secretary</i>
Step 2: Approval of the provisional meeting agenda	<i>REC Chair</i>
Step 3: Distribution of the provisional meeting agenda (SOP No. 17 on Preparing for a Meeting)	<i>REC Secretariat</i>
Step 4: Approval of the final meeting agenda	<i>REC Members</i>
Step 5: Filing of the final meeting agenda (SOP No. 23 on Management of Active Files)	<i>REC Secretariat</i>

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6. Description of Procedures

Step 1. Preparation of the draft meeting agenda. The REC Secretariat, assisted by the Member Secretary:

- A. checks the logbook or database of protocols and/or communications to see the different updates about each protocol that were submitted to the EVSU REC.
- B. uses these updates or submission lists to prepare the draft meeting agenda at least ten (10) working days prior to the next full review meeting, five (5) working days prior to the next expedited review meeting, and at least three (3) working days before a scheduled special meeting or at an earlier possible time agreed by the committee.
- C. for full review and expedited meeting, comes up with a draft meeting agenda that follows the prescribed template with the following items or categories:
 - a. Call to Order
 - b. Determination of quorum and presence of non-affiliated and non-scientist member
 - c. Approval of the provisional agenda
 - d. Disclosure of Conflict of Interest
 - e. Approval of the minutes of the previous meeting
 - f. Business arising from the minutes of the previous meeting
 - g. New business
 - i. Presentation of protocols for Full Review
 1. New protocols
 2. Resubmitted protocols
 3. Post-approval reports
 - a. Protocol amendment applications
 - b. Protocol for continuing review
 - c. Protocol deviations/ violations
 - d. Early termination reports
 - e. Study completion report form
 - f. SAEs/SUSARs/RNEs
 - ii. Reporting of protocols under Expedited Review
 1. New protocols
 2. Resubmitted protocols
 3. Post-approval reports
 - a. Protocol amendment applications
 - b. Protocol for continuing review
 - c. Protocol deviations/ violations
 - d. Study completion report form
 - iii. Reporting of protocols that are Exempt from Review
 1. Letters/ general notifications
 2. Any other matters with the permission of the REC

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3. Adjournment

- D. for a special meeting, indicates the specific protocol for review with no other inclusions.
- E. the list of protocols for the above-mentioned categories should be based on a first-come-first-serve basis. The serial arrangement of the protocol numbers must be followed. However, any study that involves vulnerable populations (vulnerable to coercion or undue influence) will only be placed on the agenda when at least one individual (EVSU REC member or independent consultant) who is knowledgeable about or experienced in working with the population will participate in the meeting (or an independent consultant has been obtained). If expertise with a specific vulnerable population is needed but not available from the EVSU REC members, an independent consultant will be obtained or the item will be scheduled for a later meeting when expertise is available.
- F. forwards the draft agenda to the REC Chair for the preparation of the provisional meeting agenda within two (2) working days before the cut-off date.

Step 2. Preparation of the provisional meeting agenda. The REC Chair, upon receipt of the draft agenda, is given at most two (2) working days:

- A. checks the content of the draft agenda with particular focus on the list of protocols using the protocol numbers vis-à-vis the listing in the logbook.
- B. ensures that the initial details of each protocol is provided
- C. includes other additional items, especially administrative matters, that will be covered during the meeting.
- D. Once done, forwards the approved provisional agenda to the REC Staff for distribution and approval by the REC members.

Step 3. Distribution of the provisional meeting agenda.

- A. Upon receipt of the provisional meeting agenda, the REC Staff distributes it to the REC members at least five (5) working days before the scheduled regular full board meeting along with the setting of the meeting schedule via Google Calendar.
- B. The REC Members and/or resource persons are invited via the Google Calendar using their institutional or any registered email accounts. Said invitation shall include the following details:
 - a. Actual date of the meeting
 - b. Time of the meeting
 - c. Venue
 - d. Provisional meeting agenda
 - e. Google Meet code for said meeting
 - f. Prompt for verification
 - g. Note for the invitee to send her/his feedback about the provisional meeting agenda within the next 3 working days.

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Step 4. Approval of the provisional meeting agenda. See SOP on Conduct of Meetings (SOP No. 19) for related details.

- A. Upon receipt of the electronic invite or Notice of Meeting (**EVSU REC F-49**), the REC members send her/his feedback or comment or approval to the provisional meeting agenda. Any additional item may still be added to the provisional agenda up to 3 working days before the meeting. This is to give time for the preparation of any materials or documents.
- B. The meeting agenda is considered approved and final during the actual meeting. A motion for its approval is raised and must be duly seconded.

Step 5 – Filing of the final meeting agenda: See SOP on Management of Active Files (SOP No. 23).

7. Glossary

Draft Meeting Agenda	- Refers to the version of the meeting agenda that is prepared by the REC Staff.
Final Meeting Agenda	- Refers to the version of the meeting agenda that is duly approved during the REC meeting.
New Protocols for Full Review	- Refer to the protocols or studies that have been submitted for review within the last 4 weeks after the last cut-off.
Post-approval Reports	- Refer to the progress reports submitted by the proponents between the time they were issued the Ethics Clearance and their completion date. This is for monitoring purposes.
Provisional Meeting Agenda	- Refers to the version of the meeting agenda that is approved by the REC Chair.

8. Forms

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9. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	May 2025	Dr. Brian John Sarno	Initial Version

10. References

- CIOMS. 2002. International Ethical Guidelines for Biomedical Research Involving Human Subjects.
- CIOMS. 2016. International Ethical Guidelines for Health-related Research Involving Humans.
- International Conference on Harmonization. 1996. Guidance on Good Clinical Practice (ICH GCP).
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). 2016. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2).
- Philippine Health Research Ethics Board (PHREB). 2020. 2020 PHREB Standard Operating Procedures.
- UCI Office of Research. “Modifications to Approved Research.” Available in <https://www.research.uci.edu/compliance/human-research-protections/researchers/modifications-to-approved-research.html#Level>.
- UNESCO. 2017. Code of Conduct Social Science Research.
- World Health Organization (WHO). 2011. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants.
- World Medical Association (WMA). 2013. Declaration of Helsinki -Ethical Principles for Medical Research Involving Human Subjects.

Prepared by:	Reviewed and approved by:	Approved by:
Research Ethics Committee (REC)	sgd. GILBERT ANTHONY O. ABAÑO, MAN, RN REC Chairperson	sgd. DENNIS C. DE PAZ, PhD University President

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1. Policy Statement

Meetings shall be presided over by the chair or designated substitute and proceed only when a quorum is declared. They 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.

2. Objective/s of the Activity

Meetings are conducted to provide an opportunity for the EVSU-REC to reach collegial decisions regarding study protocols and EVSU-REC operations, as well as to be informed of pertinent administrative matters.

3. Scope

This SOP outlines the procedures by which the EVSU-REC conducts its meetings. It covers EVSU-REC 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. Roles and Responsibilities

A. REC Secretariat

- preparing the draft meeting agenda;
- distributing the provisional meeting agenda; and
- filing the approved meeting agenda.

B. REC Chair is responsible for approving the provisional meeting agenda.

C. REC Members are responsible for reviewing and approving the final meeting agenda.

5. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Distribution of meeting materials	<i>REC Secretariat</i>
Step 2: Declaration of quorum	<i>REC Chair</i>
Step 3: Approval of the Provisional Agenda	<i>REC Chair</i>
Step 4: Declaration of Conflict of Interest	<i>REC Members</i>
Step 5: Approval of minutes of previous meeting	<i>REC Secretariat</i>

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Step 6: Discussion of “Business arising from the minutes”	<i>REC Secretariat</i>
Step 7: Review of protocols and protocol-related submissions	<i>Reviewers</i>
Step 8: Report of expedited review results	<i>Primary Reviewers</i>
Step 9: Discussion of operations-related matters	<i>REC Members</i>
Step 10: Adjournment	<i>REC Chair</i>
Step 11: Collection, storage, and disposal of meeting materials	<i>REC Secretariat</i>

6. Description of Procedures

Step 1. Distribution of meeting materials. The REC Secretariat compiles all relevant documents required for the meeting, including:

- A. Agenda
- B. Research proposals, study protocols, and amendments
- C. Informed consent documents
- D. Investigator brochures and any relevant supporting materials
- E. Reports on ongoing studies, adverse event reports, and any related documentation

The draft meeting agenda shall clearly distinguish between: Protocols for Full Review, and Protocols processed under Expedited Review (for reporting only), and Protocols exempt from review to ensure transparency and compliance.

Distribution Methods. Materials are primarily shared electronically, using a secure, password-protected system or email. The REC Secretariat confirms access with each member and addresses any technical issues. For members who prefer hard copies or require them for confidential documents, printed materials are provided in sealed envelopes. These may be hand-delivered or collected from the REC office. All materials are marked as confidential and distributed with clear handling instructions.

Confirmation of Receipt. The REC Secretariat shall confirm that each member has received and accessed the materials and address any distribution issues promptly.

Step 2. Declaration of quorum: A quorum is required to validate decisions made during the Research Ethics Committee (REC) meeting. The quorum should include scientist and non-scientist members with expertise in scientific research, ethics, and law, as well as at least one independent member of the institution.

- A. The REC Secretariat performs an attendance check at the beginning of the meeting, confirming the presence of each required member type (e.g., medical, scientific, legal, non-affiliated). Attendance is documented, listing the members present and any absentees.

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- B. The REC Chairperson declares quorum at the start of the meeting. If quorum is met, the meeting proceeds as scheduled. If a quorum is not met, the Chairperson may decide to:
 - a. Postpone the meeting to a later date, or
 - b. Reschedule discussions and decisions on certain agenda items until quorum can be met.
- C. The REC Secretariat notes the declaration of quorum (or lack thereof) in the minutes of the meeting. Any member arriving after the quorum declaration or leaving before the meeting adjournment is recorded by the REC Secretariat.
- D. If a member with critical expertise leaves and quorum is no longer met, the meeting is paused until quorum is re-established or the meeting is adjourned.

