ETHICS STANDARD OPERATING PROCEDURES

EAC RESEARCH ETHICS REVIEW COMMITTEE

2025 Edition

10th FLOOR, BLDG 7, 1113-1117 SAN MARCELINO ST., PACO, MANILA
EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph
TEL. NO.: (632) 8521 2710 local 5388

PREFACE

Research constitutes one of the three fundamental functions of higher educational institutions (HEIs), alongside instruction and extension. In alignment with the philosophy and objectives of Emilio Aguinaldo College (EAC) in pursuit of its Vision-Mission, the Yaman Lahi Foundation Inc.,- Emilio Aguinaldo College and the Center for Research and Publication (CRP) endeavors to address the challenges and demands posed by evolving socio-economic conditions in the country.

Established by the EAC Board of Trustees in 1980, the Yaman Lahi Foundation Inc. (YLFI) was formed to manage and operate the Manila and Cavite EAC Campuses. The YLFI has maintained its status as a Certified DOST Science Foundation since 1995 and in September 2025, DOST honored YLFI-EAC with the Karangalang Pilak Award during the Gawad Paninindigan sa Agham. This award was given to YLFI-EAC for its 25-year commitment to advancing science, technology, and innovation in the Philippines. The Gawad Paninindigan sa Agham is the highest accolade given by DOST to Certified Science Foundations that have made significant contributions to education, research, and community development.

To uphold the quality of research at EAC, this Ethics Standard Operating Procedures (SOPs) manual serves as a fundamental framework for the rigorous review of ethical procedures and aims to guide and oversee the activities of the EAC Research Ethics Review Committee.

Prior to the formation of the YLFI- EAC Research Ethics Review Committee, various component panels operated under existing standard operating procedures, which have now been superseded. These earlier guidelines contributed to the formulation of this comprehensive integrated manual.

The SOPs provided herein are structured to encompass the objective, scope, responsibilities, workflow, and specific instructions. Additionally, supplemental materials, including forms and references, are included to assist users in executing these procedures effectively.

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FORMS

10th FLOOR, BLDG 7, 1113-1117 SAN MARCELINO ST., PACO, MANILA
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1. CONSTITUTION OF THE EAC RESEARCH ETHICS REVIEW COMMITTEE (RERC)

1.1. Purpose

The EAC Research Ethics Review Committee (EACRERC) is an independent body constituted of medical and non-medical professionals, whose responsibility is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial and/or research study, and to provide public assurance of that protection, and among other things like reviewing, approving or providing a favorable opinion on the trial and/or research protocol, the suitability of the investigator(s), facilities, and the method and materials to be used in obtaining and documenting informed consent for human trial subjects.

While the EACRERC operates under the Office of the President and is in coordination with the Center for Research and Publication, it shall maintain its independence and uphold its competence and decision-making authority as defined in the international and national guidelines.

1.2. Scope

1.2.1. The general function and obligations of the EACRERC shall be to:

- review research project proposals and issue ethical clearance/certificates
- monitoring ongoing studies especially information about any serious adverse effects
- evaluate, comment, guide and approve amendments to the protocol
- evaluate and comment on the final report/summary of the study's findings and conclusions

1.2.2. The EACRERC reviews and monitors research that involves:

- Protocols developed by other HEIs or external agencies or organizations and independent researchers utilizing patients or human subjects participants within the Emilio Aguinaldo College.
- Protocols developed by EAC faculty members, learners, and staff utilizing patients or humans as subject participants within the EAC.
- Protocol developed by other HEIs, external agencies or organizations, external independent researchers, EAC faculty members, learners, and staff utilizing patients or humans as subject participants in areas outside of the EAC campus.

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1.2.3. The overall responsibility of the EACRERC members, officers, and secretariat is to understand and implement the SOP's of the Emilio Aguinaldo College.

1.3. Ethical Basis

1.3.1. The EACRERC is guided in its decision-making by the ethical principles and procedures stipulated in the following international guidelines and documents:

- Declaration of Helsinki (2008 and other latest editions/revisions)
- Council for International Organization of Medical Sciences (CIOMS) 2002, 2009, & 2016
- Operational Guidelines for Ethics Committees that Review Biomedical Research by the World Health Organization (WHO)
- Standard Operational Guidelines for Ethics Review of Health-Related Research with Human Participants by the World Health Organization (WHO)
- International Conference on Harmonization of Good Clinical Practice (ICH-GCP).

1.3.2. The EACRERC shall function in accordance with the national laws, regulations, and guidelines such as the:

- National Ethical Guidelines for Health and Health-Related Research 2017 by the Philippine Health Research Ethics Board (PHREB)
- Philippine Food and Drug Authority regulations and other relevant laws and regulations

1.3.3. The EACRERC recognizes that the protocols it approves may also be approved by the national and/or local accredited ethics committee prior to their implementation in specific localities or areas.

1.3.4. Though EACRERC recognizes approved protocols from other countries, the decision of the EACRERC still holds the authority to approve or disapprove the protocols to be conducted in the EAC campus.

1.3.5. Regulations and requirements of the sponsor countries conducting global protocols in the Philippines may be considered provided that EAC is a co-investigator or primary proponent of such research project.

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1.3.6. The EACRERC takes initiative to be informed, as appropriate, by the national or HEIs ethics committees and researchers of the impact of the research that has been approved by the EACRERC.

1.3.7. That all research involving human participants shall undergo ethics review by the EACRERC.

TERMS OF REFERENCE

The EAC Research Director shall attach in the appointment letter the function, scope of work, and the confidentiality, conflict of interest agreement form. The EAC Research Director (RD) shall also indicate in the appointment letter the condition of the appointment. After the member receives his/her appointment letter, the EAC RD shall provide the new member with the general policies and guidelines for the Research Ethics Review (RER) Committee including the EACRERC SOP. After one year, their appointment may be renewed by the EAC RD upon recommendation of the Dean of RER Chair for up to three (3) consecutive years.

To strive for continuity, maintenance of expertise and to enable participation of new members with fresh outlook, the EAC RD shall yearly announce a call for applicants for research ethics reviewers.

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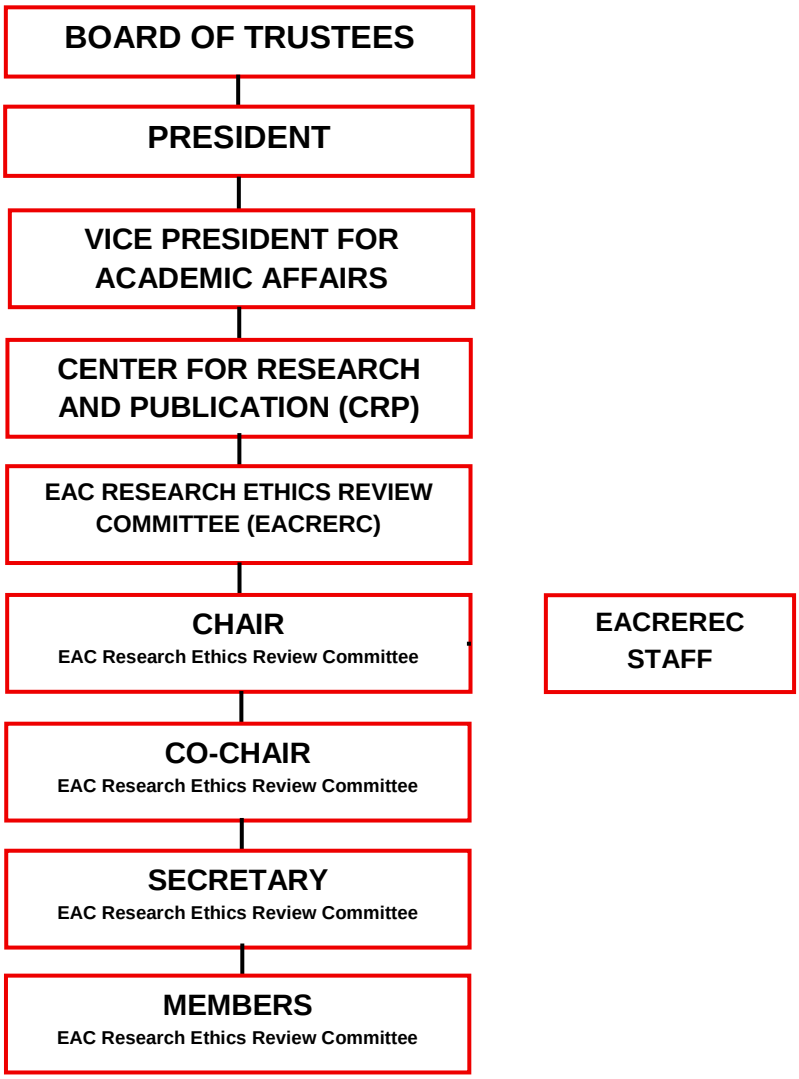
Figure 1. Organizational Structure where EACRERC Belongs



The organizational structure illustrates that the Center for Research and Publication (CRP) provides administrative oversight to the EAC Research Ethics Review Committee (EACRERC). Crucially, the EACRERC maintains its independence in carrying out its mandate to review and monitor research protocols for ethical compliance.

1.1. Policy Statement

According to EACRERC SOP 2025 Chapter 1, Section 2 titled Scope, Composition, & Structure, it is the responsibility of the EAC Research Director to formally endorse the appointment of the RER committee members to the President, Vice-President of Academic Affairs & and Vice-President of Administration. Members are selected based on their professional and personal capabilities, their ethical and scientific knowledge and expertise, as well as their willingness to volunteer and extend their time and effort to perform their functions in the EACRERC committee. The EACRERC committee is composed of at least 5 members. Membership includes persons whose primary field of specialization or expertise is in medical science, at least one member who is a general practitioner in medicine, at least one who is in a non- medical/non-scientific area, and at least one non-affiliated member. Independent consultants are invited whenever necessary to provide expert opinions on the protocol under review. Meanwhile, alternate members are invited to fulfill the requirement for quorum in the event of absence of regular EACRERC members. Members shall have prior training in Good Clinical Practice (GCP), Basic Research Ethics, Research Ethics in the Social Sciences, Ethics Standard Operating Procedures (SOPs), Research Methodology, and Research Ethics, or should be willing to undergo such training during their membership. Research Ethics Reviewers shall sign and submit confidentiality and conflict of interest agreement and curriculum vitae. Appointment of members may serve up to three (3) years.

1.2. Objective of the Activity

The selection and appointment of EACRERC members ensures that the composition of the EACRERC complies with the international, national and institutional guidelines and that appropriate expertise is taken into consideration.

1.3. Scope

This SOP is specifically applied to the selection of the members of EACRERC. This SOP begins with the call for application by the EAC Research Director and ends with the dissemination of the appointment letter of qualified applicants.

1.4. Workflow

Process Flow	Activity	Responsibility
Step 1	Call for applications	Research Director or EACRER-Chair
Step 2	Evaluation of qualification and interview	Research Director or EACRER-Chair

Step 3	Submission of endorsement letter from dean or immediate head	Research Director or EACRER-Chair
Step 4	Receipt of endorsement letter	Research Director or EACRER-Chair
Step 5	Forwarding of appointment letter and signing of Confidentiality and Conflict of Interest	New members
Step 6	Endorsement of selected RER applicants to the President, VP for Academics & VP for Administration	EAC Research Director
Step 7	Dissemination of appointment letters and rendering of services	New members
Step 8	Filling of pertinent documents in the membership file	EACRERC Staff

1.5. Description of Procedures

Step 1 – **Call for applications:** The EAC Research Director or EACRERC Chair announces a call for applications for Research Ethics Review Committee Members

Step 2 - **Evaluation of qualification and interview**: The EACRERC Chair or Research Director evaluates the qualifications of the applicants and interviews qualified applicants.

Step 3 - **Submission of endorsement letter from dean or immediate head**: After the interview, the EAC Research Director or EACRER Chair informs the qualified applicants to submit an endorsement letter from his/her dean or immediate head.

Step 4 - **Receipt of endorsement letter:** TShe EAC Research Director/ EACRER Chair receives the endorsement letter signed by the applicant's immediate head.

Step 5 - **Forwarding of appointment letter and signing of Confidentiality and Conflict of Interest:** The qualified applicant receives an appointment letter and signs a confidentiality and conflict of interest agreement form.

Step 6 - **Endorsement of selected RER applicants to the President, VP for Academics & VP for Administration:** The EAC Research Director or EACRER-Chair endorses the selected RER applicants to the President, VP for Academics & VP for Administration.

Step 7 - **Dissemination of appointment letters and rendering of services**: The qualified applicant receives her/his appointment letter and renders services according to the terms, conditions, roles, and responsibilities of the EACRERC.

Step 8 - **Filling of pertinent documents in the membership file:** The EACRERC staff will file all pertinent documents including Curriculum Vitae, signed Appointment Letter, declaration Conflict of Interest to the EAC-RERC digital folder on "Reviewer Profile".

1.6. Glossary

Alternate members - individuals who possess the qualification of specified regular members. They are called to attend a meeting and substitute for regular members to comply with quorum requirements when the regular member cannot attend the meeting.

EACRERC SOP - Emilio Aguinaldo College Research Ethics Committee Standard Operating Procedure

Confidentiality - duty to not freely disclose private/research information entrusted to an individual or organization.

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.

Independent consultants – whose presence is called upon to provide expert opinion on the protocol under review. They are not members of the EACRERC.

Non-medical – are individuals without academic degrees in the medical profession nor a master's degree in the nursing profession.