Step 3. Approval of the provisional agenda.

- A. The REC Secretariat circulates the provisional agenda to all REC members along with the meeting materials at least one week before the meeting. This allows members sufficient time to review the items listed for discussion.
- B. At the beginning of the meeting, the REC Chairperson presents the provisional agenda to the committee and asks for any last-minute additions, modifications, or reordering of items. Members may suggest changes, including adding urgent items or deferring non-urgent items if time constraints exist.
- C. Once all members agree on the final form of the agenda, the Chairperson calls for a motion to approve the agenda. A member may propose the motion to approve, and another member seconds it. This motion is then put to a vote.
- D. If there is a majority agreement on the agenda as presented or amended, the provisional agenda is formally approved. The REC Secretariat records the approved agenda in the meeting minutes, noting any amendments made during the approval process.
- E. Following approval, the meeting proceeds according to the agenda. Any further changes to the agenda require consensus among REC members.

Step 4. Declaration of Conflict of Interest.

- A. To ensure that REC members review proposals impartially and maintain the integrity of the ethical review process. PHREB guidelines require all members to disclose any personal or financial interests that may influence their objectivity.
- B. Prior to each meeting, REC members complete a **Conflict-of-Interest Disclosure Form** provided by the REC Secretariat. This form allows members to declare any direct or indirect interests that might affect their impartiality concerning the proposals under review.
- C. At the start of the meeting, the REC Chairperson asks members to verbally declare any potential or perceived conflicts of interest related to the agenda items. Members with a conflict are expected to identify the specific proposals or items to which the conflict applies.

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- D. The REC Secretariat records all declared conflicts in the meeting minutes. For each proposal with a declared conflict:
- The member may participate in the initial presentation of the study (if requested), but they must then recuse themselves from further discussion and decision-making.
 - The member leaves the meeting room during discussions and voting on the proposal in question.

If the Chairperson has a conflict, they designate another qualified REC member to lead discussions for the conflicted proposal.

- E. If a potential conflict arises during discussions, the Chairperson or a committee member may raise the issue, and the member involved is encouraged to declare it and recuse themselves accordingly.

Step 5. Approval of minutes of previous meeting.

- The REC Secretariat circulates the draft minutes from the previous meeting to all REC members at least one week in advance. This allows members ample time to review the record of discussions, decisions, and action items.
- REC members review the minutes before the meeting to verify the accuracy of recorded decisions, discussions, and attendance. Any corrections or clarifications can be prepared for discussion during the approval process.
- At the beginning of the meeting, the Chairperson calls for the formal approval of the previous meeting's minutes. Members are invited to suggest any necessary edits, corrections, or clarifications to ensure an accurate record.
- Once all corrections (if any) are noted, the Chairperson calls for a motion to approve the minutes as amended or as originally presented. A member proposes the motion for approval, which is then seconded by another member.
- The committee votes to approve the minutes. A majority agreement confirms the minutes as the official record of the previous meeting. The REC Secretariat documents the approval of the minutes, noting any changes made, in the current meeting's minutes.
- The approved minutes are archived as part of the REC's official records, accessible for reference and compliance with PHREB guidelines on record retention.

Step 6. Discussion of "Business arising from the minutes".

- Prior to the meeting, the REC Secretariat reviews the minutes of the previous meeting to identify any unresolved items, action points, or follow-up issues. These items are listed as "Business Arising from the Minutes" in the current meeting agenda. The Secretariat also provides updates on the status of each item, where available.
- The Chairperson introduces each item under "Business Arising from the Minutes" at the meeting, allowing for structured follow-up on pending matters.
- The REC discusses each item individually. Members provide updates on any assigned tasks or share new information related to the item. Specific follow-up

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actions, such as additional reviews, consultations, or communications with researchers, are discussed to ensure resolution.

- D. The committee may decide to:
 - a. Mark the item as complete if resolved.
 - b. Assign further actions or deadlines to specific members.
 - c. Defer the item to a future meeting if additional time or information is needed.
- E. Any decisions or actions required are noted by the REC Secretariat.
- F. The REC Secretariat documents all discussions, decisions, and action points related to “Business Arising from the Minutes” in the current meeting’s minutes, noting any additional tasks assigned and their deadlines.

Step 7. Review of protocols and protocol-related submissions.

- A. The REC Secretariat compiles all protocols and related submissions (e.g., amendments, renewals, adverse event reports) scheduled for review. These documents are distributed to REC members at least one week before the meeting to allow thorough review, as per PHREB guidelines.
- B. The Chairperson introduces each protocol or protocol-related submission according to the agenda. A designated REC member or the researcher (if invited) provides a brief overview of the study, its objectives, methodology, and any relevant changes or issues for discussion.]
- C. The REC members evaluate each protocol for ethical concerns, including:
 - a. Risks and benefits to participants
 - b. Informed consent process
 - c. Confidentiality and data protection
 - d. Safety monitoring and reporting

Members assess adherence to PHREB standards and applicable laws, ensuring that protocols align with ethical and regulatory requirements. For amendments, renewals, and adverse event reports, members review the changes or incidents and assess their impact on participant safety, data integrity, and the overall ethical conduct of the study.

- D. After discussion, the committee reaches a decision through voting for each protocol or submission, depending on the type of protocol being reviewed (initial, resubmission, post approval reports).
- E. The REC Secretariat records the committee’s decisions, including any required modifications or conditions, in the meeting minutes. Each decision is also documented in individual decision letters to the researchers, detailing any actions required before approval is granted.
- F. The REC Secretariat sends decision letters to researchers within five working days, specifying conditions or modifications if necessary. Approved protocols and submissions are filed for compliance and future reference, per PHREB guidelines.

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Step 8. Report of expedited and exempt review results. An expedited review is conducted outside of the full committee meeting for minimal-risk studies or minor protocol amendments that meet PHREB criteria for expedited processes. This allows the REC to process low-risk submissions efficiently without compromising ethical oversight. Exempt review on the other hand exempts from expedited and full review as these protocols are low-risk studies that meet the PHREB criteria for exempt review.

Step 9. Discussion of operations-related matters. To address ongoing operational issues, challenges, and improvements within the Research Ethics Committee (REC) that may impact its efficiency and effectiveness in conducting ethical reviews. This may include administrative processes, communication strategies, training needs, or resource allocation.

- A. The REC Secretariat compiles a list of operations-related matters for discussion, based on previous meetings, feedback from members, and any emerging issues. These items may include:
 - a. Updates on REC policies or procedures
 - b. Training sessions or workshops for committee members
 - c. Changes in regulatory requirements
 - d. Issues related to document management and record-keeping
 - e. Discussion of resources needed for effective REC operations
- B. The Chairperson introduces each item on the agenda related to operations, providing context and any relevant background information. Members are encouraged to share their insights, experiences, and suggestions for addressing the identified matters.
- C. The REC engages in an open discussion about each operational issue, focusing on:
 - a. **Challenges:** Identifying specific difficulties encountered in current operations.
 - b. **Solutions:** Proposing practical solutions or improvements to enhance operational efficiency.
 - c. **Best Practices:** Sharing successful strategies implemented by other committees or organizations that may be applicable.
- D. Members may also discuss training opportunities to improve knowledge and skills related to ethical review processes and regulatory compliance.
- E. Based on the discussion, the committee may decide to:
 - a. Implement specific changes to operations or procedures.
 - b. Schedule follow-up discussions or meetings for unresolved matters.
 - c. Assign tasks or responsibilities to members to address particular issues, with timelines for completion.
- F. The REC Secretariat documents all decisions and action items in the meeting minutes.
- G. The REC will review the status of previously identified operations-related matters at future meetings to ensure progress and accountability. Updates on the implementation of operational changes will be shared in subsequent meetings.

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Step 10. Adjournment. The meeting must be adjourned after all items on the agenda have been discussed and/or resolved. A member must move for the adjournment of the meeting, and it must be seconded for it to be declared.

Step 11. Collection, storage, and disposal of meeting materials.

- A. *Before the Meeting.* The REC Secretariat collects all relevant materials prepared for the meeting, including agendas, protocols, minutes from previous meetings, and any supporting documents related to research proposals.
During the Meeting. Members are encouraged to submit any additional documents or notes they may have generated during discussions for inclusion in the official records.
- B. *Physical Storage.* All hard copies of meeting materials (agendas, minutes, protocols, and related submissions) are securely stored in a designated filing cabinet or secure location within the REC office. Access to this storage is limited to authorized REC members and administrative staff to maintain confidentiality.
Digital Storage. Electronic copies of meeting materials are saved on a secure, password-protected digital platform (e.g., a shared drive or database) accessible only to REC members and authorized personnel. The REC Secretariat ensures that all digital files are organized by date and type (e.g., meeting minutes, proposals) for easy retrieval.
- C. Meeting materials are retained in accordance with PHREB guidelines and institutional policies, typically for a minimum of **five years** after the conclusion of the research study or until the associated research has been completed, whichever is longer. Documentation should be reviewed periodically to ensure compliance with any updated retention policies or regulations.
- D. Meeting materials may be disposed of after the retention period has expired or if they are deemed no longer necessary for reference. Hard copies of documents should be shredded or otherwise securely disposed of to protect confidential information. Electronic files should be permanently deleted from the storage system, ensuring they cannot be recovered, in compliance with data privacy standards.
- E. The REC Secretariat should maintain a record of disposed materials, including the type of documents disposed of and the method of disposal, to ensure accountability.

7. Glossary

Agenda	- A list of topics or items to be addressed in a meeting, arranged in a sequential manner. It outlines the meeting procedure and begins with a “Call to Order.”
Adjournment	- The formal closure of the meeting. A motion for adjournment is made, and the time of adjournment is recorded in the minutes.

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Ballot	- A method of voting by writing one's choice on a form. Ballots are counted to determine how the majority of members voted for decision-making.
Business Arising from the Minutes	- Matters generated from discussions in the previous meeting that require ongoing attention and reporting.
Clarificatory Interview/Meeting	- A face-to-face consultation between the REC and the researcher intended to obtain explanations or clarification regarding research issues identified by the REC.
Collegial Decision	- A course of action arrived at after group deliberation where members are considered of equal authority, such that the decision is regarded as a group action and not attributed to any one member.
Conflict of Interest	- A situation in which the aims or concerns of two (primary and secondary) interests are not compatible, such that decisions may be adversely affected.
Consensus	- The process of arriving at a decision without voting, by generating the overall sentiment of the group, such that deliberations continue until no strong objection is registered.
EVSU REC Operations Meeting Minutes	- The official record and narration of the proceedings of the REC meeting, based on the approved agenda.
Operations-Related Matters	- Items included in the agenda that are not directly related to any protocol under review.
Protocol	- Documentation of the study proposal including the rationale and significance of the study, background and literature review, objectives, study design and methodology, data collection, data analysis plan, ethical considerations, and dissemination plan.
Protocol-Related Submissions	- Other required documents submitted with the protocol such as informed consent forms, study tools (e.g., interview guide, survey questionnaire, FGD guide), CVs of proponents, and certificates of training.
Quorum	- The minimum number (i.e., majority of members) and required composition of REC members necessary for a meeting to be valid, including non-affiliated and non-scientist members.
Voting	- The act of formally manifesting a choice in a meeting.

8. Forms

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<i>FORM CODE</i>	<i>FORM TITLE</i>
<i>EVSU REC F-46</i>	Secret Ballot Form
<i>EVSU REC F-19</i>	Informed Consent Assessment Form
<i>EVSU REC F-20</i>	Decision Letter

9. History of SOP

<i>VERSION NO.</i>	<i>DATE</i>	<i>AUTHORS</i>	<i>MAIN CHANGE</i>
01	May 2025	Engr. Roxcella T. Reas	Initial Version

10. 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 2017
Philippine Health Research Ethics Board Standard Operating Procedures 2022

Prepared by:	Reviewed and approved by:	Approved by:
<i>Research Ethics Committee (REC)</i>	sgd. GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	sgd. DENNIS C. DE PAZ, PhD <i>University President</i>

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	19B – Conduct of Special REC Meetings	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

1. Policy Statement

The EVSU Research Ethics Committee (EVSU-REC) may convene a Special Meeting when urgent matters arise that require immediate ethical review and cannot be deferred to the next scheduled Full Review meeting.

Special meetings shall be conducted to ensure the timely protection of research participants, particularly in cases involving:

- A. Reportable Negative Events (RNE)
- B. Serious Adverse Events (SAE) or SUSARs
- C. Protocol deviations or violations with significant risk
- D. Urgent amendments affecting participant safety
- E. Early termination of studies with safety implications

Special meetings shall follow the same principles of quorum, independence, and ethical deliberation as regular Full Review meetings.

All decisions made during special meetings shall be reported in the next scheduled Full Review meeting for transparency and documentation.

2. Objective of the Activity

This SOP aims to ensure timely REC response to urgent ethical issues, protect the rights, safety, and welfare of research participants, and maintain continuity and integrity of REC oversight.

3. Scope

This SOP applies to the conduct of Special REC Meetings for urgent review of research-related matters requiring immediate action. The procedure begins with the identification of urgent matters and ends with the documentation and reporting of decisions to the Full Board.

4. Roles and Responsibilities

A. REC Chairperson

1. determine the need for a **Special Meeting**;
2. approve the meeting schedule and agenda;
3. preside over the meeting;
4. ensure quorum and proper deliberation;
5. confirm and sign REC decisions.

B. Member-Secretary

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1. assist the Chair in preparing the agenda;
2. ensure quorum requirements are met;
3. oversee documentation of deliberations and decisions.

C. REC Secretariat

1. coordinate the schedule of the Special Meeting;
2. notify REC members and invited participants;
3. prepare and distribute documents;
4. record meeting minutes;
5. communicate REC decisions;
6. file documents and update the protocol database.

D. REC Members

1. review documents prior to the meeting;
2. participate in deliberation;
3. declare conflicts of interest and inhibit when necessary;
4. make decisions through consensus or voting.

E. Researcher(s) (if invited)

1. provide clarification on the matter under review;
2. respond to questions from the REC.

5. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Identification of urgent matter requiring special meeting	<i>REC Chair / REC Secretariat</i>
Step 2: Approval and scheduling of Special Meeting	<i>REC Chair</i>
Step 3: Notification of REC members and distribution of documents	<i>REC Secretariat</i>
Step 4: Conduct of Special Meeting (with quorum)	<i>REC Chair / REC Members</i>
Step 5: Decision-making (voting)	<i>REC Members</i>
Step 6: Communication of REC decision	<i>REC Secretariat</i>
Step 7: Filing of documents and reporting to next Full Board	<i>REC Secretariat</i>

6. Description of Procedures

Step 1. Identification of Urgent Matter.

Urgent matters may be identified by:

1. REC Chair
2. REC members
3. REC Secretariat

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4. Researchers

Step 2. Approval and Scheduling. The REC Chair determines the necessity of a Special Meeting and approves the date, time, and agenda.

Step 3. Notification and Document Preparation. The REC Secretariat notifies members at the earliest possible time, provides relevant documents for review, and invites the Researchers when necessary.

Step 4. Conduct of Special Meeting. The Special Meeting shall meet quorum requirements, follow standard REC deliberation procedures, and ensure conflict of interest disclosure and inhibition.

Step 5. Decision-Making. The REC deliberates and decides through voting, when necessary.

Possible decisions include:

1. approval
2. request for modification
3. suspension of study
4. termination of study
5. other appropriate actions

Step 6. Communication of Decision. The REC Secretariat prepares the **Decision Letter (Ethics Clearance)**, signed by the REC Chairperson, and communicates it to the concerned party within five (5) working days after the decision.

Step 7. Filing and Reporting.

The REC Secretariat:

1. files all meeting documents in the protocol file;
2. updates the protocol database;
3. ensures that all decisions made during the Special Meeting are reported in the next scheduled Full Board meeting for transparency and documentation.

7. Glossary

Special Meeting	A meeting convened outside the regular schedule to address urgent ethical concerns.
Quorum	Minimum number of REC members required to conduct official business.
Full Board	The convened REC meeting with quorum for decision-making.
Conflict of Interest	A situation where a member's personal or professional interest may affect impartial judgment.

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8. Forms

FORM CODE	FORM TITLE
<i>EVSU REC F-49</i>	Notice of EVSU REC Meeting

9. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	April 2026	Dr. Cara Luz Buar	Initial Version

10. References

PHREB National Ethical Guidelines (2022)
PHREB SOP Workbook (2020)
EVHRDC SOP Manual (2022)

Prepared by:	Reviewed and approved by:	Approved by:
<i>Research Ethics Committee (REC)</i>	sgd.	sgd.
	GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	DENNIS C. DE PAZ, PhD <i>University President</i>

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1. Policy Statement

The meeting minutes shall be based on the approved agenda and shall be the basis of the decision letter on protocols.

2. Objective of the Activity

The preparation of the minutes of the meeting ensures the proper documentation of the procedures and decisions in an EVSU-REC meeting.

3. Scope

This SOP includes EVSU-REC actions related to the documentation of the proceedings of a meeting, the final output of which is the minutes of the meeting. This SOP begins with the entry of preliminary information on the

4. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Entry of preliminary information on the minutes template	<i>REC Secretariat</i>
Step 2: Preparation of the draft minutes	<i>REC Secretariat and Member-Secretary</i>
Step 3: Notation of the draft minutes	<i>REC Chair</i>
Step 4: Approval of the minutes in the next REC meeting	<i>REC Chair and Members</i>
Step 5: Filing of the approved minutes (SOP on Managing Active Files (SOP#__))	<i>REC Secretariat</i>

5. Description of Procedures

Step 1. Entry of preliminary information on the minutes template. The Minutes Template (**EVSU REC F-47**) serves as a structured framework for documenting the discussions, decisions, and action items from REC meetings, ensuring consistency, clarity, and compliance with PHREB guidelines.

A. Before the meeting, the REC Secretary should prepare the minutes template by entering the following preliminary information:

- a. **Meeting Title:** Clearly indicate that it is a meeting of the Research Ethics Committee (REC).

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- b. **Date:** Enter the date of the meeting.
 - c. **Time:** Record the start time of the meeting.
 - d. **Location:** Specify the venue of the meeting (e.g., physical location or virtual platform).
 - e. **Attendees:** List all members present, including:
 - i. Names and titles of REC members
 - ii. Names of any guests or presenters (e.g., researchers presenting protocols)
 - iii. Acknowledgment of any members absent with or without notice.
 - f. **Quorum Declaration:** Indicate whether a quorum was present or not, including a brief statement from the Chairperson regarding the quorum status.
 - g. **Agenda Items:** Include the agenda items to be discussed, referencing the provisional agenda circulated prior to the meeting. This may also include any additional items introduced during the meeting.
- B. Use clear headings and bullet points to organize the preliminary information, making it easy to read and navigate. Maintain a consistent format throughout the document for clarity.
- C. After entering the preliminary information, the Secretary can save the minutes template and prepare to fill in additional sections during the meeting, such as detailed discussions, decisions, and action items related to each agenda item. Once completed, the minutes will be reviewed and approved at the beginning of the next REC meeting.