Non-scientific – are individuals whose primary interest is not in any of the natural, physical and Social sciences and whose highest formal education is a bachelor's degree.

Non-affiliated – are regular members who are not in the roster of personnel or staff of the Institution. They are not employees of the institution, nor do they receive regular salary or stipend from the institution.

1.7. Forms

Curriculum Vitae Template
Appointment Letter
Confidentiality and Conflict of Interest Agreement

1.8. History of SOP

Version No.	Date	Authors	Main Change
1	30 January 2025	VAS	First Draft
2	01 October 2025	EACRERC Members 2025	Added policy statement, scope, glossary, history and references

1.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020

2.1. Policy Statement

The EACRERC shall be composed of a Chair, Co-Chair, and Member-Secretary, who shall be selected from among its members. They shall be elected by the members in a special meeting presided by a temporary presiding officer. Elected officers will be endorsed to the Research Director, subject to the confirmation of the President, the Vice President for Academic Affairs, and the Vice President for Administration. The appointments shall remain in effect until the expiration of their respective terms.

Each designated officer/member of the EACRERC shall be given an honorarium in accordance with the EAC Research Ethics Reviewers Honorarium Policy.

2.2. Objective of the Activity

The designation of officers aims to ensure that the appointed officers exhibit high standard of qualification, adheres to institutional policy and practice; and the implementation of the ethics review fee.

2.3. Scope

This SOP is specifically applied to the designation of officers of EACRERC including the honorarium for reviewers. This SOP begins with the call for a special meeting to elect officers and ends with the filing of appointment documents of officers.

2.4. Workflow

Process Flow	Activity	Responsibility
Step 1	Call for a special meeting	Research Director
Step 2	Election of temporary presiding officer	EACRERC members
Step 3	Nomination of a specific official	EACRERC members
Step 4	Election of a specific official	EACRERC members
Step 5	Endorsement of elected officials to the Research Director	Temporary Presiding Officer
Step 6	Endorsement to President, VP for Academic Affair, and VP for Administration	Research Director
Step 7	Signing of Conforme	Elected officers

Step 8	Filing of appointment documents	EACRERC Staff

2.5. Description of Procedures

Step 1 – **Call for a special meeting:** The EACRERC staff, upon the instruction of the Research Director, send a Notice of Meeting to all members stating the purpose of the meeting to elect officers.

Step 2 – **Election of temporary presiding officer:** The EACRERC members will elect a temporary presiding officer to preside over the election later.

Step 3 – **Nomination of specific official:** The temporary presiding officer presides over the nomination process for the Vice-Chair and Member Secretary.

Step 4 – **Election of a specific official:** Election of officers shall be by secret ballot and is based on the majority rule. A tie shall be settled by a “toss-coin”.

Step 5 – **Endorsement of elected officials to the Research Director:** The temporary presiding officer will endorse the elected officers to the Research Director.

Step 6 – **Endorsement to President, VP for Academic Affair, and VP for Administration:** The Research Director in turn will endorse the elected officers to the President, VP for Academic Affair, and VP for Administration for the confirmation of their appointment.

Step 7 – **Signing of Conforme**: The EACRERC staff notifies the officers of their appointments and the need to sign the conforme. The concerned officers forthwith report to the EACRERC office to sign the conforme documents.

Step 8 – **Filing of appointment documents:** The EACRERC Staff files the appointment papers accordingly.

2.6. Ethics Review Fee

To sustain the operation of the RER Committee, the EAC may implement ethics review fees for internal and external clients depending on the PHREB level of accreditation.

2.7. Payment Procedure

2.7.1. The EACRERC Secretariat/Staff of the Chair issues Research Ethics Application Payment Slip (REAPS) to the external client for the payment of a fee for each protocol submitted for ethics review, approval & conduct of research.

2.7.2. For in-person payment transaction, the client pays to the Cashier the account specified in the REAPS.

2.7.3. For online payment transaction, the client deposits the payment as specified in the REAPS.

2.7.4. The Cashier issues an official receipt (OR) upon request by the client.

2.7.5. The client presents proof of payment to the EACRERC Secretariat/Staff.

2.7.6. The EACRERC Secretariat/Staff records the details of payment of the database.

2.7.7. The EACRERC Secretariat/Staff shall schedule for the committee of the protocol review meeting if the research protocol is for a full review process.

2.7.8. For Post-Approval review, the client shall pay the corresponding amount for continuing or amendment review.

2.8 EAC Honorarium Policy

2.8.1. An honorarium for research ethics reviewers may be given to a member of the EAC Research Ethics Review Committee for satisfactory rendering of the work specified herein.

2.8.2. Honoraria shall not exceed 25% of the employee's annual basic salary under the Republic Act No. 10352.

2.8.3. Honoraria may be released at the end of each school year only if the reviewers submit related supporting documents and upon endorsement of the EAC Research Director subject to the availability of funds.

2.8.4. Internal and external research ethics reviewers shall be compensated for one (1) reviewed research paper or manuscript, not per learner or faculty researcher.

2.8.5. For ethics reviewers holding teaching positions in their respective affiliated institutions, honorarium shall be based on the current per-hour teaching rate or faculty rank of EAC.

2.9. Glossary

Special meeting – an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like selection of officer, approval of a revised or new SOP, report of critical research problem that requires immediate action.
Secret Ballot – is a system of casting votes (opinions or choices) such that the voters are not identified or are anonymous.
Majority rule – is a policy based on the principle that the decision made by the greater number should be carried/accepted.
Conforme – acceptance of or agreement to an assignment or designation.

2.10. Forms

EACRER FORM 10 (A): Minutes of the Meeting
Appointment Letter
Confidentiality and Conflict of Interest Agreement

2.11. History of SOP

Version No.	Date	Authors	Main Change
1	02 October 2025	EACRERC Members 2025	First Draft
2	28 January 2026	EACRERC Members 2026	Second Draft

2.12. References

Ateneo De Naga University Institutional Research Ethics Committee Standard Operating Procedures Manual 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2017
National Center for Mental Health Research Ethics Committee Standard Operating Procedure 2023

3.1. Policy Statement

EACRERC shall invite at least one (1) independent consultant whose expertise shall be used to advise the EACRERC members on the technical aspects of the protocol under review. They may be represented by a non-scientist. These consultants are not members of the committee and cannot vote.

3.2. Objective of the Activity

This activity aims to ensure that the appointment of independent consultants conforms with institutional practice and complements the pool of expertise in the EACRERC.

3.3. Scope

This SOP is specifically applied to the appointment of the members of EACRERC. This SOP begins with the identification of the protocols that need an expert opinion and ends with inclusion of the new independent consultant to the pool of existing independent consultants.

3.4. Workflow

Process Flow	Activity	Responsibility
Step 1	Identification of Protocols that requires an independent consultant	EACRERC-Chair
Step 2	Identification of independent consultant	EACRERC-Chair
Step 3	Formal appointment as independent consultant	EACRERC Staff
Step 4	Receipt of signed appointment letter and Confidentiality and Conflict of Interest	EACRERC Staff
Step 5	Inclusion in the pool of independent consultant	EACRERC Staff

3.5. Description of Procedures

Step 1 – **Identification of Protocols that requires an independent consultant:** The EACRERC Chair will determine which study protocol requires an expert that may not be present in the present pool of EACRERC reviewers.

Step 2 – **Identification of independent consultant:** The EACRERC Chair will conduct an informal search of possible independent consultant whose expertise is in line with the study protocol to be discussed. Once a possible independent consultant has been identified, the EACRERC Chair will approach him/her and invite him/her to sit for the full board meeting. If he/she agrees, the EACRERC Chair will instruct the EACRERC Staff to prepare an appointment letter and confidentiality and conflict of interest agreement.

Step 3 – **Formal appointment as independent consultant:** The EACRERC Chair will send the appointment letter and confidentiality and conflict of interest agreement to the independent consultant to formalize their appointment as independent consultant.

Step 4 – **Receipt of signed appointment letter and confidentiality and conflict of interest:** The EACRERC staff receives the signed appointment letter and confidentiality and conflict of interest and files it to the appropriate folder.

Step 5 – **Inclusion in the pool of independent consultant:** The name of the new independent consultant will now be included in the list of independent consultants.

3.6. Glossary

Independent consultant – refer to resource persons whose expertise will be consulted if none of the reviewers in the pool is an expert on the study protocol under review. They may be invited to sit in during the full board meeting.

Expertise - a proficiency, skill or know-how possessed by experts in a certain academic or Professional field.

Expert – a person who is specially qualified and trained in a particular field.

3.7. Forms

Appointment Letter
Confidentiality and Conflict of Interest Agreement

3.8. History of SOP

Version No.	Date	Authors	Main Change
1	01 October 2025	EACRERC Members 2025	First Draft

3.9. References

Ateneo De Naga University Institutional Research Ethics Committee Standard Operating Procedures Manual 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2017

4.1. Policy Statement

Study protocols may be exempted from ethical review in accordance with the criteria listed in the 2022 National Ethical Guidelines for Health and Health-related Research (NEGHHR 2022). Initial Review Procedure Section 45. The EACRERC Chair, or their representative, shall determine the proposal's exemption from review or the kind of review required, whether full or expedited review. The decision to be exempt from review is upon the discretion of the EACRERC Chair for efficiency and interest of time.

Study protocols that may be exempted are:

4.1.1. Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis, protocols).

4.2.2. Protocols that do not involve more than minimal risks or harms, provided that;

4.2.2.1. Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;

4.2.2.2. Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording), if the following criteria are met:

4.2.2.2.1. 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; and

4.2.2.2.2. The investigator 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.

4.2.3. Protocols that involve the use of publicly available data or information.

4.2. Objective of the Activity

This SOP aims to classify study protocols that will not require ethical review. Moreover, it aims to demonstrate the due diligence and high standards in the system of protection of human participants.

4.3. Scope

This SOP is specifically applied to the classification of exempt review of submitted study protocols. It begins with the receipt of study protocol documents and ends with the Filing of documents in the protocol file folder and update the protocol database.

4.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Receipt of study protocol documents	EACRERC staff	1-2 working days
Step 2	Evaluation of study protocol	EACRERC-Chair/Co-Chair	3 working days
Step 3	Approval of exempt from review	EACRERC-Chair/Co-Chair	1 working day
Step 4	Preparation of Certificate of Exemption	EACRERC Staff	1 working day
Step 5	Release of Certificate of Exemption to the Principal Investigator	EACRERC Staff	1 working day
Step 6	Filing of documents in the protocol file folder and update the protocol database	EACRERC Staff	1 working day

4.5. Description of Procedures

Step 1 – **Receipt of study protocol documents:** The EACRERC staff receives the study protocol documents from the PI. S/he assigns a protocol code and encodes them in the digital database.

Step 2 – **Evaluation of study protocol:** The EACRERC Chair/Co-Chair will assess the completeness, accuracy, and adequacy of study protocol documents submitted by the PI, and evaluate if the study protocol will qualify for exempt from review based on the following criteria:

a.) Protocols that involve the use of publicly available data or information.
b.) The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.

c.) Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) and there will be no disclosure of the human participant's 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.
d.) Protocols for Institutional Quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests.
e.) Research studies that involve systematic review or meta-analysis protocols that involve human participants nor identifiable human tissue, biological samples, and data.

Step 3 – **Approval of exempt from review:** If the EACRERC Chair/Co-Chair determines that the study protocol sufficiently qualifies for exemption of review, s/he will direct the EACRERC staff to prepare the Certificate of Exemption.
Step 4 – **Preparation of Certificate of Exemption:** The EACRERC staff will prepare the Certificate of Exemption and forwards to the EACRERC Chair for signature.
Step 5 – **Release of Certificate of Exemption to the Principal Investigator:** Once it has been signed by the EACRERC Chair/Co-Chair, the EACRERC staff will release the Certificate of Exemption to the Principal Investigator.
Step 6 – **Filing of documents in the protocol file folder and update the protocol database**: The complete protocol folder, including all protocol-related documents, is filed for safekeeping in the storage cabinet and update protocol database for exemption from review.

4.6. Glossary

PI – Principal Investigator

Exempt from Review - a decision made by the EACRERC Chair or designated member of the committee regarding a submitted study proposal based on criteria in the NEGHHR 2022 The Ethics Review Process Guideline 47-48.3. This means that the protocol will not undergo an expedited nor a full review.

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

4.7. Forms

EACRERC Form 5 (A): Certification of Exemption from Ethics Review

4.8. History

Version No.	Date	Authors	Main Change
1	01 October 2025	EACRERC Members 2025	First Draft

4.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2017
National Center for Mental Health Research Ethics Committee Standard Operating Procedure 2023

5.1. Policy Statement

An expedited review shall be conducted for study protocols that (1) do not entail more than minimal risk to the study participants, and (2) do not have study participants belonging to a vulnerable group, and (3) the study procedures do not generate vulnerability. The results of the initial review shall be released to the principal investigator within twenty-one (21) days after the submission of all the required documents. The study protocol that underwent expedited review and approved shall be reported in the subsequent regular committee meeting.

5.2. Purpose

Expedited Review aims to demonstrate due diligence and high standards in the system of protection of human participants.

5.3. Scope

This SOP is specifically applied to the initial review of protocols and post-approval submissions which do not entail more than minimal risk to study participants, whose participants do not belong to vulnerable groups, and where vulnerability issues do not arise. This SOP begins with the receipt of study documents, assigned of protocol code, encoding of the study documents in the database and ends with the filling of documents in the protocol file folder and updating the protocol database.