Step 2. Preparation of the draft minutes. The draft minutes serve as a preliminary record of the discussions, decisions, and actions taken during the REC meeting, ensuring accountability and transparency in the committee's operations. The draft minutes should include the following key sections:

- a. **Heading:** Include the meeting title, date, time, location, and a list of attendees (both present and absent).
- b. **Call to Order:** Note the time the meeting was called to order by the Chairperson.
- c. **Approval of Previous Minutes:** Record any discussions or amendments made regarding the approval of minutes from the previous meeting.
- d. **Business Arising from the Minutes:** Summarize any follow-up discussions or actions taken on unresolved items from the previous meeting's minutes.
- e. **Review of Protocols:** Document the discussions and decisions made regarding each protocol or protocol-related submission, including:
 - i. Brief description of each protocol
 - ii. Key ethical considerations discussed
 - iii. Decisions made (approved, conditionally approved, modifications required, etc.)
 - iv. Any specific conditions or recommendations for the protocol.

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- f. **Expedited Review Results:** Summarize outcomes of any expedited reviews conducted since the last meeting, including decisions and key points discussed.
 - g. **Operations-Related Matters:** Record discussions related to the operations of the REC, including any challenges identified, solutions proposed, and action items assigned.
 - h. **Action Items:** Clearly outline any tasks assigned to specific members, along with deadlines for completion.
 - i. **Next Meeting:** Note the date, time, and location of the next scheduled meeting.
- A. The REC Secretariat should prepare the draft minutes promptly after the meeting, ideally within 3–5 working days, to ensure timely circulation and feedback.
 - B. Use clear and concise language, avoiding jargon and ensuring that the content accurately reflects the discussions without personal opinions. Maintain a consistent format throughout the document, using headings, bullet points, and numbering where appropriate for clarity.
 - C. Once the draft is prepared, the REC Secretariat circulates it to all REC members for review and feedback. Members should be encouraged to provide comments or corrections within a specified timeframe (e.g., 3 working days).
 - D. After incorporating feedback, the REC Secretariat finalizes the minutes for approval at the next REC meeting. Any amendments made during the approval process should be documented.

Step 3 - Notation of the draft minutes. Notation in the draft minutes serves to provide context, clarify decisions made, and outline the process of approval for the official record of the meeting. It helps ensure transparency and accountability in the documentation of REC activities.

- A. The following key elements should be included in the notation of the draft minutes:
 - a. **Date and Time of the Meeting:** Clearly state the date and time the meeting was held at the beginning of the minutes.
 - b. **Attendees:** List all attendees, indicating their roles (e.g., REC members, guests, presenters) and noting any absentees.
 - c. **Quorum Declaration:** Include a statement confirming whether a quorum was present, along with any implications if it was not.
- B. Each agenda item discussed should be clearly marked with a heading or numbering system. Include brief notations under each agenda item summarizing the key points of discussion, including:
 - a. Main arguments or positions presented
 - b. Any questions raised by members
 - c. The rationale for decisions made
- C. Clearly denote the outcome of discussions with distinct statements, such as: “Approved,” “Conditionally Approved,” “Modifications Required,” “Deferred,” or “Disapproved.” For action items, include:
 - a. Specific tasks assigned

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- b. Names of individuals responsible for completing each task
- c. Deadlines for completion, if applicable
- D. If any changes were made to the previous meeting minutes, note these amendments explicitly in the draft. Document any feedback received during the circulation of the draft minutes and any actions taken in response.
- E. At the end of the draft minutes, include a notation indicating the process for final approval:
 - a. State that the draft minutes will be reviewed and approved at the next REC meeting.
 - b. Indicate who prepared the draft minutes and the date they were prepared.

Example of Notation in Draft Minutes

Here's a simplified example of how notation may look in draft minutes:

Meeting Title: REC Meeting

Date: October 30, 2024

Time: 10:00 AM

Location: Conference Room A

Attendees:

- Prof. Gilbert Anthony Abaño (Chairperson)
- Engr. Roxcella Reas
- (Absent: Dr. Ghost)

Quorum Declaration: Quorum was present.

1. Approval of Previous Minutes

- The minutes from the meeting held on September 25, 2024, were approved with no amendments.

2. Business Arising from the Minutes

- Follow-up on the feedback regarding the consent form was discussed. Action item assigned to Dr. Doe to revise by November 15, 2024.

3. Review of Protocols

- Protocol #12345 was **Approved**. Key ethical considerations discussed included participant safety and informed consent processes.

Prepared by: Engr. Roxcella Reas

Date Prepared: October 31, 2024

- Date and venue of meeting
- Member's attendance (members present and absent)
- Presence of Independent consultants, researchers, guests, and observer's attendance (if any)
- Time when the meeting was called to order
- Declaration of Quorum
- Name of Presiding officer
- Conflict of Interest (COI) declaration
- Items discussed, issues raised, and resolutions

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- REC decisions and recommendations
- Name and signature of person who prepared the minutes
- Name and signature of the Chair and date of notation

Step 4. Approval of the minutes in the next REC meeting

A. At the beginning of the next REC meeting, the Chairperson introduces the draft minutes from the previous meeting, emphasizing their importance as the official record of discussions and decisions. The Chairperson may summarize key points from the draft minutes, including significant decisions, action items, and any outstanding matters.

B. The draft minutes should have been circulated to all members prior to the meeting (at least one week in advance) to provide them ample time to review and prepare any corrections or comments.

C. The Chairperson opens the floor for discussion regarding the draft minutes, inviting members to propose any corrections, clarifications, or amendments. Members can address specific sections or suggest general revisions to ensure the accuracy and completeness of the minutes. Any corrections made during this discussion should be noted by the REC Secretary.

D. Once all necessary amendments have been discussed and addressed, the Chairperson calls for a motion to approve the minutes as amended or as presented. A member makes the motion, and another member seconds it.

E. The Chairperson conducts a vote on the motion to approve the minutes. Members may vote verbally or by raising their hands, depending on the committee's established practice. The approval requires a simple majority (more than half) of members present.

F. The REC Secretary records the outcome of the vote in the current meeting's minutes, noting any amendments made to the draft. If approved, the minutes are considered the official record of the previous meeting and will be filed accordingly.

G. After the meeting, the Secretary ensures that the approved minutes are distributed to all members, researchers, and relevant stakeholders, if necessary. The approved minutes are then archived in both physical and digital formats for compliance and future reference.

Step 5 - Storage of the approved minutes: Proper storage of approved minutes is essential for maintaining accurate records of REC meetings, ensuring compliance with PHREB guidelines, and facilitating transparency and accountability in the committee's operations.

A. Approved minutes should be organized in a secure filing cabinet or designated area within the REC office. Each meeting's minutes should be stored in chronological order, using labeled folders for easy retrieval. Access to the physical storage of minutes should be restricted to authorized REC members and administrative staff to protect confidentiality and sensitive information.

B. Approved minutes should be saved in a secure, password-protected digital platform (e.g., a shared drive, cloud storage, or institutional database) that is accessible only to REC members and authorized personnel. Use a consistent naming convention for digital files, such as "REC_Minutes_[Date]" (e.g., "REC_Minutes_2024-10-30"), to

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facilitate easy identification and retrieval. Create an organized folder structure within the digital repository to categorize approved minutes by year and month, making it straightforward to locate specific documents.

C. Approved minutes should be retained in accordance with PHREB guidelines and institutional policies, typically for a minimum of **five years** after the conclusion of the research study or until the associated research has been completed, whichever is longer. Periodic reviews of stored minutes should be conducted to ensure compliance with updated retention policies or regulations.

D. Regular backups of digital files should be performed to prevent data loss due to technical failures or accidental deletions. This may involve automated backups to an external server or cloud service. Ensure that backup procedures comply with institutional data management policies.

E. Once the retention period has expired, old approved minutes may be disposed of securely. Shred hard copies to protect confidential information. Permanently delete electronic files, ensuring they cannot be recovered. See SOP on Managing Active Files.

6. Glossary

Meeting 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”.
Draft Meeting Minutes	- Proceedings of the meeting prepared by the Secretariat under the supervision of the Member-Secretary.
Provisional Meeting Minutes	- Proceedings of the meeting that have been noted or approved by the Presiding Officer.
Final Meeting Minutes	- Proceedings of the meeting that have been approved by the REC members.
Real-time Recording	- The process of documenting the minutes of the meeting as the meeting proceeds simultaneously.
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.

7. Forms

FORM CODE	FORM TITLE
<i>EVSU REC F-47</i>	Minutes Template

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8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	May 2025	Engr. Roxcella T. Reas	Initial Version

9. 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 2017
Philippine Health Research Ethics Board Standard Operating Procedures 2020

Prepared by:	Reviewed and approved by:	Approved by:
<i>Research Ethics Committee (REC)</i>	sgd.	sgd.
	GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	DENNIS C. DE PAZ, PhD <i>University President</i>

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	21 – Communicating REC Decisions	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

1. Policy Statement

The REC shall communicate its decisions to the researcher(s) within five (5) working days after a review. The communication document shall include clear instructions/ recommendations for guidance of the researcher(s), and must be written on an official stationery of the EVSU REC and signed by the REC Chair.

2. Objective of the Activity

The management of communicating REC decisions ensures that all stakeholders are appropriately informed of the results of deliberations of the REC.

3. Scope

This SOP covers REC actions related to communicating REC decisions about protocols that were submitted for review. It begins with the finalization of recommendations of the committee or the reviewers and ends with the filing of the decision document in the protocol file.

4. Roles and Responsibilities

A. REC Secretariat

- transfer all pertinent information from the minutes of meeting about the committee's decision on the protocol to the Decision Letter (Ethics Clearance);
- prepare the draft providing the coverage of the Ethics Clearance as well as the responsibilities of the applicant;
- forward the Decision Letter to the Member Secretary for review to the REC Chair for approval;
- store the Decision Letter in the appropriate folders; and
- communicate with the applicant about the recommendations from the committee or the reviewer or the approval of the protocol.

B. The Member-Secretary

- review the recommendations transferred by the REC Staff from the minutes of meeting using the Summary of Reviewers' Comment and Actions Taken.

C. The REC Chair

- finalize the recommendations of the committee for protocols that were under full review and the recommendations of the reviewers for those that have gone through expedited review; approve and sign the Decision Letter (Ethics Clearance).

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5. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Finalization of recommendations of the committee, in case of full review (SOP No. 05 Full Review), or Finalization of recommendations of reviewers, in case of expedited review (SOP No. 04 Expedited Review)	<i>REC Chair</i>
Step 2: Transfer of information from the minutes of the meeting to the REC decision letter (Ethics Clearance)	<i>REC Secretariat and Member-Secretary</i>
Step 3: Approval of the REC decision document	<i>REC Chair</i>
Step 4: Communication of REC decision document to researcher(s)/proponent(s)	<i>REC Secretariat</i>
Step 5: Storage of the decision document in the protocol file (SOP No. 24 Management of Active Files)	<i>REC Secretariat</i>

6. Description of Procedure

Step 1. Finalization of recommendations of the committee (in case of full review) or reviewers (in case of expedited review).

- A. The REC Chair reviews if all the comments and recommendations are clear and already final.
- B. For finalization of the Committee's Recommendations, see SOP on Full Review (SOP No. 05) or for finalization of Reviewers' Recommendations, see SOP on Expedited Review (SOP No. 04).

Step 2. Transfer of information from the minutes of the meeting to the REC decision letter (Ethics Clearance)

- A. For protocols under full review:
 - a. Within two (2) working days, the designated PRs or ICs finalize the findings and recommendations using the Summary of Reviewer's Comments and Summary of Actions Taken forms and thereafter forward the documentation to the Member-Secretary for review.
 - b. Within three (3) working days the Member-Secretary reviews the filled forms vis-à-vis the minutes of the meeting where the protocol was presented for full review. Once done, the Member-Secretary forwards the documentation to the REC Chair for final decision.
 - c. Within three (3) working days, the REC Chair finalizes the decision for the protocol under full review. Once done, s/he informs the REC Secretariat of the final decision and instructs her/him to communicate the decision to the researcher(s).
- B. For protocols under expedited review:

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- a. the REC Chair:
 - i. reviews the evaluation results and the recommended actions provided by designated PRs
 - ii. makes the final decision about the protocol
 - iii. informs the REC Secretariat of the final decision
 - iv. instructs the REC Staff to communicate the final decision to the researcher(s)/proponent(s)
- b. Within five (5) working days, the REC secretariat:
 - i. prepares all the necessary decision documents for release to the proponents/researchers including the Decision Letter (Ethics Clearance), when applicable
 - ii. records into the Logbook of Communications the release of said documents
- C. The tasks assigned to the REC Secretariat are done within five (5) working days from the date of the REC meeting (for full review) or the submission of review (for expedited review), while the tasks of the Member-Secretary is given three (3) working days from the date of receipt of the Summary of Reviewer's Comment and Actions Taken.

Step 3. Approval of the REC decision document.

- A. For protocols with recommendations from the committee (for full review) or the reviewers (for expedited review), the REC Chair:
 - a. ensures that all details are in place;
 - b. asks the REC Secretariat to communicate with the applicant the recommendations from the committee or the reviewers, whichever is applicable.
- B. For item 1, the REC Chair reviews the Summary of Actions Taken and to approve the protocol.
- C. For protocols with accepted final reports and signed Study Completion Reports (**EVSU REC F-48**):
 - a. the REC Secretariat prepares the Decision Letter (Ethics Clearance) (**EVSU REC F-20**) stating that researcher(s) have complied with all the requirements and standards set forth by the EVSU REC
 - b. the PRs or Ics and the REC Chair sign the Ethics Clearance,
 - c. once signed, the REC Secretariat releases to the researcher(s) their Ethics Clearance.

Step 4 – Communication of REC decision document to researcher(s)/proponent(s):

1. Within five (5) working days from the finalization of the decision forms, the REC Secretariat:
 - a. communicates, through email, the recommendations and the specific instructions to comply with the recommendations from the REC as a whole using the applicable forms:
 - i. Summary of Reviewers' Comments and Suggestions (**EVSU**

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REC F-50). The researcher(s)/proponent(s) should use this form as reference on observations of the reviewers about the protocol.

- ii. Summary of Actions Taken (*EVSU REC F-51*). The researcher(s) need to check the specific recommendations from the PRs or Ics or the REC Members and provide in the column on *Actions Taken* the specific actions done to address the recommendations as well as the specific page(s) where the introduced changes can be found
- iii. or the Decision Letter (Ethics Clearance) (*EVSU REC F-20*). The researcher(s) must take note of the specific obligations s/he/they must perform while the Ethics Clearance is still active.
- b. enters into the Logbook of Outgoing Communications (*EVSU REC F-52*) the email correspondence about the Summary of Reviewers' Comments and Suggestions (*EVSU REC F-50*) and Actions Taken (*EVSU REC F-51*) or the Decision Letter whichever is applicable;
- c. notes the receipt of the applicant.
2. The REC Chair oversees the conduct of these activities.

Step 5 – Storage of the decision document in the protocol file: The original version of the approved decision documents shall be placed inside the designated folder of each protocol. See SOP on Managing Active Files (SOP No. 24) for the details.

7. Glossary

Expedited Review Refers to 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. It shall be required also for study protocols that (1) do not entail more than minimal risk to the study participants, (2) do not have study participants belonging to a vulnerable group, and (3) do not generate vulnerability.

Full Review Refers to 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. It shall be required also for protocols that entail greater than minimal risk to participants or those that involve vulnerability issues.

8. Forms

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FORM CODE	FORM TITLE
<i>EVSU REC F-20</i>	Decision Letter (Ethics Clearance)
<i>EVSU REC F-48</i>	Study Completion Report
<i>EVSU REC F-50</i>	Summary of Reviewers' Comments and Suggestions
<i>EVSU REC F-51</i>	Summary of Actions Taken
<i>EVSU REC F-52</i>	Logbook of Outgoing Communications

9. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	May 2025	Dr. Thea C. Galos	Initial Version

10. References

- Human Use (ICH). 2016. *Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)*.
- Philippine Health Research Ethics Board (PHREB). 2015. *A Workbook for Developing Standard Operating Procedures*.
- Philippine Health Research Ethics Board (PHREB). 2017. *National Ethical Guidelines for Health and Health-Related Research*.
- Philippine Health Research Ethics Board (PHREB). 2020. *2020 PHREB Standard Operating Procedures*.
- UCI Office of Research. "Modifications to Approved Research." Available in <https://www.research.uci.edu/compliance/human-research-protections/researchers/modifications-to-approved-research.html#Level>.
- UNESCO. 2017. *Code of Conduct Social Science Research*.
- World Medical Association (WMA). 2013. *Declaration of Helsinki -Ethical Principles for Medical Research Involving Human Subjects*

Prepared by:	Reviewed and approved by:	Approved by:
Research Ethics Committee (REC)	sgd. GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	sgd. DENNIS C. DE PAZ, PhD <i>University President</i>

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	22 – Management of Incoming and Outgoing Communications	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

1. Policy Statement

Incoming and outgoing communications must be documented to monitor and track them, serving as evidence of the quality of service and operational efficiency of the REC. All communications must be accurately and appropriately logged in both a physical logbook and an electronic database. The communications related to protocols will be kept separate from the administrative ones. Incoming communications should be addressed promptly.

All incoming protocol-related submissions shall be checked for completeness by the REC Secretariat. Incomplete submissions shall be returned to the sender without processing, with a notification indicating the missing requirements.

Protocol-related documents may be submitted through **various modes**, including but not limited to: printed (hard copy) submissions, and electronic submissions via email or official platforms as prescribed by the REC.

2. Objectives of the Study

This activity aims to establish accountability and create an efficient and effective tracking system for the management of incoming and outgoing documents and communications of the REC.

3. Scope

The scope outlines the actions taken by the REC to systematically manage incoming and outgoing documents. It emphasizes the importance of organizing these communications and ensuring timely and appropriate responses from the REC. The process begins with the sorting of all incoming and outgoing communications and concludes with the proper storage or filing of these documents, ensuring easy access and retrieval for future reference.

4. Roles and Responsibilities

- A. REC Chair** is responsible for taking actions on the incoming communications of the REC.
- B. REC Secretariat** is responsible for the sorting, logging, and recording, and filing of communications of the REC both incoming and outgoing is being made by the REC Secretariat.

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5. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Sorting of both incoming/outgoing communications	<i>REC Secretariat</i>
Step 2: Logging and recording of incoming/outgoing communications	<i>REC Secretariat</i>
Step 3: Taking action on incoming communications	<i>REC Chair</i>
Step 4: Filing of incoming/outgoing communications and updating of respective Databases	<i>REC Secretariat</i>

6. Description of Procedures

Step 1. Sorting of incoming/outgoing communications. Communications that will be received by the REC includes letters, official memoranda, emails, among others. The REC secretary will classify the communications whether it is protocol related or not. If protocol-related, the secretary identifies if it is an initial submission, resubmission, post-approval submissions, or notification of decision and responds accordingly depending on the type of communications. While if it is process-related communications, (i.e. letters, official memoranda, inquiries), the REC secretary identifies the type of communication for more accurate response. Similar process applies to communications received via email. Upon receipt of protocol-related submissions, the REC Secretariat shall verify whether all required documents and forms are complete in accordance with REC submission requirements. If the submission is incomplete, it shall be returned to the proponent without further processing, with appropriate instructions for compliance.

Step 2. Logging and recording of incoming/outgoing communications. After identifying the type of incoming or outgoing communication, the REC secretary records it in the Logbook of Incoming (**EVSU REC F-53**). and Outgoing Communications (**EVSU REC F-52**). The incoming logbook should include the following information: (a) title of the study or communication, (b) name of the researcher or person submitting the documents, (c) date and time of submission, (d) type of document, (e) name of the recipient, and (f) actions taken. For communications received via email, the REC secretary sends an initial response and informs the Chair of REC about the communication for appropriate action. All email communications will be logged in the incoming/outgoing logbook, noting that they were received through email.