5.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Receipt of Study Documents, Assignment of Protocol Code, and Encoding of the study documents in the database	EACRERC Staff	1-2 working days
Step 2	Assignment of reviewer/s	EACRERC Chair/Co-Chair	3 working days
Step 3	Notification and Provision of documents and evaluation forms to reviewer/s	EACRERC Staff	1-2 working days

Step 4	Review of documents	Reviewer/s	7 working days
Step 5	Submission of evaluation forms	Reviewer/s	1-2 working days
Step 6	Consolidation and Finalization of the review result	EACRERC Chair and EACRERC Staff	3 working days
Step 7	Communication of review results to the PI	EACRERC Staff	2 working days
Step 8	Filing of documents in the protocol file folder and updating the protocol database	EACRERC Staff	1 working day

5.5. Description of Procedures

Step 1 – **Receipt of Study Documents, Assignment of Protocol Code, and Encoding of the study documents in the database:** The EACRERC Staff will receive and checks the completeness of the documents submitted by the PI. S/he then assigns a Protocol Code and encodes them in the database but returns any incomplete or incorrect submissions. All incomplete protocol submissions are returned to the PI indicating the reasons and additional instructions on how to address or revise the content of applications forms submission. The EACRERC staff notifies the PI automatically for returned protocol submissions.

Step 2 – **Assignment of Reviewer/s:** The EACRERC Chair/Co-Chair will conduct a preliminary review of the submitted study protocol to determine the appropriate type of review. It will be qualified for expedited review based on the following criteria:

a.) The research poses low risk
b.) The study does not involve vulnerable populations
c.) The study does not involve the collection of stigmatizing information
d.) The study uses anonymized or archived samples
e.) Continuing review of clinical trials that do not involve further recruitment of participants
f.) Continuing review of studies previously classified under expedited review
g.) Study protocol amendments that are administrative in nature and do not affect the study protocol and;
h.) Study protocol amendments that do not change the overall risk profile of the study

If classified under expedited review, two separate reviewers may be assigned to evaluate the study protocol and the informed consent form. The medical/scientific primary reviewer may also review the informed consent form, while the non-scientific reviewer may review the study protocol if it falls within their area of expertise. The EACRERC Chair may likewise review the study protocol if it is within their field of expertise.

Step 3 – **Notification and Provision of documents and evaluation forms to reviewer/s:** The EACRERC Staff gathers the pertinent documents; for initial submissions: the complete protocol and related documents; for post approval submissions: the pertinent information from the retrieved protocol and the report itself. The EACRERC staff uploads copies of protocol and all protocol-related documents to the shared google drive and informs reviewer/s through electronic mail. Primary reviewer/s must confirm acceptance of review within three (3) working days after being given the opportunity to assess any conflict of interest, availability and suitability to make the necessary review. If the primary reviewer fails to respond within the timeframe, the EACRERC Chair will reassign the study protocol to another reviewer.

Step 4 – **Review of documents:** The reviewer/s accomplish the Protocol Assessment Form (Form 2G) and/or Informed Consent Assessment Form (Form 2E). The primary reviewer sign and indicate the date of assessment. However, if upon assessment of the reviewer/s have found any information in the protocol and/or ICF that would require full board review, they may recommend it accordingly. (See SOP No. 06 for Full Board Review).

Step 5 – **Submission of evaluation forms:** The reviewer/s submit the Assessment forms within seven (7) seven days from the receipt of the protocol review documents. The accomplished forms must be uploaded to the shared drive, duly signed and dated. The EACRERC staff will check for the completeness in entries of the form.

Step 6 – **Consolidation and Finalization of the review result:** The EACRERC staff shall consolidate the results of the reviewers' evaluations and submit them to the EACRERC Chair for finalization. In the event of differing opinions, the EACRERC Chair may determine which review to adopt to ensure the efficiency of the review process. The reviewers may recommend whether the protocol should be approved, modified, or disapproved.

- If no issues are identified, the reviewer/s may classify the protocol as *Approved*. Accordingly, the issuance of the Research Ethics Clearance (Form 5B) may be recommended to the EACRERC Chair for endorsement and release.

- If there are findings, reviewers shall recommend revisions. Recommended revisions may be as follows:

    - *Minor modifications* - a recommended revision applying to protocols found to have particular aspect/s on its study or related document that do not impact on potential risks/harms to participants and on the integrity of the research (e.g. incomplete documentation, informed consent elements, unsatisfactory informed consent format).

    - *Major modifications* - a recommended revision applying to protocols found to have significant aspect/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data, statistical analysis,

mitigation of risk, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research.

- If *Disapproved*, the study protocol will automatically be forwarded to Full Board for discussion and decision.

Step 7 - **Communication of review results to the PI:** See SOP on Communicating REC Decisions (SOP # 23)

Step 8 - **Filing of documents in the protocol file folder and updating the protocol database:** See Sop on Managing Active Files (SOP # 25)

5.6. Glossary

Expedited Review - is the ethical evaluation of a research proposal and other protocol- related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.

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

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

Reviewer- a regular member of the Research Ethics Committee who is assigned to assess a research protocol, the Informed Consent, and other research-related submissions based on technical and ethical criteria established by the committee.

5.7. Forms

EACRER Form 2 (E): Informed Consent Evaluation Form
EACRER Form 2 (G): Protocol Evaluation Form
Decision Letter

5.8. History of SOP

Version No.	Date	Authors	Main Change
1	03 October 2025	EACRERC Members 2025	First Draft

5.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

6.1. Policy Statement

A full review shall be conducted when a proposed study entails more than minimal risk to study participants or when study participants belong to vulnerable groups or when a study generates vulnerability to participants. Only protocols submitted for, at least, 2 weeks before a scheduled meeting shall be included in the agenda for full review. Full review shall be conducted through a primary reviewer system. If necessary, independent consultants and or the proponents shall be invited during the meeting to clarify certain issues. The decision shall be communicated to the proponent within six weeks after submission of required documents.

6.2. Objective of the Activity

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

6.3. Scope

This SOP is specifically applied to initial, resubmissions and post-approval submissions which are classified as entailing more than minimal risk to study participants or whose participants belong to vulnerable groups. This SOP begins with the receipt of study documents, assignment of protocol code, and encoding of the study documents in the database and ends with the filing of protocol-related documents.

6.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Receipt of Study Documents, Assignment of Protocol Code, and Encoding of the study documents in the database	EACRERC Staff	1-2 working days
Step 2	Assignment of reviewer/s	EACRERC Chair	3 working days
Step 3	Notification and Provision of documents and evaluation forms to reviewer/s	EACRERC Staff	1-2 working days
Step 4	Provision of related documents to the rest of the members	EACRERC Staff	1 working day
Step 5	Review of documents	Reviewer/s	14 working days
Step 6	Presentation of review findings and	Reviewer/s	

	recommendations during a Committee meeting (SOP on Conduct of meeting (SOP # 21)		1 working day
Step 7	Discussion of technical and ethical issues	EACRERC Members	
Step 8	Summary of issues and resolutions	EACRERC Chair	
Step 9	Committee action	EACRERC Chair and members	
Step 10	Documentation of Committee deliberation and action (SOP on Preparing the Meeting Minutes (SOP # 22)	EACRERC Staff	1-2 working days
Step 11	Communicating Committee Action to the PI (See SOP # 23)	EACRERC Chair and EACRERC Staff	1 working day
Step 12	Filing of protocol-related documents and Updating of the Protocol Database	EACRERC Staff	1 working day

6.5. Description of Procedures

Step 1 - **Receipt of Study Documents, Assignment of Protocol Code, and Encoding of the study documents in the database:** The EACRERC Staff receive and check the completeness of the documents submitted by the PI. S/he then assigns a Protocol Code and encodes them in the database but returns any incomplete or incorrect submissions. All incomplete protocol submissions are returned to the PI indicating the reasons and additional instructions on how to address or revise the content of applications forms submission. The EACRERC staff notifies the PI automatically for returned protocol submissions.

Step 2 - **Assignment of reviewer/s:** The EACRERC Chair will conduct a preliminary review of the submitted study protocol to determine the appropriate type of review. It will be qualified for full review based on the following criteria:

a.) Collection of blood samples by venipuncture, finger stick, and other invasive medical procedures like cutting, removing, or puncturing the skin or inserting any medical instruments into the body of the participants.
b.) The use of non-invasive medical devices that are not yet approved or cleared for marketing and public use by the Bureau of Health Devices and Technology (BHDT),

including non-invasive clinical practice or procedures that are not yet approved or cleared by medical regulating agencies.

c.) The clinical studies of drugs and medical devices that significantly increase the risks or decrease the acceptability of the risk associated with the use of the product even if it is approved by the Food and Drug Administration or BHDT.

d.) Research that involves more than minimal risk or involves protected or vulnerable populations, such as children, prisoners, physically disabled, or cognitively disabled individuals.

e.) Research protocols that involve the intentional deception of participants, wherein misleading or inaccurate information is provided, encompass studies in which the risk level exceeds minimal standards. This includes scenarios that may be personally intrusive, induce stress, or potentially lead to trauma, with stress manifesting in various forms such as physical, psychological, social, financial, or legal.

If classified for full review, two separate reviewers may be assigned to initially evaluate the study protocol and the informed consent form. The medical/scientific primary reviewer may also review the informed consent form, while the non-scientific reviewer may review the study protocol if it falls within their area of expertise. The EACRERC Chair may likewise review the study protocol if it is within their field of expertise.

Step 3 - **Notification and Provision of documents and evaluation forms to reviewer/s:** The EACRERC staff uploads copies of protocol and all protocol-related documents to the shared google drive and informs reviewer/s through electronic mail. Reviewer/s must confirm acceptance of review within three (3) working days after being given the opportunity to assess any conflict of interest, availability and suitability to make the necessary review. If the primary reviewer fails to respond within the timeframe, the EACRERC Chair will reassign the study protocol to another reviewer.

Step 4 - **Provision of related documents to the rest of the members:** The staff provides the rest of the members of the EACRERC with an executive summary of the study proposal (included among the submitted documents in the Protocol package, Form 2A Application) three (3) days before the committee meeting, at the latest.

Step 5 - **Review of documents:** The reviewer/s accomplish the Protocol Assessment Form (Form 2G) and/or Informed Consent Assessment Form (Form 2E). The primary reviewer/s sign and indicate the date of assessment. Their assessment will be used as guide during the discussion in the full board review.

Step 6 - **Presentation of review findings and recommendations during a Committee meeting (SOP on Conduct of meeting (SOP # 21):** The reviewer/s submit their findings and recommendations (Form 2G: Protocol Assessment Form and Form 2E: ICF Assessment Form) to the EACRERC Chair, three (3) days before the meeting and present these during the actual meeting. If a reviewer/s cannot attend the meeting, the Chair exercises his/her prerogative to take over the role of the reviewer/s so that the meeting can proceed.

Step 7 - **Discussion of technical and ethical issues:** The EACRERC Chair leads the discussion of the technical and ethical issues using the Protocol Assessment Form (Form 2G)

and the Informed Consent Assessment Form (Form 2E) and the assessment of the primary reviewers as guides for an orderly exchange of ideas.

Step 8 - **Summary of issues and resolutions:** The EACRERC Chair summarizes the technical and ethical issues that were identified, the issues that were resolved not resolved, including the recommendations for the issues that were not resolved.

Step 9 - **Committee action:** The EACRERC Chair emphasizes the points discussed by all members in a summary and recommends action for compliance and proposes the action. Committee decides on action which may be either of the following:

- Approved
- Minor Modifications
- Major Modifications
- Disapproved

Decision of the EACRERC is arrived at by voting and the majority decision is arrived at and is adopted. If there is a strong objection, the deliberation continues until the strong objector is convinced. A clarificatory interview with the Principal Investigator may be requested to further elaborate on the study.

Step 10 - **Documentation of Committee deliberation and action:** See SOP on Preparing the Meeting Minutes (SOP# 22).

Step 11 - **Communication of Committee Action to the researcher:** See SOP on Communicating
EACRERC Decisions (SOP # 23).

Step 12 - **Filing of protocol-related documents and Updating of the Protocol Database:** See SOP on Managing Active Files (SOP # 25)

6.6. Glossary

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

Full Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.

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

Major Modification – is a recommended revision of significant aspects/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data

statistical analysis, mitigation of risks, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research.

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

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

6.7. Forms

EACRER Form 2 (E): Informed Consent Evaluation Form
EACRER Form 2 (G): Protocol Evaluation Form
Decision Letter
EACRER Form 10 (A): Minutes of the Meeting

6.8. History of the SOP

Version No.	Date	Authors	Main Change
1	03 October 2025	EACRERC Members 2025	First Draft

6.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

7.1. Policy Statement

EACRERC shall require the submission of a set of pertinent documents for an application (submitted online or in-person) for an application for ethical review to be accepted. A preliminary evaluation shall determine whether a research proposal is exempted from or needs to undergo ethical review based on the NEGHHR 2022 Initial Review Procedure Section 45.

7.2. Objectives

Management of Initial Submissions ensures that study documents are complete, properly recorded, and properly evaluated to determine appropriate action or type of review.

7.3. Scope

This SOP is specifically applied to the management of initial submission. The EACRERC shall accept initial reviews only for the study protocol submitted by the faculty, staff, and students of the institution. This SOP begins with the receipt of study documents for initial review and ends with entry of protocol information in the database.

7.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Receipt of Study Documents and determination of completeness of submission	EACRERC Staff	1-2 working days
Step 2	Entry into the logbook	EACRERC Staff	1 working day
Step 3	Determination of type of review	EACRERC Chair	3 working days
Step 4	Preparation of protocol folder	EACRERC Staff	1 working day

7.5. Description of Procedures

Step 1 - **Receipt of Study Documents and determination of completeness of submission:** The EACRERC office is open from 8:00 AM to 5:00 PM, Monday to Saturday, during which the staff accepts study documents submitted online (sent via email to: research.ethics@eac.edu.ph) or in-person. S/he checks the completeness of the of the

documents and returns the set of documents if it is incomplete. A protocol package must include the following:

Technical Documents:

1. EACCRP Form 1 (A) 2025: Letter of Intent
2. EACCRP Form 1 (B) 2025: Technical Evaluation of Thesis/Dissertation Proposal (required for undergraduate and graduate learners)
3. EACCRP Form 1 (C) 2025: Technical Evaluation of Research Project Proposal for Grant/Funding (if applicable)
4. EACCRP Form 1 (D) 2025: Curriculum Vitae

Protocol Review Documents:

1. EACRER Form 2 (A) 2025: Application for Research Ethics Clearance
2. EACRER Form 2 (B) 2025: Informed Consent Form in English
3. EACRER Form 2 (C) 2025: Informed Consent Form in Local Language (if applicable)
4. EACRER Form 2 (D) 2025: Assent Form for Children (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
5. EACRER Form 2 (E) 2025: Informed Consent Assessment Form
6. EACRER Form 2 (F) 2025: Protocol Template
7. EACRER Form 2 (G) Protocol Assessment Form

Study Specific Documents (*requested at the reviewer's discretion, but otherwise optional*):

1. Research Proposal Manuscript
2. Survey Questionnaire
3. Interview Questionnaire

Once the documents have been completed, the EACRERC staff will provide the PI with Form 2H: Protocol Application Checklist Acknowledgement.

S/he will assign Protocol Code to the study protocol package following the Format: **EACRER YYYY-NNN,** where **YYYY** represents the year, while the **NNN** represents the sequential protocol number as received by the EACRERC staff. All protocols for exempt, expedited, and full review are coded similarly.

Step 2 – **Entry into the logbook:** The EACRERC staff will input the necessary information in the EACRERC Protocol Database (in a google sheets) for official documentation, which contains the following:

- Protocol Code
- Study Protocol Title
- Date Issued the Protocol Application Checklist Acknowledgement
- Purpose of the Study
- Name of Principal Investigator

- Email Address and Contact Information
- School/Department/Affiliation
- Category of Protocol Review (exempted, expedited, or full review)
- Funding Agency (if applicable)
- Name of Reviewer/s
- Date of Notice of Panel Action/Decision
- Date of Research Ethics Clearance or Approval
- Due Date of Progress Report (for funded project)
- Expiration Date of Research Ethics Clearance
- Due Date of Final Report
- Status
- Additional Remarks

After encoding, s/he will endorse the study protocol to the EACRERC Chair for the determination of the type of review.

Step 3 - **Determination of type of review:** The EACRERC Chair conducts a preliminary review of the study protocol to determine the type of review it requires (exempt, expedited, or full board) and processes it accordingly based on the classification.

Step 4 - **Preparation of protocol folder:** The EACRERC staff uploads the protocol documents in Google Drive and labels it accordingly.

7.6. Glossary

Protocol package – refers to the set of pertinent documents (protocol and forms) submitted to the EACRERC for review.
Preliminary review – initial evaluation of protocol package done by the EACRERC Chair to determine the type of review appropriate for the study.
Coding - a unique number assigned to a protocol indicating the year and series it was received.
Database – a collection of information that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

7.7. Forms

EACCRP Form 1 (A): Letter of Intent
EACCRP Form 1 (B): Technical Evaluation of Thesis/Dissertation Proposal (required for undergraduate and graduate learners)
EACCRP Form 1 (C): Technical Evaluation of Research Project Proposal for Grant/Funding (if applicable)
EACCRP Form 1 (D): Curriculum Vitae

EACRER Form 2 (A): Application for Research Ethics Clearance
EACRER Form 2 (B): Informed Consent Form in English
EACRER Form 2 (C): Informed Consent Form in Local Language (if applicable)
EACRER Form 2 (D): Assent Form for Children (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
EACRER Form 2 (E): Informed Consent Assessment Form
EACRER Form 2 (F): Protocol Template
EACRER Form 2 (G) Protocol Assessment Form
EACRER Form 2 (H): Protocol Application Checklist Acknowledgement
Database

7.8. History of the SOP

Version No.	Date	Authors	Main Change
1	03 October 2025	EACRERC Members 2025	First Draft

7.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

8.1. Policy Statement

EACRERC shall require a resubmission of a protocol that requires either minor or major modification/s not later than 4 weeks after receipt of the Decision Letter. Minor modifications shall undergo expedited review while major modifications shall undergo full review.

8.2. Objective of the Activity

Management of resubmission ensures that the researcher addressed the required modifications before approval of the protocol.

8.3. Scope

This SOP is specifically applied to the resubmission of revised or modified protocols that have been previously reviewed by the EACRERC. The procedure begins with the receipt of the revised protocol documents and ends with filing of the documents and updating the database.

8.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Receipt and Entry in the Logbook	EACRERC Staff	1-2 working days
Step 2	Sending of documents to the reviewer/s	EACRERC Staff	1 working day
Step 3	Review of resubmissions	Reviewer/s	5 working days
Step 4	Communication of Decision	EACRERC Staff	1 working day
Step 5	Filing of documents and update the database	EACRERC Staff	1 working day

8.5. Description of Procedures

Step 1 – **Receipt and entry in the logbook:** The EACRERC staff receives the revised study documents and checks the completeness of the documents. Once verified as complete, the EACRERC staff will upload the revised study documents to the google drive in their dedicated folder.

Step 2 – **Sending of documents to the reviewer/s:** The EACRERC staff will notify the reviewer/s that the revised study documents has been uploaded to the Google Drive in the dedicated folder of the study protocol.

Step 3 – **Review of resubmissions:** The reviewer/s conduct review of the resubmitted protocol by referring to the resubmission form (Form 2I: Review of Resubmitted Protocol Form) noting the different recommendations made by the EACRERC and evaluating whether these were satisfactorily addressed in the resubmitted protocol. The reviewer/s may choose the following action:

- If approved, Research Ethics Clearance may be recommended for release.
- If minor modifications, the PI will have to resubmit the protocol documents with modifications according to the recommendation.
- If major modifications/disapprove, it will undergo Full Review to discuss and be processed accordingly.

Step 4 – **Communication of Decision:** The EACRERC prepares the Research Ethics Clearance for approved resubmitted protocols, which the EACRERC Chair will sign. If the protocol needs to be modified, the PI will be notified.

Step 5 – **Filing of documents and update the database**: The staff gathers all the pertinent documents related to the resubmission (revised protocol, assessment forms, excerpts of minutes, approval letter,) and enters the relevant information on resubmission in the appropriate protocol database.

8.6. Glossary

Resubmission – the revised study proposal that is re-forwarded to the EACRERC following the recommendations from the initial review.

Study Documents – include all materials (protocol and forms) pertinent to a research proposal that have to be submitted to the EACRERC for a comprehensive review.

8.7. Forms

EACRER Form 2 (I): Review of Resubmitted Form
EACRER Form 5 (B): Research Ethics Clearance
Decision Letter

8.8. History of the SOP

Version No.	Date	Authors	Main Change
1	04 October 2025	EACRERC Members 2025	First Draft

8.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

9.1. Policy Statement

EACRERC shall require the submission of progress reports at a frequency based on the level of risk of the study. This requirement shall be explicitly stated in the Approval Letter. In accordance with NEGHRIHP 2022, Action on Submissions, Subsection 56.1.1., a progress report must be submitted at least once a year, or as requested by the EACRERC.

All protocols are required to submit a progress report at least once a year, sixty (60) days prior to the expiration date of the Research Ethics Clearance, or as otherwise decided by the EACRERC. Protocols that previously underwent expedited review shall automatically undergo expedited review for the progress report, while those that previously underwent full board review shall likewise undergo full board review. This requirement shall be explicitly stated in the Research Ethics Clearance.

9.2 Objective of the Activity

This activity aims to ensure that the conduct of the study follows the approved protocol and that the safety and welfare of study participants are promoted.

9.3. Scope

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

9.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Receipt and entry to database of incoming and outgoing protocols of the progress report	EACRERC Staff	1-2 working days
Step 2	Notification of Chair and Reviewer/s	EACRERC Staff	1 working day
Step 3	Communication of Decision	EACRERC Staff	1 working day
Step 4	Filing of progress report and committee decision	EACRERC Staff	1 working day

	and update of the database		

9.5. Description of Procedures

Step 1 – **Receipt and entry to database of incoming and outgoing protocols of the progress report:** EACRERC staff receives the progress report and enters the date and pertinent information in the EACRERC database. S/he then uploads the progress report in the designated folder in the Google Drive database of the study protocol, where other pertinent documents are also stored.

Step 2 – **Notification of Chair and Reviewer/s:** The EACRERC staff notifies the EACRERC Chair and previously assigned Reviewer/s that the progress report has been uploaded to the google drive in the designated folder and is now ready for review. As a general rule, progress reports of Expedite Protocols will undergo Expedited Review while progress reports reviewed at Full Board should go through Full Board Review as well.

Step 3 – **Communication of Decision:** The EACRERC communicates the committee action, see SOP 22: Communicating EACRERC Decisions. For progress reports, the committee action may be “approved” or “additional information required” or “specific action/s required from the researcher”. EACRERC Staff prepares a draft of the committee decision based on either an expedited review report or minutes of a meeting. The Chair signs the decision letter as follows: Approval, request for additional information or specific action/s.

Step 4 – **Filing of Progress Report and committee decision and update of the database:** The Staff files the progress report and a copy of the committee decision in the appropriate protocol folder. She/he proceeds to update the pertinent protocol database.

9.6. Glossary

Progress Report – description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Form 4(B). The frequency of submission at least once a year or as requested by the EACRERC.

Expedited Review – is the ethical evaluation of a research proposal and other study documents, a resubmission, and after-approval submissions, conducted by only two members of the committee.

Full Review – is the ethical evaluation of a research proposal, other study documents, or 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.

Database– a collection of information (e.g. regarding protocols) that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

9.7. Forms

EACRER Form 4 (B): Progress Report Form
Decision Letter
Database

9.8. History

Version No.	Date	Authors	Main Change
1	03 October 2025	EACRERC Members 2025	First Draft

9.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

10.1. Policy Statement

The EACRERC shall require the submission of proposed amendments for review and approval before their implementation. This requirement shall be explicitly stated in the Research Ethics Clearance.

10.2. Objective of the Activity

This activity aims to ensure that the conduct of the study is incompliance with the approved protocol such that any change such as amendments does not impact safety and welfare of study participants.

10.3. Scope

This SOP is specifically applied to the review of amendments. It begins with the receipt and entry of the submission of amendment to Database of incoming documents and the protocol database and ends with filing of the amendments and committee decision in the protocol file.

10.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Receipt and entry to logbook	EACRERC Staff	1-2 working days
Step 2	Determination of type of review: expedited (SOP 5 on Expedited Review) or Full Review (SOP 6 on Full Review)	EACRERC Chair	1-3 working day
Step 3	Communication of committee action	EACRERC Chair and Staff	1 working day
Step 4	Filing of Amendment and Decision letter and update of the protocol database	EACRERC Staff	1-2 working days

10.5. Description of Procedures

Step 1 – **Receipt and entry to database:** The EACRERC Staff receives the Protocol Amendment Application Form 3A and other protocol-related documents issued by the EACRERC and enters the date and pertinent information in the database of incoming documents. All pertinent documents are uploaded to the google drive in the designated folder of the study protocol.

Step 2 – **Determination of type of review: Expedited or Full Review:** The EACRERC Staff forwards the completed amendment to the EACRERC Chair for determination of review type, and it will proceed accordingly.

Step 3 – **Communication of committee decision:** The EACRERC communicates the committee action, see SOP # 23: Communicating EACRERC Decisions. For amendments, the committee action may be any of the following "approved", "additional justification/information required", "reconsent required" or disapproved. Staff prepares a draft of the committee decision based on either an expedited review report or minutes of a meeting. The Chair signs the decision letter as follows: Approval, request for additional justification/information or specific action/s e.g. reconsent required or disapproved.

Step 4 – **Filing of Amendments and Decision Letter and update of the protocol database:** The EACRERC Staff files the Amendment and a copy of the committee decision in the appropriate protocol folder. S/he proceeds to update the protocol database.

10.5. Glossary

Amendment – Any change or revision in the protocol made after its approval.

Database– a collection of information (e.g. regarding protocols) that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

10.6. Forms

EACRER Form 3 (A): Amendment Form
Decision Letter
Database

9.8. History

Version No.	Date	Authors	Main Change
1	January 2025	VAS	First Draft
2	04 October 2025	EACRERC Members 2025	Added policy statement, scope, glossary, history and references

9.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

11.1. Policy Statement

Researchers shall report protocol deviations and violations in the conduct of approved research within a week from the detection of the protocol violation/deviation. Major protocol violations undergo full review.

11.2. Objective of the Activity

Review of protocol deviations and violations aims to ensure that the safety and welfare of human participants in the study are safeguarded and that the credibility and integrity of data are maintained.

11.3. Scope

This SOP specifically 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 update of the database.