Step 3 . Taking Action on Incoming Communications. The Chair of the REC is responsible for making the official response and will sign all outgoing communications. If the Chair is on leave, the Vice-Chair is authorized and sign outgoing communications with the Chair's approval. The REC secretary will send the response to the original source or deliver the outgoing communication to the intended

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recipient. All outgoing documents will be logged in the incoming/outgoing logbook. The outgoing logbook should include the following details: (a) title of the study or communication, (b) name of the researcher or recipient of the outgoing documents, (c) date and time the document was released, (d) type of document, (e) name of the Secretariat releasing the document, and (f) remarks.

Step 4. Filing of incoming/outgoing communications and updating of respective Databases. The REC secretary organizes all communications in their appropriate folders. Protocol-related documents will be placed in the designated protocol folder, and the protocol file index and database will be updated accordingly. For process-related documents, including SOPs, member files, meeting agendas, minutes, and other administrative materials, the Secretariat will store and file them in their respective folders.

7. Glossary

Incoming Communications	- are documents which are directed to and received at the REC office.
Outgoing Communications	- are documents generated within the REC office intended for individuals or offices related to the operations of the REC.
Process-related File/Documents	- documents that pertain to the operations of the REC and are not directly related to a study or protocol. Examples include the SOPs, Membership files, Agenda and minutes files, administrative issuances.
Protocol-related File/Documents	- consist of all other documents aside from the proposal/protocol itself that are required to be submitted for review, e.g., Informed Consent Form, Survey Questionnaire, CV of proponent, advertisements, In-depth Interview Guide Questions Indexing System.

8. Forms

FORM CODE	FORM TITLE
<i>EVSU REC F-52</i>	Logbook of Outgoing Communications
<i>EVSU REC F-53</i>	Logbook of Incoming Communications

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9. History of SOP

<i>VERSION NO.</i>	<i>DATE</i>	<i>AUTHORS</i>	<i>MAIN CHANGE</i>
01	May 2025	Prof. Bernard Niño Q. Membrebe	Initial Version

10. 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 2017
- Philippine Health Research Ethics Board Standard Operating Procedures 2020
- Mariano Marcos Memorial Hospital and Medical Center Research Ethics Review Committee Standard Operating Procedures 2021

Prepared by:	Reviewed and approved by:	Approved by:
<i>Research Ethics Committee (REC)</i>	sgd. GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	sgd. DENNIS C. DE PAZ, PhD <i>University President</i>

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	23 – Management of Active Files	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

1. Policy Statement

Active files shall be kept and stored in secured cabinets, arranged in a safe and orderly manner that allows easy identification and retrieval of accurately recorded results. Access to the active files shall be governed by the SOP on Managing Access to Confidential Files (SOP No. 25).

2. Objectives of the Study

The management of active files ensures accessibility, easy retrieval of current files, and protection of those that require confidentiality. Further, the research data and files will be protected from hazards and other catastrophic events.

3. Scope

This SOP covers procedures related and non-related to protocols accepted for review, undergoing review, or have been approved by the REC. This SOP begins with the classification and coding of active files and ends with the periodic updating of the file.

4. Roles and Responsibilities

A. REC Secretariat is responsible for the sorting, logging, and recording, and filing of active files of the REC.

5. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Classification and coding of Active Files	<i>REC Secretariat</i>
Step 2: Preparation of the Protocol Folder	<i>REC Secretariat</i>
Step 3: Periodic updating of the Protocol File	<i>REC Secretariat</i>

6. Description of Procedures

Step 1. Classification and Coding of Active Files: The REC secretariat under the supervision of the Member-Secretary classifies active files as follows:

- A. Initial Submission
- B. Resubmission
- C. Progress Report
- D. Amendment
- E. Protocol Deviation
- F. Protocol Violation
- G. SAE Serious Adverse Event (SAE)
- H. Suspected Unexpected Serious Adverse Reaction – (SUSAR)
- I. Early Termination

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J. Continuing Review

K. Final Report/ Close Out Report

The REC Secretariat assigns a code to the Initial Submission and indicates the same for the rest of the submissions related to the initial submission (refer to SOP 06 Management of Initial Submissions).

Step 2. Preparation of the Protocol Folder: The REC Secretariat files all documents pertaining to a study in a vertical folder that is labeled on the front cover and along the spine with: **Protocol Code- Study Title – Proponent’s Family Name – Sponsor or Funding Agency – Institution Affiliation**. The REC Secretariat attaches a protocol index on the inside front cover that indicates the contents of the folder.

Step 3. Periodic Updating of the Protocol File: The REC Secretariat ensures that the documents are filed in chronological order such that the most recent documents are topmost for files and rightmost for hanging filing/files. These documents include the following:

- A. Study Protocol (Original and Revised) versions
- B. Informed Consent (Original and Revised) versions
- C. Reports: Progress, Protocol Deviation/Violation, SAE/SUSAR, Final, Amendment, Early Termination, Site Visit Reports
- D. Assessment Forms for each of the submitted and reviewed reports which should be signed and dated
- E. Excerpts of Minutes of Meetings when the protocol and reports were included in the agenda
- F. Decision and Approval Letters
- G. Communications

The REC Secretariat updates the protocol index each time a new document is added to the file. The protocol folder is periodically checked for orderliness and completeness. Precautionary measures must be employed to ensure safety and security of research data and records from natural and man-made hazards such as possible corruption of computer files.

7. Glossary

Incoming Communications

- Documents which are directed to and received at the REC office.

Outgoing Communications

- Documents generated within the REC office intended for individuals or offices related to the operations of the REC.

Process-related File/Documents

- Documents that pertain to the operations of the REC and are not directly related to a study or protocol. Examples include the SOPs, Membership files, Agenda and minutes files, administrative issuances.

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**Protocol-related
File/Documents**

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

8. History of SOP

<i>VERSION NO.</i>	<i>DATE</i>	<i>AUTHORS</i>	<i>MAIN CHANGE</i>
01	May 2025	Prof. Segundina Devota Dilao	Initial Version

9. 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 2017
Philippine Health Research Ethics Board Standard Operating Procedures 2020
Mariano Marcos Memorial Hospital and Medical Center Research Ethics Review Committee Standard Operating Procedures 2021

Prepared by:	Reviewed and approved by:	Approved by:
<i>Research Ethics Committee (REC)</i>	sgd. GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	sgd. DENNIS C. DE PAZ, PhD <i>University President</i>

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	24 – Archiving	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

1. Policy Statement

The archive shall include physical and electronic copies of manuscripts of approved and/or accepted Final Reports, approved Early Termination reports, and reports whose researcher has not submitted a response to the REC recommendation after 60 working days.

A separate physical storage shall be provided for the physical manuscripts, while a separate external hard drive shall be provided for the electronic documents. These documents shall be kept for three (3) years. After three (3) years, these documents shall be expunged from the archive.

2. Objectives of the Activity

The archive will ensure an efficient retrieval of information for compliance with national and international standards.

3. Scope

This SOP includes procedures related to storage, retrieval, and disposal of documents that are classified as inactive, terminated or completed. This SOP begins with the acceptance of final or early termination reports and identification of a manuscript as inactive to the inclusion of the files in the archives and update of the protocol database, and ends with the expunging of the manuscripts.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Acceptance of Final or Early Termination Reports (SOP 13 on Review of Final Reports, SOP 14 Review of Early Termination Reports, and Identification of a Protocol as Inactive)	<i>REC Chair and Members</i>
Step 2: Updating of corresponding folder	<i>REC Secretariat</i>
Step 3: Transfer of the protocol folder to the archives and update of the Protocol Database	<i>REC Secretariat</i>
Step 4: Approval of request for information from archived protocol (SOP 25 Management of Access to Confidential Files)	<i>REC Chair and Members</i>
Step 5: Expunging of files from the archive and update of the Protocol Database	<i>REC Secretariat</i>

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	24 – Archiving	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

5. Description of Procedures

Step 1. Acceptance of Final or Early Termination Reports. The REC members approve or accept the final report or early termination report during a meeting (SOP13 Review of Final, Report; SOP 14 Review of an Early Termination Report). In the identification of an Inactive File, the REC staff informs the Member Secretary of the failure of a concerned researcher(s) to respond to the recommendations of the REC in the last 3 months during which time the researcher(s) has been appropriately reminded of the requirement. This is included in the agenda of the next meeting where the protocol is declared inactive.

Step 2. Updating of Corresponding Folder. The REC Secretariat files the Final or Early termination report in the corresponding protocol folder, including the excerpts of the minutes that approved the report or declared the protocol as inactive.

Step 3. Transfer of the Protocol Folder in the Archives and Update of the Protocol Database. The REC Secretariat checks whether the documents listed in the protocol file index are complete and removes extraneous documents. Thence, the staff transfers the folder to the archive section and updates the protocol database to reflect that such has been archived.

Step 4: Request for Information from the Archive. The requesting party will accomplish Archived File Request Form (EVSU REC F-54). The REC Secretariat will inform the Member-Secretary of the request and will be added to the agenda in the next meeting for deliberation.

Step 4. Approval of Request for Information from an Archived Protocol. The REC will deliberate if the request can be approved or not. Decisions on this matter will be based on SOP 25 Management of Access to Confidential Files. If a request is not granted, the REC Secretariat will provide the requesting party with a copy of the portion of the minutes stating the reason for the denial of their request.

Step 5. Expunging of Files from the Archive and Update of the Protocol Database. All files that have reached the three-year storage limit will be deleted from the hard drive of the archive, while hard copies will be shredded. The REC Secretary will then update the protocol database to show that it has been permanently deleted.