11.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Receipt and documentation of report of protocol violations and deviations	EACRERC Staff	1-2 working days
Step 2	Notification of Chair and primary reviewers	EACRERC Staff	1 working day
Step 3	Determination of type of review: expedited (SOP 5 on Expedited Review) or Full Review (SOP #6 on Full Review)	EACEACRERC Chair	1-3 working days
Step 4	Inclusion of report in the agenda of the next EACRERC regular meeting	EACRERC Chair and Staff	1 working days
Step 5	Communication of committee action	EACRERC Chair and Staff	1-2 working day
Step 6	Filing of all related documents and update of the protocol database	EACRERC Staff	1 working days

11.5. Description of Procedures

Step 1 - **Receipt and documentation of report of protocol violations and deviations:** The EACRERC the receives the report on protocol deviation or violation in the appropriate report form (Form 7A: Protocol Violation or Deviation Report) and records this in the logbook for incoming documents. S/he then uploads the report form in the designated folder of the study protocol in the google drive where all the other pertinent documents can be found.

Step 2 - **Notification of Chair and primary reviewers**: The EACRERC Staff notifies the EACRERC Chair and the reviewer/s of the report of deviation and violation.

Step 3 – **Determination of type of review: Expedited or Full Review:** The EACRERC Chair and primary reviewer/s determine the type of review such that major protocol violations undergo full review. Otherwise, the protocol deviation undergoes expedited review. See SOP #5: Expedited Review and SOP #6: Full Review.

Step 4 – **Inclusion of report in the agenda of the next EACRERC regular meeting:** The EACRERC Chair includes the report on protocol deviation and violation in the Agenda of the next meeting if it is for Full review or the decision report if Expedited review.

Step 5 – **Communication of committee action:** The EACRERC Staff prepares the draft decision based on the report of the expedited review or the minutes of the meeting in the full review. Possible decisions include one or several of the following: (1) submission of additional information, (2) submission of corrective action and preventive action, (3) invitation to a clarificatory interview, (4) Requirement for an amendment (5) site visit, (6) suspension of recruitment, and (7) withdrawal of ethical clearance.

Step 6 – **Filing of all related documents and update of the protocol database:** The EACRERC Staff collates and files the retrieved protocol documents, the report on protocol deviation and violation and the decision letter in the appropriated protocol file and updates the protocol database with the relevant information.

11.6. Glossary

Protocol Deviation – non-compliance with the approved protocol that does not increase risk or decrease benefit to participants or does not significantly affect their rights, safety or welfare or the integrity of data. Example: missed visit, non-submission of a food diary on time.

Protocol Violation - non-compliance with the approved protocol that increases risk or decreases benefit to participants or significantly affects their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.

Full Review - is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.

Expedited Review- is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.

Site Visit – is an activity of the EACRERC where an assigned team goes to the research site or office for specific monitoring purposes.

Clarificatory Interview/meeting – is a meeting or consultation of the EACRERC with the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the EACRERC.

11.7. Forms

EACRER Form 7 (A): Protocol Deviation/Violation Report Form
Decision Letter

11.8. History

Version No.	Date	Authors	Main Change
1	04 October 2025	EACRERC Members 2025	First Draft

11.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

12.1. Policy Statement

The EACRERC shall require the submission of reports of SAEs and SUSARs by Principal Investigator within seventy-two (72) hours after knowledge of Principal Investigator of its occurrence, and a complete report is submitted within 14 days. Onsite SAE/SUSARs shall be reviewed in the full board review while trending of offsite SAEs/SUSARs shall be reported every 6 months.

12.2. Objective of the Activity

Review of SAE and SUSAR reports aims to ensure that the safety and welfare of human participants in the study site are safeguarded and that information on SAEs and SUSARs are properly documented and evaluated.

12.3. Scope

This SOP is specifically applied to the review of reports of SAEs in various studies and SUSARs in clinical trials. This SOP begins with the receipt and documentation of submission of report of SAEs and SUSARs in the logbook and ends with the filing of all related documents and update of the protocol database.

12.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Report SAE and SUSAR	Principal Investigator	72 hours
Step 2	Receipt and documentation of submission of report of SAEs and SUSARs in the Database Incoming & Outgoing Protocols	EACRERC Staff	1 working day
Step 3	Notification of RERC Chair	EACRERC Staff	1 working day
Step 4	Submission of report to SAE Subcommittee or point person:	EACRERC Staff	1 working day
Step 5	Inclusion of report of SAE Subcommittee or point person in EACRERC meeting agenda:	EACRERC Chair and EACRERC Staff	1-2 working days
Step 6	Communication of committee action	EACRERC Chair and Staff	1-2 working day

Step 7	Filing of all related documents and update of the protocol database	EACRERC Staff	1 working days

13.5. Description of Procedures

Step 1 – **Report SAE and SUSAR:** SAE's and SUSAR's must be reported by the Principal Investigator to the EACRERC.

Serious adverse event (SAE) that are not consistent with the subject's participation in research that meets any of the following criteria:

- Results in death
- Is life-threatening
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability or incapacity
- Results in in congenital anomaly/birth defect or
- Any adverse event that, based on appropriate medical judgment, may jeopardize the participant's health and may require medical or surgical intervention to prevent any of the aforementioned outcomes.

Step 2 – **Receipt and documentation of submission of report of SAEs and SUSARs in the Database Incoming & Outgoing Protocols:** The Staff receives the accomplished SAE/SUSARs report forms (Form 4A: Unanticipated Adverse Event Report Form) and enters the submission into the logbook. The EACRERC Staff notes whether the submission is within the required timeline.

Step 3 – **Notification of the EACRERC Chair:** The EACRERC Staff notifies the EACRERC Chair via email or SMS about the report and informs him/her that it has been uploaded to the designated folder of the study protocol in the Google Drive.

Step 4 - **Submission of report to SAE Subcommittee or point person:** The EACRERC Chair forwards the report and pertinent documents to the primary reviewers (or to the SAE/SUSAR Subcommittee) for action which should not be later than three (3) days prior to the next committee meeting.

Step 5 - **Inclusion of report of SAE Subcommittee or point person in EACRERC meeting agenda:** The suggested action/decision of either the primary reviewer or the SAE/SUSAR Subcommittee is included in the Agenda of the next meeting (see SOP on Preparing the Meeting Agenda). for ratification or discussion and final decision. Possible actions include: notation with no further action required, further information or action required or suspension of recruitment.

Step 6 - **Communication of EACRERC recommendation to the Principal Investigator/researcher:** See SOP # 23 on Communicating EACRERC decisions.

Step 7 - **Filing of all related documents and update of the protocol database:** See SOP on Managing Active Files (SOP # 25).

12.6. Glossary

SAE (Serious Adverse Events) – is an event observed during the implementation of a study where the outcome is any of the following:

- Death
- Life threatening
- Hospitalization (initial or prolonged)
- Disability or permanent damage
- Congenital anomaly/ birth defect
- Required intervention to prevent permanent impairment or damage (devices)
- Other serious (important medical) events whether or not it is related to the study intervention.

SUSAR (Suspected Unexpected Serious Adverse Reactions) - is a noxious response to a drug that is
not described in the Investigator's Brochure nor in the drug insert.

12.7. Forms

EACRER Form 4 (A): Unanticipated Adverse Event Report Form
Decision Letter

12.8. History

Version No.	Date	Authors	Main Change
1	04 October 2025	EACRERC Members 2025	First Draft

12.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

13.1. Policy Statement

The Principal Investigator is required to submit an RNE report within seventy-two (72) hours upon their discovery of the Reportable Negative Event. A special meeting will be called upon the evaluation of the level of the risk involved.

13.2. Objective of the Activity

Review of RNE reports aims to ensure that the safety and welfare of the human participants, as well as the researchers are protected and the information on RNEs are properly documented and evaluated.

13.3. Scope

This SOP applies to the review of RNE reports. This SOP begins with the receipt and documentation of submission of RNE report in the logbook and ends with the filing of all related documents and update of the protocol database.

13.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Report and submission of RNE report	Principal Investigator	72 hours
Step 2	Receipt and documentation of submission of RNE reports in the logbook	EACRERC Staff	1 working day
Step 3	Retrieval of pertinent protocol file	EACRERC Staff	1 working day
Step 4	Notification of RERC Chair	EACRERC Staff	1 working day
Step 5	Call for special meeting	EACRERC Chair	1 working day
Step 6	Deliberation on the RNE	EACRERC members	1 working day
Step 7	Communication of committee action to the Principal Investigator (SOP 23 on	EACRERC Chair and Staff	1-2 working day

	Communication of REC Decisions) and to the Institutional		
Step 8	Filing of all related documents and update of the protocol database	EACRERC Staff	1 working days

13.5. Description of Procedures

Step 1 - **Report and submission of RNE report:** The Principal Investigator shall immediately report any occurrence of reportable negative event and submit RNE report within seventy-two (72) house upon their discovery of the reportable negative event to the EACRERC.

Step 2 - **Receipt and documentation of submission of RNE reports in the logbook:** The EACRER staff receives the accomplished RNE report form and logs the submission in the logbook. The EACRERC notes whether the submission falls within the prescribed timeline.

Step 3 - **Retrieval of pertinent protocol file:** The EACRERC staff retrieves the approved protocol file and check the primary reviewers of the study.

Step 4 - **Notification of the EACRERC Chair:** The EACRERC staff notify the EACRERC Chair about the report and submit the RNE report as well as the retrieved documents. The EACRERC Chair shall evaluate the level of risk the reportable negative event poses and may decide whether or not to call for a special meeting.

Step 5 - **Call for Special Meeting:** The EACRERC staff prepares for a special meeting (SOP #21). The Principal Investigators, alongside his/her other members may be invited to attend for a clarificatory meeting.

Step 6 - **Deliberation on RNE:** The EACRERC Chair leads the discussion of the special meeting. S/he summarized the RNE report and informs the rest of the members of the presence of the research team for a clarificatory meeting. Safety issues are evaluated such as the identification of risks to the participants and research team, nature and effectivity of preliminary interventions with or without the help of community constituents/authority, impact on integrity of data and completion of the research. The Research team is excused and the REC members deliberate on possible options, as follows:

- recommend suspension of the study until risk is resolved.
- withdrawal of ethical clearance
- submission of a plan to mitigate risk/harm
- require an amendment to the protocol
- uphold original ethical clearance

Step 7 - **Communication of REC recommendation to the researcher:** See SOP #23 on Communicating REC decisions.

Step 8 - **Filing of all related documents and update of the protocol database:** See SOP #25 on Managing Active Files

13.6.Glossary

Reportable Negative Events (RNE) - are occurrences in the study site that indicate risks or actual harms to participants and to members of the research team and to integrity of data. Examples are brewing hostilities in the research community, natural calamities, unleashed dogs, threats of harassment, etc.,

Special meeting – an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like selection of officer, approval of a revised or new SOP, report of critical research problem that requires immediate action

Clarificatory Meeting/ Interview – is a face-to-face meeting or consultation of the REC with the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the REC.

12.3. Forms

Form 7 (B): Reportable Negative Event
Notice of Meeting
Decision Letter

12.8. History

Version No.	Date	Authors	Main Change
1	21 January 2026	EACRERC Members 2025	First Draft

12.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

14.1. Policy Statement

The EACRERC shall require the submission of an application for Continuing Review at least 4 weeks before the expiration of the ethical clearance of a protocol. Protocols that underwent Full review in its initial submission shall undergo Full review in its application for Continuing review. Similarly, protocols that underwent Expedited review shall undergo Expedited review in its application for Continuing review.

14.2. 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 participants are promoted and the integrity of data protected beyond the period of initial ethical clearance and up to the end of the study.

14.3. Scope

This SOP specifically applies to the management of application for continuing review. This SOP begins with the receipt of an application for continuing review and ends with the entry to logbook and protocol database.

14.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Receipt of the application for Continuing Review and entry to Logbook (SOP #25 Management of Active Files)	EACRERC Staff	1 working day
Step 2	Notification of EACRERC Chair	EACRERC Staff	1 working day
Step 3	Determination of type of review: expedited (SOP #5 Expedited Review) or full review (SOP #6 Full Review)	EACRERC Chair	1 working day
Step 4	Communication of committee action	EACRERC Chair and Staff	1-2 working day
Step 5	Filing of all related documents and update of the protocol database	EACRERC Staff	1 working days

14.4. Description of Procedures

Step 1 – **Receipt of the application for Continuing Review and entry to logbook (SOP # 24 Management of Active Files):** The EACRERC Staff receives, logs and enters in the

protocol database the information included in the application for Continuing review (Form 3B: Continuing Review Application).

Step 2 – **Notification of EACRERC Chair:** The EACRERC Staff notifies the EACRERC Chair and the Primary Reviewers regarding the submission and the summary of the reports submitted and decisions made during the period of effectivity of initial ethical clearance.

Step 3 - **Determination of type of review: expedited or full review:** The EACRERC Chair shall determine the type of review based on the policy that protocols that underwent Full review in its initial submission shall undergo Full review in its application for Continuing review. Similarly, protocols underwent Expedited review shall undergo Expedited review in its application for Continuing review (see SOP #5: Expedited Review and SOP 6: Full Review).

Step 4 – **Communication of committee action:** The Staff prepares the draft decision based on the report of the expedited review or the minutes of the meeting in the full review. The EACRERC Chair finalizes and signs the decision letter. Possible decisions include the following: Approval, Additional information required, submission of an explanation for failure to submit required reports or disapproval.

Step 5 – **Filing of all related documents and update the protocol database:** The Staff files the application for Continuing review, the recommendations of the reviewers and decision letter in the appropriate protocol folder.