6. Forms

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<i>FORM CODE</i>	<i>FORM TITLE</i>
<i>EVSU REC F-54</i>	Archive File Request

7. History of SOP

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01	May 2025	Prof. Stephen Paul G. Cajigas	Initial Version

8. 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 2017
Philippine Health Research Ethics Board Standard Operating Procedures 2020
Mariano Marcos Memorial Hospital and Medical Center Research Ethics Review Committee Standard Operating Procedures 2021

Prepared by:	Reviewed and approved by:	Approved by:
<i>Research Ethics Committee (REC)</i>	sgd.	sgd.
	GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	DENNIS C. DE PAZ, PhD <i>University President</i>

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	25 – Management of Access to Confidential Files	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

1. Policy Statement

Access to the REC confidential files shall be regulated and limited to REC members and REO Head. Other persons with legitimate interest in these files (e.g. institutional authorities, regulatory agencies, sponsors) shall be allowed to access specific files with proper justification. Researcher(s) shall be allowed access only to their own protocol files upon request.

2. Objective of the Activity

Management of access to confidential files helps protect the intellectual property rights of researchers and enhances the credibility and integrity of the REC.

3. Scope

This SOP includes procedures related request for access, approval, supervision of retrieval, and return of confidential files in the safekeeping of the REC.

4. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Acceptance and logging of request for access to confidential files	<i>REC Secretariat</i>
Step 2: Approval of request for access to confidential files.	<i>REO Head, REC Chair</i>
Step 3: Supervision of use of retrieved document(s).	<i>REO</i>
Step 4: Return of document(s).	<i>REC</i>

5. Description of Procedures

Step 1. Acceptance and logging of request for access to confidential files

A. Who can request for information?

- The incumbent members of the REC, upon an approved motion in an REC meeting, may access active and archived files of the REC.
- Researcher(s) may request for access of their active and/or archived files.
- Sponsors may request access to active and/or archived files of research/studies they have sponsored.
- Other interested parties (institutional authorities, regulatory agencies) may also request access to active and/or archived files.

Request for access will start with filling-out a Request Access Form (**EVSU REC F-55**). The REC Secretariat then logs this request, then checks who is approving authority for such request.

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Step 2. Approval of request for access to confidential files

A. Request for access to confidential files may be approved by the REC Chair for any of the following:

1. Requesting party is the researcher/s themselves, or
2. Research/study was exempt from or expedited review.

If the research/study was under full review, the REO Secretariat that received the request must include the request in the agenda of the next REC meeting.

B. The decision on the request will be communicated to the requesting party through email.

Step 3. Supervision of use of retrieved document(s).

A. If a request for information from an archived protocol is granted, the REC Secretariat will access the file of the concerned protocol. If the information requested is only a portion of a page in the protocol, the REC Secretariat will only provide such portion. Else, entire page(s) may be provided. The requesting party may only peruse the documents in the premises of the Research Ethics Office (REO).

Step 4. Return of document(s).

A. When the requesting party is done perusing the document(s), the REO Staff must ensure that the entire document(s) are returned.

6. Forms

FORM CODE	FORM TITLE
<i>EVSU REC F-55</i>	Request Access Form

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	May 2025	Prof. Stephen Paul G. Cajigas	Initial Version

8. References

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:	Reviewed and approved by:	Approved by:
<i>Research Ethics Committee (REC)</i>	sgd. GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	sgd. DENNIS C. DE PAZ, PhD <i>University President</i>

	EASTERN VISAYAS STATE UNIVERSITY RESEARCH ETHICS COMMITTEE		
	26 – Management of Queries and Complaints	Version No:	01-00
		Approval Date:	06/27/26
		Effective Date:	08/17/26

1. Policy Statement

All queries and complaints from clients, patients, or research participants shall be addressed promptly and appropriately, with due diligence. The nature of each query will determine whether it can be resolved by the REC secretariat or needs to be referred to the primary reviewers of the specific protocol. Queries that can be resolved by the REC secretariat will be addressed immediately, while those requiring further expertise will be referred to the primary reviewers. All complaints will be referred to the REC Chair for an initial risk assessment. Complaints deemed to be of minimal risk will be referred to the primary reviewers for resolution. Complaints assessed as more than minimal risk will be escalated to a special meeting within 48 hours, involving the committee en banc, with the primary reviewers leading the discussion.

2. Objective of the Activity

Managing queries and complaints aims to promote public trust and confidence in the institution, particularly within the EVSU Research Ethics Committee (REC), by ensuring transparency and responsiveness. Additionally, it seeks to safeguard the rights and well-being of all clients, patients, and research participants throughout the query and complaint management process.

3. Scope

This SOP encompasses the management of queries and complaints from research participants, their families, or any other stakeholders involved in studies that have received ethical approval from the REC. It begins with the receipt, logging, and acknowledgment of queries and complaints and extends to the resolution, documentation, and inclusion of these matters in the agenda of the REC meeting. All queries and complaints must be received through designated channels and logged in a secure database with a unique identifier. An acknowledgment receipt is sent within 24 hours, including the expected timeline for resolution and contact details. The REC Secretariat conducts an initial review to categorize the query or complaint, escalating urgent issues to the REC Chair. A thorough investigation is conducted, including reviewing documents, interviewing parties, and consulting experts if necessary. A formal response is drafted and communicated to the complainant, with all steps documented. A summary of the query or complaint and its resolution is included in the next REC meeting agenda for review and systemic improvement recommendations. Follow-up communication ensures complainant satisfaction, and feedback is logged for continuous SOP improvement.

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	26 – Management of Queries and Complaints	Version No:	01-00
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		Effective Date:	08/17/26

4. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Receipt, logging, and acknowledgement of queries and complaints (SOP on Managing REC Incoming and Outgoing Communications)	<i>REC Secretariat</i>
Step 2: Referral of query or complaint to competent authority. 2.1 Referral of protocol-related query to primary reviewers. 2.2. Referral of all complaints to the REC Chair	<i>REC Secretariat</i>
Step 3: Formulation of response 3.1. Protocol-related queries 3.2. Minimal-risk complaints 3.3. More than minimal risk complaints : en-banc committee	<i>Primary Reviewers</i> <i>Primary Reviewers</i> <i>REC Chair and REC members</i>
Step 4: Communication of response	<i>REC Secretariat</i>
Step 5: Logging of the response and inclusion in the agenda of the REC meeting	<i>REC Secretariat</i>

5. Description of Procedures

Step 1. Receipt, logging, and acknowledgement of queries and complaints: The REC will maintain a logbook dedicated to queries and complaints which will include date, time, name of concerned party, specific protocol number and title, name of researcher(s), and nature of query or complainants shall accomplish the form on Query/Complaint (**EVSU REC F-56**) to be properly coded by the REC Secretary.

Step 2. Referral of query or complaint to competent authority. The REC Secretariat refers queries and complaints to the REC Chair to determine the level of risk affected by the issue. Non-protocol related queries or complaints to the REC Secretary to the REC Chair. Minimal risk complaints are referred to the Primary Reviewers of the concerned protocol as well as other protocol related queries. Complaints that involve more than minimal risk are referred to the REC Members through a special meeting that shall be called within three (3) working days. The REC Secretary notifies the concerned Primary Reviewers that they will lead the discussion and provides relevant materials to them in advance as reference.

Step 3. Formulation of response. For queries, the Primary Reviewers shall accomplish the portion on “Action Taken” on the Query/Complaints. For minimal risk

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complaints, the Primary Reviewers accomplish Query/Complaints form. For more than minimal risk, the REC may choose any of the following options: a. Constitute a site visit team to gather more information, verification, and clarification regarding the source and cause/s of the complaint for its resolution; b. Designate the Primary Reviewers to meet with the complainants and the researcher (preferably separately) for clarification of issues and obtain suggestions for resolution; and c. Formulate recommendation, if satisfied with the adequacy of information and/or – request for explanation/justification from the researcher – accept request/demand of participant – recommend suspension of further recruitment – recommend amendment of protocol and re-consent of participants – others.

Step 4. Communication of response. The REC Secretariat through the guidance of the Member-Secretary, prepares the official communication of response to queries and complaints using the form for Query/Complaint Response to be duly signed by the REC Chair.

Step 5. Logging of the response and inclusion in the agenda of the REC meeting. The REC Secretariat stores the signed forms in the protocol folder.

6. Forms

<i>FORM CODE</i>	<i>FORM TITLE</i>
<i>EVSU REC-55</i>	Request for Access to Confidential Files Form
<i>EVSU REC F-56</i>	Query/Complaint

7. History of SOP

<i>VERSION NO.</i>	<i>DATE</i>	<i>AUTHORS</i>	<i>MAIN CHANGE</i>
01	May 2025	Prof. Christopher C. Bacungan	Initial Version

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8. References

- EVHRDC (2022). Eastern Visayas Health Research and Development Consortium- Ethics Review Committee Standard Operating Procedure (SOP) Manual
- PHREB (2022). National Ethical Guidelines for Research Involving Human Participants.
- PHREB (2020). Philippine Health Research Ethics Board Standard Operating Procedures.
- USC (2022). University of San Carlos Research Ethics Review Committee SOP Manual

Prepared by:	Reviewed and approved by:	Approved by:
<i>Research Ethics Committee (REC)</i>	sgd.	sgd.
	GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	DENNIS C. DE PAZ, PhD <i>University President</i>

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1. Policy Statement

The REC shall designate a team to regularly review its set of SOPs every two (2) years or as deemed necessary to determine its continuing relevance and effectiveness to its operations.

2. Objective of the Activity

This SOP aims to ensure efficiency, transparency, and consistency of EVSU REC operations. The SOP manual needs to be periodically reviewed to determine the need for new SOPs or revision in order to respond to emerging operational issues of the EVSU REC.

3. Scope

This SOP applies to all EVSU REC activities involved in the development of its SOPs and their revisions as published and distributed by EVSU. This SOP begins with the proposal and approval for writing of a new SOP or revising existing SOPs and ends with the inclusion of the new or revised SOP in the SOP Manual and its dissemination.