14.6. Glossary

Continuing Review - is the decision of the EACRERC to extend the ethical clearance of a study based on an assessment that the research is proceeding according to the approved protocol and there is reasonable expectation of its completion.

Expedited Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.

Full Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.

Database– a collection of information (e.g. regarding protocols) that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

14.7. Forms

EACRERC Form 3 (B): Continuing Review Application Form
Database
Decision Letter

14.8. History

Version No.	Date	Authors	Main Change
1	06 October 2025	EACRERC Members 2025	First Draft

14.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

15.1. Policy Statement

EACRERC shall require the submission of the final report not later than sixty (60) days after the end of the study. Final reports shall undergo either expedited or full review.

15.2. Objective of the Activity

This activity 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.

15.3. Scope

This SOP is specifically applied to the management and review of final reports submitted by proponents 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.

15.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Receipt of final report and entry into logbook (SOP on Management of Active Files (SOP# 25)	EACRERC Staff	1 working day
Step 2	Notification of EACRERC Chair	EACRERC Staff	1 working day
Step 3	Expedited Review (SOP # 5) or Full Review (SOP # 6)	EACRERC Chair	1 working day
Step 4	Communication of Committee Action	EACRERC Chair and Staff	1-2 working day
Step 5	Filing of the Final Report and related documents and update of protocol files	EACRERC Staff	1 working days

15.5. Description of Procedures

Step 1 – **Receipt of final report and entry into logbook:** The EACRERC Staff receives and enters the date of receipt of the final report into the logbook. S/he then uploads it in the designated folder of its study protocol in the google drive.

Step 2 – **Notification of EACRERC Chair:** The EACRERC Staff notifies the EACRERC Chair and the reviewer/s of the receipt of the Final Report.

Step 3 – **Expedited Review (SOP 4) or Full Review (SOP 5):** (See SOP 5 Expedited Review or SOP 6 Full Review). Generally, final reports are classified for expedited review, unless

otherwise indicated by the specificity of the submitted information. Under expedited review, action is finalized at the level of the reviewer/s within ten (10) working days.

Step 5 – **Communication of committee action:** (SOP # 23 Communication EACRERC Decisions) Once the final report is approved, the PI is informed of the following:

- The study protocol is classified as inactive.
- Ethical clearance is expired effective on the day of the notice of decision.
- Study protocol records will be made available for three (3) years in the archives after the expiration date.

Step 6 – **Filing of the Final Report and related documents and update the protocol files:** The EACRERC staff stores the signed final report documents in the protocol file folder, when no further action is expected from the PI. S/he will transfer the final report documents to the archived files.

15.6. Glossary

Final Report– is a summary of the outputs and outcomes (including documented risks and benefits) of the study upon its completion, as well as the status of all participants. The EACRERC requires the accomplishment of the Final Report form within a reasonable period after the end of the study.

PI – refers to the Principal Investigator of the study. The person responsible for the study.

Database – a collection of information that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated.

15.7. Forms

EACRERC Form 4 (C): Final Report Form
Decision Letter

15.8. History

Version No.	Date	Authors	Main Change
1	January 2025	VAS	First Draft
2	07 October 2025	EACRERC Members 2025	Added policy statement, scope, glossary, history and references

15.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

16.1. Policy Statement

When a decision for early termination of the research has been made, the well-being and safety of study participants that have already been recruited shall be a primary consideration and the plan for termination shall reflect this concern. Early termination reports shall undergo full review.

16.2. Objective of the Activity

Review of early termination reports aims to ensure that the decision takes into consideration the safety and welfare of study participants that have already been recruited and that there is adherence to the principle of fairness for all concerned.

16.3. Scope

This SOP is specifically applied to the review of early termination reports. This SOP begins with the receipt and entry to the logbook of the early termination reports and ends with the communication of committee action to the researcher/investigator and updating of the protocol database.

16.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Receipt of the early termination report and entry into the logbook (SOP #25 Management of Active Files)	EACRERC Staff	1 working day
Step 2	Notification of EACRERC Chair and members	EACRERC Staff	1 working day
Step 3	Full Review (SOP 6)	EACRERC Chair	1 working day
Step 4	Communication of committee action	EACRERC Chair and Staff	1-2 working day

16.5. Description of Procedures

Step 1 – **Receipt of the early termination report and entry into the logbook (SOP # 25 Management of Active Files):** The EACRERC Staff receives the early termination report and enters the appropriate information into the logbook (SOP # 25 Management of Active Files).

Step 2 – **Notification of EACRERC Chair and members:** The EACRERC staff informs the EACRERC Chair and the primary reviewers by email about the report and the summary of documents that have been submitted. S/he waits for further instructions.

Step 3 – **Full Review (SOP # 6):** The EACRERC Chair instructs the EACRERC staff to include the report in the agenda of the next meeting and to ensure that the primary reviewers are given the necessary documents so that s/he can prepare the presentation during the next

meeting (SOP 6 Full Review). The reviewer/s conduct a full review of the contents of the early termination protocol package, and make recommendations on how study termination will be carried out of primary importance are the safety data for participants that have already been recruited, as well as a plan that includes steps and procedures on how the safety and well-being of these participants can be ensured moving forward.

Step 4 – **Communication of committee action:** The EACRERC considers the following possible decisions in the review of an early termination report: acceptance of the decision with no further action; request for additional information; or requirement for further action. The staff prepares a draft of the committee decision based on the minutes of the meeting (SOP # 23 Communicating EACRERC Decisions) for signature of the Chair. S/he updates the protocol database accordingly.

16.6. Glossary

Early Termination - refers to the decision of the researcher, principal investigator, the institution, or sponsor to end the implementation of a study before its completion.

Termination package - refers to the entitlements of study participants in the event of discontinuance of the study, which can come in the form of access to the study intervention, treatment, or information, for purposes of adherence to the principle of fairness for all concerned.

Full Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.

Database – a collection of information (e.g. regarding a protocol/s) that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

16.7. Forms

EACRER Form 8 (B): Early Termination Report Form
Decision Letter
Database

16.8. History

Version No.	Date	Authors	Main Change
1	07 October 2025	EACRERC Members 2025	First Draft

16.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

17.1. Policy Statement

The EACRERC shall consider the perspective of the researcher regarding the feasibility and acceptability of EACRERC recommendations including its disapproval. Appeals of researchers shall undergo full review and shall be resolved within six weeks (24 working days) upon receipt of the fully documented appeal.

17.2. Objective of the Activity

Management of appeals ensures fairness, transparency and comprehensiveness of ethics review that takes into consideration the perspective of the researcher.

17.3. Scope

This SOP is specifically applied to the management of appeals. It 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.

17.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Receipt of an appeal	EACRERC Staff	1 working day
Step 2	Notification of EACRERC Chair and reviewer/s	EACRERC Staff	1 working day
Step 3	Inclusion in Agenda of the next regular meeting	EACRERC Chair and Reviewer/s	1 working day
Step 4	Discussion of and deliberation of the appeal	EACRERC Chair and Members	1 working day
Step 5	Communication of committee action	EACRERC Chair and Staff	1-2 working days
Step 6	Filing of documents and updating of the protocol database	EACRERC Staff	1 working day

17.5. Description of Procedures

Step 1 – **Receipt of an Appeal:** The EACRERC staff receives the letter of appeal and enters the pertinent information into the logbook.

Step 2 – **Notification of EACRERC Chair and reviewer/s:** The EACRERC staff notifies the EACRERC Chair and the primary reviewers about the letter of appeal and awaits further instructions.

Step 3 – **Inclusion in the Agenda of the next regular meeting:** The EACRERC Chair instructs the staff to include the appeal in the agenda of the next 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 4 – **Discussion and deliberation of the appeal:** The primary reviewer summarizes the protocol and the previous discussion of the issues in the protocol as background to the appeal. The EACRERC

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 consensus) whether to accept any or all of the points raised in the appeal.
Step 6 – **Communication of Committee Action:** Based on the deliberations, the EACRERC Chair summarizes the decision points and instructs the EACRERC staff to prepare the draft decision letter for his/her finalization and forwarding to the researcher. (SOP # 23: Communicating EACRERC Decisions).

Step 7 – **Filing of documents and update of protocol database:** The staff files all the documents into the appropriate folder and updates the protocol database accordingly.

17.6. Glossary

Appeal – a request of a researcher/ investigator for a reconsideration of the EACRERC recommendation.

Primary reviewer – is a member of the EACRERC who is assigned to do an in-depth evaluation of research related documents using technical and ethical criteria established by the committee.

Protocol File/Folder – is an organized compilation of all documents (in physical or electronic form) related to a study.

Protocol database - a collection of information (e.g. regarding protocols) that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

17.7. Forms

Decision Letter

17.8. History

Version No.	Date	Authors	Main Change
1	07 October 2025	EACRERC Members 2025	First Draft

17.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

18.1. Policy Statement

The EACRERC shall conduct visits of selected sites of approved protocols that fall within the following established criteria for such visits: (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 from the and (e) multiple studies conducted by a researcher.

18.2. Objective of the Activity

Site visits are mechanisms with which the EACRERC monitors compliance with approved protocols, informed consent form, process and continuing protection and promotion of participant's dignity, rights and well-being.

18.3. Scope

This SOP is specifically applied to the conduct of site visits. It begins with the selection of the site to be visited and ends with filing of Site Visit Reports in the protocol folder and updating of the protocol database.

18.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Selection of site to visit	EACRERC members	1 working day
Step 2	Notification of PI	EACRERC Staff	1 working day
Step 3	Creation of Site Visit Team	EACRERC Chair	3 working days
Step 4	Conduct of site visit	Site Visit Team (members)	1 working day
Step 5	Draft of report and presentation of report during meeting and discussion for recommendations	Site Visit Team (members)	1-2 working days
Step 6	Transmittal of the Final Report and Recommendations to the Researcher/Investigator	EACRERC Staff	1 working day
Step 7	Filing of documents and updating of the protocol database	EACRERC Staff	1 working day

18.5. Description of Procedures

Step 1 – **Selection of site to visit:** The EACRERC may decide to conduct a site visit based on the following reasons: (a) consistent non-submission or failure to submit after-approval requirements; (b) reports of major protocol noncompliance, (c) a significant number of serious

adverse events, or (d) reports of complaints form study participants. The selection of site to visit may be recommended by the primary reviewers.

Step 2 – **Notification of PI:** Once identified, the EACRERC staff will send an official letter via email

about the intention of the EACRERC to conduct a site visit. The letter shall include a date and time for the visitation. The schedule must be agreeable to both parties.

Step 3 – **Creation of Site Visit Team:** The EACRERC Chair shall assign three (3) members of the Committee to conduct the site visit. It shall be composed of one (1) Primary Reviewer (which will serve as the team head), one (1) Medical member who reviews SAEs/SUSARs, and one (1) EACRERC member. The EACRERC staff then prepares the relevant documents such as the latest version of the approved protocol and informed consent documents, and other documents (like protocol deviation reports) and a copy of the Study Site Visit Report Form.

Step 4 – **Conduct of site visit:** The team shall assess the study site based on the following considerations:

(a) Check the study protocol version being used.
(b) Verify if the study site is using the latest recently approved version of the Informed Consent.
(c) Check if the post-approval documents have been submitted and approved by the EACRERC
(d) Security, privacy, and confidentiality of the documents at the study site.
(e) Facilities of the study site
(f) Determination of the protection of the rights, safety, and welfare of human participants in the study.

At the end of the visit, the study site visit team presents the findings to the study team.

The study visit team shall accomplish the Study Visit Report Form within seven (7) working days from the date of visit and must be submitted to the EACRERC staff to be logged in the log of incoming documents.
The presentation of study site visit report will be included in the meeting agenda during the regular meeting.

Step 5 – **Draft of report and presentation of report during meeting and discussion for recommendations:** The team head (primary reviewer) shall finalize the report based on the agreed and consolidated observations and recommendations from all the team members. The findings shall be presented to the rest of EACRERC members for deliberation and approval. The final recommendations shall be a consensus among all the members.

Step 6 – **Transmittal of the Final Report and Recommendations to the Researcher/Investigator:** The staff prepares a summary of the findings and

recommendations of the EACRERC based on the deliberations during the meeting. The EACRERC Chair finalizes the draft for transmittal to the Researcher/ investigator. (SOP # 23 Communicating EACRERC Decisions)

Step 7 – **Filing of the Site Visit documents and update of the Protocol database:** The EACRERC staff files the Site Visit Report and the recommendations in the appropriate folder and updates the protocol database accordingly. (SOP # 25 Management of Active Files)

18.6. Glossary

Site Visit -is an action of the EACRERC (based on established criteria) in which an assigned team goes to the research site or office for specific monitoring purposes.

After-approval reports – are reports, e.g. progress report, protocol deviation/violation report, amendment, early termination report, final report, application for continuing review, required by the EACRERC for submission by the researcher/investigator after the study has been approved for implementation.

Protocol Violation- non-compliance with the approved protocol that may result in an increased risk or decreased benefit to participants or significantly affects their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion 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 assigned to do an in-depth evaluation of the research-related documents using technical and ethical criteria established by the committee.

Full Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.

Decision - the result of the deliberations of the EACRERC in the review of a protocol or other submissions.

Protocol File/Folder – is an organized compilation of all documents (physical or electronic form) related to a study.

Protocol Database - a collection of information regarding protocols that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated.

18.7. Forms

EACRER Form 8 (A): Site Visit Report

18.8. History

Version No.	Date	Authors	Main Change
1	07 October 2025	EACRERC Members 2025	First Draft

18.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

19.1. Policy Statement

The EACRERC shall have a regular schedule of meetings every 1st Friday of the month or only as needed. Meetings can be held online or face-to-face to allow flexibility and convenience for all members. Special meetings shall be held to resolve issues that require immediate attention, e.g. safety of participants, protocol violation that impact research integrity.

19.2. Objective of the Activity

Preparing for a meeting aims to contribute to a smooth, orderly, and efficient conduct of meetings.

19.3. Scope

This SOP is specifically applied to preparing for a meeting. It covers all activities prior to the conduct of an EACRERC meeting. This begins with the preparation of the agenda and ends with the notification of EACRERC Members and confirmation of attendance.

19.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Preparation of the agenda (SOP # 20 Preparation of Meeting Agenda)	EACRERC Member-Secretary and EACRERC Staff	1 working day
Step 2	Assembly of materials and documents for needed for the meeting	EACRERC Staff	2 working days
Step 3	Preparation of presentation and recording equipment, and/or food arrangements for the meeting	EACRERC Staff	1 working day
Step 4	Notification of EACRERC Members and confirmation of attendance	EACRERC Member-Secretary and EACRERC Staff	1-2 working days

19.5. Description of Procedures

Step 1 - **Preparation of the agenda (SOP # 20 Preparation of Meeting Agenda):** See SOP #19 Preparation of Meeting Agenda.

Step 2 – **Assemble of materials and documents needed for the meeting:** The EACRERC staff gathers the documents and materials for the meeting based on the provisional agenda,

e.g copies of the provisional agenda, provisional minutes of the previous meeting, protocols an related documents submitted, at least two (2) weeks before the meeting, post-approval reports expedited review reports, administrative memos, etc.

Step 3 – **Preparation of presentation and recording equipment, and/or food arrangements:** The staff ensures that the following are prepared and available for the meeting: laptop (2), projector, and screen, microphones (3), adequate food and drinks/water depending on the expected duration of the meeting, respective honoraria of committee members.

Step 4 – **Notification of EACRERC Members and confirmation of attendance:** The member secretary supervises the staff in the preparation of the Notice of Meeting that includes the provisional agenda. The staff sends the notice of meeting to the members of the committee, at least, one week before the schedule and follows-up the confirmation of attendance to ensure quorum.

19.6. Glossary

Regular Meeting - a periodically scheduled assembly of the EACRERC

Special Meeting - an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like selection of officer, approval of a revised or new SOP, report of critical research problem that requires immediate action

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”.

19.7. Forms

Provisional Agenda
Notice of Meeting

19.8. History of SOP

Version No.	Date	Authors	Main Change
1	January 2025	VAS	First Draft
2	08 October 2025	EACRERC Members 2025	Added policy statement, scope, glossary, history and references

19.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

20.1. Policy Statement

The meeting agenda shall be based on the submissions received, at the latest, two (2) weeks before the scheduled regular meeting. It shall follow an established template for meeting agenda. The provisional agenda shall be included in the Notice of Meeting.

20.2. Objective of the Activity

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

20.3. Scope

This SOP describes how the EACRERC determines what items are to be included in the agenda of 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.

20.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Preparation of the draft meeting agenda	EACRERC Member-Secretary and EACRERC Staff	1 working day
Step 2	Preparation of the provisional meeting agenda	EACRERC Chair	3 working days
Step 3	Distribution of the provisional meeting agenda (SOP # 19 Preparing for a Meeting)	EACRERC Staff	1 working day
Step 4	Approval of the provisional meeting agenda	EACRERC Members	1 working day
Step 5	Filing of the final meeting agenda (SOP # 25 on Management of Active Files)	EACRERC Staff	1-2 working days

20.5. Description of the Procedures

Step 1 – **Preparation of the draft meeting agenda:** The staff under the supervision of the Member Secretary prepares the draft agenda two (2) weeks before the scheduled meeting, using the Meeting Agenda. The agenda includes the following:

1. Call to Order
2. Declaration of Quorum
3. Approval of the Provisional Agenda
4. Disclosure of Conflict of Interest
5. Review and Approval of the Minutes of the Previous Meeting
6. Business Arising from the Minutes

7. New Business:
   - 7.1. Initial Review of Protocols
   - 7.2. Review of Resubmissions
   - 7.3. Review of After Approval Submissions
   - 7.4. Report on Expedited Review of Protocols
   - 7.5. Report on Expedited Review of After-Approval Submissions
   - 7.6. Report of Site Visits

8. Other Matters

Step 2 - **Preparation of the provisional meeting agenda:** The EACRERC Chair reviews the draft agenda (within 2 days) as the basis of preparing the provisional agenda for inclusion in the Notice of Meeting.

Step 3 - **Distribution of the provisional meeting agenda**: The EACRERC staff will email the provisional meeting agenda to all the members. It shall be included in the Notice of the Meeting.

Step 4 - **Approval of the provisional meeting agenda**: The EACRERC members approve the provisional agenda during the meeting. (SOP # 20 Conduct of Meeting).

Step 5 - **Filing of the final meeting agenda**: The staff files the final (approved) meeting agenda in a special folder that contains all meeting agenda in chronological order. See SOP # 24 Managing Active Files).

20.6. Glossary

Draft Meeting Agenda – the order of business that includes the list of topics or items recommended for discussion in a meeting. This is endorsed to the EACRERC Chair for his/her approval.
Provisional Meeting Agenda – is the order of business that includes the list of topics or items approved for discussion in a meeting by the EACRERC Chair.
Final Meeting Agenda - is the order of business that includes the list of topics or items approved for discussion in a meeting by the EACRERC Members in a regular or special meeting.

20.7. Forms
Provisional Agenda

20.8. History of SOP

Version No.	Date	Authors	Main Change
1	08 October 2025	EACRERC Members 2025	First Draft

19.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

21.1. Policy Statement

Meetings shall be presided by the Chair or designated substitute and shall proceed only when quorum is declared, and shall be guided by the approved agenda. The presence of a conflict of interest among the members shall be disclosed prior to the discussion of protocols for review. Regular monthly meetings shall be conducted every 1st Friday of the month.

21.2. Objective of the Activity

Meetings are conducted to provide an opportunity for EACRERC to arrive at collegial decisions regarding study protocols and EACRERC operations and to be informed of pertinent administrative matters.

21.3. Scope

This SOP is specifically applied to the conduct of meetings. It covers EACRERC actions and activities from the time the meeting is called to order, and quorum is declared until the time that the meeting is adjourned. This SOP begins with the distribution of meeting materials and ends with the collection, storage, and disposal of meeting materials.

21.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Distribution of meeting materials	EACRERC Staff	1 working day
Step 2	Call to order	EACRERC Chair	
Step 3	Declaration of quorum	EACRERC Member-Secretary	
Step 4	Approval of the provisional agenda	EACRERC Members	
Step 5	Declaration of conflict of interest (COI)	EACRERC Staff	
Step 6	Approval of minutes of the previous meeting	EACRERC Members	
Step 7	Discussion of "Business arising from the minutes"	EACRERC Members	
Step 8	Review of protocols and protocol-related submissions (SOP 5 Full Review)	EACRERC Chair and Members	

Step 9	Review of results of expedited review (SOP 4 Expedited Review	Assigned Reviewer/s	
Step 10	Adjournment	EACRERC Chair	
Step 11	Collection, storage, and disposal of meeting materials	EACRERC Staff	

21.5. Description of Procedures

Step 1 – **Distribution of meeting materials:** The EACRERC staff distributes, through email, the EACRERC forms, research protocols, and other related documents for discussion **one (1) week prior to the meeting** to be used during the meeting.

Step 2 – **Call to order:** The EACRERC Chair declares the formal opening of the Meeting at the appointed time and place once majority of the members are present.

Step 3 – **Determination of Quorum:** The EACRERC member-secretary determines that there is quorum. Confirmation of quorum is done at the start of the meeting and reconfirmation is done every time a decision needs to be made. Quorum is defined as the presence of at least 50%+1 regular member at least three to five (3-5) of whom are described as follows:

1. Scientific and/or medical member(s) with expertise on the study protocols being reviewed
2. At least one (1) non-scientist
3. At least one (1) non-affiliated member of the institution (who can be represented by non-scientist as the case may be)
4. Representation of both female and male members
5. A member or invited guest with expertise on the item to be discussed.

An alternate member shall be invited to fulfill the quorum quota in the event of an absence of a regular member.

In studies involving children, a pediatrician or child development expert should be present. A pediatrician or child development is need for quorum and is able to vote for decisions during the meeting.

Step 4 – **Approval the provisional agenda:** The EACRERC Chair will announce the meeting agenda and will ask members to approve it. EACRERC members are welcome to make suggestions for additional items to discuss and modify the meeting agenda to include them.

Step 5 – **Declaration of Conflicts of Interest:** EACRERC members with Conflicts of Interest must declare it upon the probing of the EACRERC Chair. Once identified, they will be asked to leave the room unless they are asked to reply to questions for clarification. Quorum should be maintained when conflicted members leave the room. They return to the room after the discussion and decision-making process of the EACRERC.

Step 6 – **Approval of the minutes of previous meeting:** The minutes of the meeting during the previous meeting will be discussed for approval for possible comments or corrections, if there's none then it shall be approved.

Step 7 – **Discussion of "Business Arising from the Minutes**: The EACRERC Chair will update the EACRERC Members on the business arising from the previous minutes or may assign a member to do it.

Step 8 – **Report of protocols and protocol-related submissions:** The primary reviewer will discuss their findings about the submitted documents. After that, the EACRERC Chair will open the floor for discussion. The PI may be called upon for a clarificatory interview. Lastly, the EACRERC Chair summarizes all the points raised and recommendations made by the members.

Step 9 – **Review of results of expedited review:** The EACRERC Chair reports the approved expedited review protocols.

Step 10 – **Adjournment:** The EACRERC Chair formally closes the meeting after determination that all the Meeting Agenda items have been discussed.

Step 11 – **Collection, storage, and disposal of meeting materials:** Meeting must be adjourned after all items in the agenda have been discussed and/or resolved. A member must move for the adjournment of the meeting, and seconded, for it to be declared.

21.6. Glossary

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

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

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

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

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

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

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

Clarificatory Interview/meeting – is a face-to-face consultation between the EACRERC and the researcher for the purpose of obtaining explanations or clarity regarding some research

issues identified by the EACRERC to make these issues less confusing or more comprehensible.

21.7. Forms

EACRER Form 10 (A): Minutes of the Meeting
EACRER Form 2 (G): Protocol Assessment Form
EACRER Form 2 (E): Informed Consent Assessment Form

21.8. History of SOP

Version No.	Date	Authors	Main Change
1	08 October 2025	EACRERC Members 2025	First Draft

20.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

22.1. Policy Statement

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

22.2. Objective of the Activity

The preparation of the minutes of the meeting ensures proper documentation of the procedures and decisions in an EACRERC meeting.

22.3. Scope

This SOP is specifically applied to the preparation of meeting minutes. This SOP begins with the entry of preliminary information on the minutes template and ends with the filing of the approved minutes.

22.4. Process Flow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Entry of preliminary information on the minutes template	EACRERC Staff	1 working day
Step 2	Preparation of the draft minutes	EACRERC Member Secretary and EACRERC Staff	3 working days
Step 3	Notation of the draft minutes	EACRERC Chair	1 working day
Step 4	Approval of the minutes in the next EACRERC meeting	EACRERC Chair and Members	1 day
Step 5	Filing of the of the approved minutes (SOP # 24 Managing Active Files)	EACRERC Staff	1-2 working days

22.5. Description of Procedures

Step 1 – **Entry of preliminary information on the minute's template:** The EACRERC staff will use a prepared minutes template to take note of the proceedings of the meeting. Basic information such as protocol number, title, name of PI, of each protocol submission for review is filled out to the meeting minutes template before the meeting date.

Step 2 – **Preparation of the draft minutes:** The EACRERC will do real time note-taking as the meeting progress. Comments and recommendations on scientific issues, ethical issues, and informed-consent issues are mandatory and prioritized in the notetaking. No attribution to a member is stated in the minutes. The Member-Secretary checks the prepared draft of the minutes by the next day.

Step 3 – **Notation of the draft minutes:** The minutes of the meeting shall include the following:

- Date and venue of the meeting
- Members attendance (members present and absent)
    - Presence of independent consultants, primary investigators, 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
    - EACRERC decisions and recommendations
    - Name and signature of person who prepared the minutes
    - Name and signature of the EACRERC Chair and date of notation

The complete draft of the meeting minutes will be submitted to the Chair for correction and finalization after four (4) days from the date of the meeting. Similarly, it will be sent to the members for any possible corrections, if there is any. Members have five (5) days to review and comment. All corrections coming from the members will be incorporated in the final version of the meeting minutes. The final version together with the Notice of Meeting for the next EACRERC meeting is distributed.

Step 4 – **Approval of the minutes in the next EACRERC meeting:** Approval of the minutes is done through a formal motion from any member of the committee and seconded accordingly.

Step 5 – **Filing of the approved minutes:** The approved meeting minutes will be filed in the folder for Minutes of the Meetings. It is filed in a centralized file compartmentalized by year and by review panel for easy retrieval.

22.6. Glossary

Draft Meeting Minutes – Proceedings of the meeting prepared by the Panel 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 Panel members.