4. Roles and Responsibilities

A. REC Member/s Proponent/s initiate/s the filing of proposals for new SOPs or revisions to the existing ones; drafts the new or revised SOP; and submits the draft version to the REC Chair for review.

B. REC Secretariat is responsible for receiving and verifying all SOP proposals, whether for new documents or revisions; checks for the completeness of each submission; compares submissions against existing SOPs or the SOP Manual; confirms that proposed changes are clearly marked (additions highlighted, deletions struck through); acknowledges receipt of all documents; code the SOPs appropriately; notifies the REC Chair of new requests; forwards approved electronic copies of SOPs to the Quality Assurance Office for upload; stores the physical copies; and updates the relevant database.

C. REC Chair includes the SOP proposals and draft versions to meeting agenda for consideration; directs the proponent to draft new or revised SOPs once approved by the EVSU REC; and ensures the dissemination of all approved SOPs.

D. REC Members evaluates and determines the merits of both the initial proposal and the subsequent draft during a meeting, ultimately approving them for further progression.

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5. Workflow

<i>ACTIVITY</i>	<i>RESPONSIBILITY</i>
Step 1: Proposal and approval for revision or writing of a new SOP	<i>Any REC Member, REC Secretariat, REC Chair</i>
Step 2: Drafting of the new or revised SOP	<i>REC Chair, REC Member-proponent, REC Secretariat</i>
Step 3: Review and approval of SOP	<i>REC Chair, REC Members, Member-Secretary, EVSU President</i>
Step 4: Inclusion of the new or revised SOP in the SOP Manual and its dissemination	<i>REC Secretariat, REC Chair</i>

6. Description of Procedures

Step 1. Proposal and approval for revision or writing of a new SOP:

1. REC Member/s propose the writing of a new SOP or the revision of an existing SOP on the basis of any of the following:
 - a. obsolescence;
 - b. recommended by PHREB; updating;
 - c. new operational issues encountered;
 - d. other substantial justification/s.
2. The process of initiating the writing of a new SOP or the revision of an existing SOP is as follows:
 - a. The REC Member-proponent files with the REC Staff the proposal, which shall contain the following:
 - i. the statement of the new SOP or revision of an existing SOP;
 - ii. the reason for the new SOP or revision of an existing SOP;
 - iii. the statement of any untoward effects with original protocol;
 - iv. the statement of expected untoward effects because of the new SOP or revision of an existing SOP.
 - b. After receipt of the filing, the REC Staff...
 - i. confirms the request of the REC Member for the writing of a new SOP or the revision of an existing SOP.
 - ii. checks the completeness of the contents of the proposal.
 - iii. compares the proposal and the SOP Manual (for new SOP) or existing SOP (for revision of an existing SOP), as the case maybe, and related documents.
 - iv. checks that the proposed revision should be bold or highlighted and the deleted matter should be made strikethrough for easy verification.
 - v. stamps, writes the date, and acknowledges receipt of the proposal.
3. The process in approving the writing of a new SOP or the revision of an existing SOP is as follows:

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- a. Upon receipt of the proposal and after comparing as afore-stated, the REC Staff notifies the REC Chair about it within two (2) working days from the acknowledgment of receipt of the proposal.
- b. The REC Chair includes in the agenda the consideration of the proposal (SOP on Preparing the Meeting Agenda [SOP No. 19]).
- c. The EVSU REC determines the merits of the proposal during the meeting (SOP on the Conduct of Special and Regular Meetings [SOP No. 20]).

Step 2. Drafting of the new or revised SOP:

1. The REC Chair directs the REC Member who proposed the proposal to draft the new or revised SOP as approved by the EVSU REC.
2. The REC Member-proponent drafts the new or revised SOP approved by the EVSU REC.
3. In the drafting of a new or revised SOP, the REC Member complies with the following contents:
 - a. number and version
 - b. title
 - c. policy statement
 - d. objective/s of the activity
 - e. scope
 - f. responsibilities
 - g. workflow
 - h. detailed instructions
 - i. glossary
 - j. forms
 - k. document history
 - l. references
 - m. appendices
4. The EVSU REC adopts the SOPs by using the following code: For minor change/s: **SOP XX-YY-ZZ**, where XX can refer to the SOP number, YY the Version of the SOP (starting from 01), ZZ minor changes in the SOP (starting from 0), i.e. SOP 01/01-00.

For major change/s:

SOP XX/YY, where XX can refer to the SOP number, YY the Version of the SOP (starting from 01).

5. The page of the SOP shall look like as follows:
 - a. name and logo of EVSU
 - b. name of EVSU REC
 - c. SOP code

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- d. SOP number and title
- e. approval date
- f. effective date
- g. page number
- h. SOP content and a footer indicating the file name, directory and path included, of the corresponding electronic document, if the file can be accessed through a website or uniform resource locator (URL) or a server

Step 3. Review and approval of SOP:

1. The REC Member-proponent drafts a version to be submitted to the REC Chair.
2. The REC Chair includes the proposal in the REC meeting agenda (SOP on Preparing the Meeting Agenda [SOP No. 19]).
3. The EVSU REC determines the merits of the draft version during the meeting (SOP on the Conduct of Special and Regular Meetings [SOP No. 20]) based on the following:
 - a. determination of favorable action;
 - b. deferment;
 - c. documentation of action.
4. In case the draft version is approved by the EVSU REC, the REC Secretariat sends it to the following for signature within the corresponding periods: Member Secretary (within three [3] working days from approval); REC Chair (within two [2] working days from signing by the Member Secretary; Research Director (within two [2] working days from signing by the REC Chair; EVSU President (within three [3] working days from signing by the REC Chair), otherwise, the REC Member-proponent shall be informed of the action taken by the EVSU REC within five (5) working days from the meeting of the EVSU REC.
5. The approved draft version contains the signature and date of signing of the REC Chair, and the EVSU President.
6. For purposes of determining the approved date of the approved draft version, it is the approval by the EVSU REC which shall be considered. The signatures of the REC Chair, the Research Director, and the EVSU President are only for the formal approval and shall not be considered in determining the approved date.
7. The approved SOP shall take effect twenty (20) working days following the posting of the electronic copy of the new or revised SOP by the Quality Assurance Office unless otherwise provided by the EVSU REC.

Step 4. Inclusion of the new or revised SOP in the SOP Manual and its dissemination:

1. The new or revised SOP will be made available through the following:
 - a. hard copy;

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- b. electronic copy.
2. The REC Secretariat serves as the official custodian of the approved aforementioned copies of the new or revised SOP.
3. The printed copy of the new or revised SOP is available at the REC office.
4. Within two (2) working days from the signing by the EVSU President, the REC Secretariat, upon the instruction of the REC Chair...
 - a. forwards the electronic copy of the new or revised SOP to the Quality Assurance Office with a letter of request:
 - i. to upload it within three (3) working days in the documents management system; and
 - ii. thereafter to immediately notify the EVSU REC, through the REC Chair, the date when the said electronic copy is uploaded.
5. One (1) working day after the notification of the successful uploading of the electronic copy of the new or revised SOP by the Quality Assurance Office, the REC Chair notifies the academic community about the availability of the copy of the new or revised SOP.
6. In reproducing the new or revised SOP, the following procedure is observed:
 - a. reproduction must be based on a request to be approved by the REC Chair, based on the following considerations:
 - i. valid purpose;
 - ii. compliance with EVSU's existing policies, rules, and regulations; and
 - iii. other condition/s that may be approved by the EVSU REC in a regular meeting.
 - b. The REC Secretariat stamps on the reproduced copy, indicating that it is just a duplicate copy.
7. In case of a revised SOP, the old version retired or superseded shall be stored separately from the new version, the REC Secretariat...
 - a. physically removes the old version of the SOP from its location and physically transfers it to the archiving section (SOP on Archiving of Terminated and Inactive Files [SOP No. 25]); replaces the revised SOP with the newly approved version.
 - b. updates the computer system unit and back-up files accordingly.

7. Glossary

Major change Any change in the policy statement and/or objectives of the SOP.

Minor change Any change which does not involve the policy statement and/or objectives of the SOP

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Proposal

A written suggestion to make a new SOP or to revise an existing SOP.

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	May 2025	Dr. Maria Cecelia A. Gomez	Initial Version

9. References

- CIOMS. (2016). International ethical guidelines for health-related research involving humans.
- Eastern Visayas Health Research and Development Consortium Ethics Review Committee (EVHRDC-ERC). (2024). Standard operating procedure.
- International Conference on Harmonization. (1996). Guidance on good clinical practice (ICH GCP).
- Philippine Health Research Ethics Board (PHREB). (2015). A workbook for developing standard operating procedures.
- Philippine Health Research Ethics Board (PHREB). (2017). National ethical guidelines for health and health-related research.
- Philippine Health Research Ethics Board (PHREB). (2020). 2020 PHREB Standard operating procedures.
- UCI Office of Research. “Modifications to Approved Research.” Available in <https://www.research.uci.edu/compliance/human-research-protections/researchers/modifications-to-approved-research.html#Level>.
- UNESCO. (2017.) Code of conduct social science research.
- World Health Organization (WHO). (2011). Standards and operational guidance for ethics review of health-related research with human participants.
- World Medical Association (WMA). (2013). Declaration of Helsinki -Ethical principles for medical research involving human subjects.

Prepared by:	Reviewed and approved by:	Approved by:
<i>Research Ethics Committee (REC)</i>	sgd. GILBERT ANTHONY O. ABAÑO, MAN, RN <i>REC Chairperson</i>	sgd. DENNIS C. DE PAZ, PhD <i>University President</i>



EASTERN VISAYAS STATE UNIVERSITY

Building Globally Competitive Professionals...

VISION

A premier institution of learning in the ASEAN region by 2040

MISSION

*Develop Competent and Productive Professionals with Positive
Values for Sustainable Development*

CORE VALUES

E – Excellence

V – Virtue

S – Service

U – Unity



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