22.7. Forms

EACRER Form 10 (A): Minutes of the Meeting

22.8. History of SOP

Version No.	Date	Authors	Main Change
1	09 October 2025	EACRERC Members 2025	First Draft

22.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

23.1. Policy Statement

The EACRERC shall communicate its decisions to the researcher within six weeks after the receipt of complete set of submission documents. The communication document shall include clear instructions/recommendations for guidance of the researcher, must be written on an official stationery of the EACRERC and signed by the Chair.

23.2. Objective of the Activity

The management of communicating EACRERC decisions ensures that all stakeholders are appropriately, accurately and promptly informed of the results of deliberations of the EACRERC.

23.3. Scope

This SOP is specifically applied to actions related to the communicating EACRERC decisions (e.g. actions to applications submitted to the EACRERC). This SOP 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.

23.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Finalize recommendation of the Review Panel (SOP #5 Full Review) or Finalize recommendations of primary reviewers (SOP #4 Expedited Review)	EACRERC Chair	1 working day
Step 2	Transfer information from meeting of the minutes or reports to EACRERC decision forms or templates	EACRERC Member Secretary and EACRERC Staff	3 working days
Step 3	Approval of the EACRERC decision document	EACRERC Chair	1 working day
Step 4	Transmittal of EACRERC decision to PI	EACRERC Staff	1 working day
Step 5	Filing of the decision document in the protocol file (SOP # 25 Managing	EACRERC Staff	1-2 working days

	Active Files) and Update of Protocol Database		

23.5. Description of Procedures

Step 1 – **Finalization of recommendations of the committee (SOP #6 Full Review) or reviewers (SOP #5 Expedited Review):** The EACRERC Chair shall follow the appropriate guidelines based on the type of review conducted—SOP #6 for Full Review study protocols and SOP #5 for Expedited Review study protocols.

Step 2 -**Transfer of Information from meeting minutes to EACRERC decision forms or templates:** The EACRERC staff fills out the Form 2I: Resubmission Form based on the report of the reviewer/s (Expedited Review) or minutes of the meeting (Full Review), or Form 5B: Ethics Clearance, if the review indicates approved.

Step 3 – **Approval of the decision document:** The EACRERC Chair signs the document prepared by the EACRERC staff.

Step 4 – **Transmittal of EACRERC decision to PI:** After signing, the EACRERC staff emails the PI the Resubmission Form (Form 2I) or the Ethics Clearance.

Step 5 – **Filing of the decision document in the protocol file and Update of Protocol Database:** The EACRERC staff files Form 2I: Resubmission Form or Ethics Clearance in the protocol file folder and updates the Protocol database. The Staff files a duplicate copy of the Notification or Approval letter in the protocol file folder and updates the Protocol database**.**

23.6. Forms

EACRER Form 2 (I): Review of Resubmitted Protocol Form
EACRER Form 5 (B): 2025: Ethics Clearance
EACRER Form 10 (A):Minutes of the meeting

23.7. Glossary

Expedited Review - is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.

Full Review– is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.

Database - a collection of information about proposals that is structured and organized for easy access, management, interpretation, analysis and updating. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

23.8. History of SOP

Version No.	Date	Authors	Main Change
1	08 October 2025	EACRERC Members 2025	First Draft

23.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

24.1. Policy Statement

All communications shall be recorded accurately and appropriately in a physical logbook and electronic database. Protocol-related communications are separated from administrative communications. Incoming communications shall be acted upon promptly.

24.2. Objectives of the Activity

The management of EACRERC incoming and outgoing documents/communications aims to establish accountability and an efficient and effective tracking system.

24.3. Scope

This SOP is specifically applied to the management of incoming/outgoing communications. This SOP begins with the sorting of incoming/outgoing communications and ends with the storing or filing of incoming/outgoing communications.

24.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Sorting of incoming/outgoing communication	EACRERC Staff	1 working day
Step 2	Recording of incoming/outgoing communication	EACRERC Staff	1 working day
Step 3	Acting on incoming communication	EACRERC Chair or EACRERC Member-Secretary	1 working day
Step 4	Filing of incoming/outgoing communications and Updating of database	EACRERC Staff	1 working day

24.4. Description of Procedures

Step 1 – **Sorting of incoming/outgoing communication:** The EACRERC staff will separate the protocol-related communications from the administrative communications.

Step 2 – **Recording of incoming/outgoing communications:** The EACRERC staff logs every protocol-related document received in the Database Incoming & Outgoing Protocols.

Step 3 – **Acting on incoming communication:** The EACRERC staff responds on incoming communications and the Chair finalizes the response by signing the protocol-related document for outgoing communications.

Step 4 – **Filing of incoming/outgoing communications and Updating of database:** The EACRERC staff file Protocol-related communications in the study protocol file while non protocol-related documents are filed in the appropriate administrative file on the day that they are submitted.

24.5. Forms

Logbook for Incoming Communication
Logbook for Outgoing Communication

24.6. Glossary

Incoming Communications – are documents which are directed to and received at the EACRERC office.

Outgoing Communications – are documents generated within the EACRERC office intended for individuals or offices related to the operations of the EACRERC.

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

Protocol-related Documents - consist of all other documents aside from the proposal/proposal itself that are required to be submitted for review, e.g., Informed Consent Form, Survey Questionnaire, CV of proponent, etc.

24.8. History of SOP

Version No.	Date	Authors	Main Change
1	09 October 2025	EACRERC Members 2025	First Draft

24.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

25.1. Policy Statement

Active files shall be kept in a secured cabinet, arranged in an orderly manner that shall allow easy identification and retrieval. Access to the active files shall be governed by SOP on Managing Access to Confidential Files (SOP # 27).

25.2. Objective of the Activity

The management of active files ensures accessibility, easy retrieval of current files, and protection of those that require confidentiality.

25.3. Scope

This SOP is specifically applied to management of active files. This SOP begins with the classification and coding of active files and ends with the periodic updating of the file.

25.5. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Classification and coding of Active Files	EACRERC Member-Secretary and EACRERC Staff	1 working day
Step 2	Preparation of the Digital Protocol Folder	EACRERC Staff	1 working day
Step 3	Periodic updating of the Protocol File	EACRERC Secretary and EACRERC Staff	1 working day

25.5. Description of Procedures

Step 1 – **Classification and coding of Active Files:** See SOP #7 Management on Initial Submission for the assignment of Protocol Code, which will indicate the same for the rest of the submission related to the initial submission.

The EACRERC Staff under the supervision of the EACRERC Member-Secretary classifies the active files as follows:

1. Initial Submission
2. Resubmission
3. Progress Report
4. Amendment
5. Protocol Deviation

6. Protocol Violation
7. SAE Serious Adverse Event (SAE)
8. SUSAR – Suspected Unexpected Serious Adverse Reaction
9. Early Termination
10. Continuing Review
11. Final Report/Close Out Report

Step 2 – **Preparation of the Digital Protocol Folder:** The EACRERC files all digitized documents on a study in a digital folder that is labeled with: EACRERC Code- Study Title - Proponent's Family Name – Unit/Sponsor. A word file is created to indicate the protocol index and the contents of the folder.

Step 3 – **Periodic Updating of the Protocol File:** The staff ensures that the documents are filed
in chronological order such that the most recent documents are topmost. These documents include the following:

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

The staff updates the protocol index each time a new document is added to the file. The protocol folder is periodically checked for orderliness and completeness.

25.6. Glossary
Study File Index - is a chronological record of the documents in the proposal file. The proposal index is in table form indicating the date of filing, the nature of the document filed, the name and signature of the person who filed and an extra column to record any movement of the document. The index is pasted inside the cover page of the proposal file/folder for easy reference and checking.

25.7. Forms
Study File Index

25.8. History of SOP

Version No.	Date	Authors	Main Change
1	09 October 2025	EACRERC Members 2025	First Draft

25.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

26.1. Policy Statement

Files of studies which have been terminated or completed or declared inactive shall be kept in a separate storage for three (3) years. Studies of Researchers who have not resubmitted their proposals within 3 months after receiving the Notification Letter shall be considered inactive.

26.2. Objective of the Activity

Archiving inactive, terminated, or completed protocols ensures efficient retrieval of information from the files for reference and compliance with national and international guidelines.

26.3. Scope

This SOP is specifically applied to archiving of study protocols. This SOP begins with the acceptance of final or early termination reports and identification of a protocol as inactive and ends with the inclusion of the files in the archives and update of the protocol database.

26.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Acceptance of Final or Early Termination Reports (SOP #14 Review of Final Reports, SOP # 15 Review of Early Termination Reports, and Identification of a Protocol as Inactive.	EACRERC Members, EACRERC Chair	1 working day
Step 2	Updating of corresponding protocol folder	EACRERC Staff	1 working day
Step 3	Transfer of the protocol folder in the archives and Update of the Protocol Database	EACRERC Staff	1 working day

26.5. Description of the Procedures

Step 1 - **Acceptance of Final or Early Termination Reports and Identification of an Inactive File:** The EACRERC members approve or accept the final report or early termination report during a meeting (SOP # 15 Review of Final, Report; SOP # 16 Review of an Early Termination Report). In the identification of an Inactive File, the staff informs the EACRERC Member Secretary of the failure of a concerned researcher/ proponent/ investigator to respond to the recommendations of the EACRERC in the last three (3) months during which time the researcher/proponent/investigator 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 the corresponding active file:** The EACRERC staff 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. The protocol code shall be updated to include the date when it is archived, e.g. EACRER YYYY-NNN-YYYYYMM (EACRER 2025-001-202512)

Step 3 - **Transfer of the Protocol Folder in the Archives and Update of the Protocol Database:** The EACRERC staff checks whether the documents listed in the protocol file index are complete and removes extraneous documents. The EACRERC staff transfers the folder to the archive section and updates the protocol database.

26.6. Glossary

Final Report – is a summary of the outputs and outcomes of the study upon its completion. The EACRERC requires the accomplishment of the Final Report form within a reasonable period after the end of the study.

Inactive Study – a study whose proponent has not communicated with the EACRERC with regard to issues pertaining to the approval or implementation of the study – within a period of time required by the EACRERC.

Active Study – is an ongoing study, implementation of which is within the period covered by ethics clearance.

Archiving- is the systematic keeping of proposal files in storage after the studies have been completed with final reports accepted or terminated or declared inactive.

Confidentiality of Documents – pertains to the recognition and awareness that certain documents that have been entrusted or submitted to the EACRERC must not be freely shared or disclosed.

Controlled document – pertains to the document that have been entrusted or submitted to the UPVREB that must not be freely shared or disclosed such that it is appropriately tagged, and its distribution carefully tracked, monitored and appropriately recorded

26.7. Forms

Study File Index

26.8. History of SOP

Version No.	Date	Authors	Main Change
1	09 October 2025	EACRERC Members 2025	First Draft

26.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

27.1. Policy Statement

Access to the EACRERC confidential files shall be regulated and limited to EACRERC members and staff. 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. Researchers/Investigators shall be allowed access only to their own protocol files upon request.

27.2. 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 EACRERC.

27.3. Scope

This SOP is specifically applied to the management of access to confidential files. This SOP begins with the receipt of the request to access and ends with the return of the documents to the protocol folder.

27.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Receipt and logging of request for access to confidential files	EACRERC Staff	1 working day
Step 2	Approval of requests for access and retrieval of documents	EACRERC Chair or EACRERC Member-Secretary	1 working days
Step 3	Supervision of use of retrieved document	EACRERC Staff	1 working day
Step 4	Return of document to the files	EACRERC Staff	1 working day

27.5. Description of Procedures

Step 1 – **Receipt and logging of request for access to confidential files:** The EACRERC staff receives request to access specific files and directs this to the EACRERC Member-Secretary or EACRERC Chair (if the EACRERC Member-Secretary is unavailable) for approval.

Step 2 – **Approval of requests for access and retrieval of documents:** The EACRERC Member-Secretary or EACRERC Chair will review the reason for the request and approves if

it is justified. The requesting individual shall sign the confidentiality agreement, after then the EACRERC staff retrieves the requested file.

Step 3 – **Supervision of use of retrieved document**: Generally, access to the document is for room use only, however copy of the requested document may be allowed on a case-to-case basis, upon the approval of the EACRERC Chair. If approved, the EACRERC staff produces the exact number of copies approved by the EACRER Chair. The recipient signs the EACRERC log upon receipt of the copies.

Step 4 – **Return the document to the files:** The EACRERC staff who retrieved the document is responsible for returning the document in the protocol file folder, ensuring the all the documents are complete as per Protocol File Index.

27.6. Glossary

Room-use Restriction – the rule that limits the use of a document within the designated premises

27.7. Forms

Request Letter
Database
Borrower's log
Disclosure of COI

27.8. History of SOP

Version No.	Date	Authors	Main Change
1	10 October 2025	EACRERC Members 2025	First Draft

27.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

28.1. Policy Statement

Queries and complaints from clients, patients, or research participants shall be attended to promptly and appropriately while exercising due diligence. The nature of queries shall determine whether they can be answered by the EACRERC staff or referred to the primary reviewers of the specific protocol. All complaints shall be referred to the Chair who shall determine the level of risk involved. Complaints of minimal risk shall be referred to the primary reviewers for resolution. Complaints of more than minimal risk shall be taken up in a special meeting within 48 hours for deliberation by the committee en banc with the primary reviewers leading the discussion.

28.2. Objective of the Activity

Managing queries and complaints aims to promote public trust and confidence in the institution, especially in the EACRERC and to ensure that the rights and well-being of participants are attended to.

28.3. Scope

This SOP is specifically applied to the management of queries and complaints. This SOP begins with the receipt, logging, and acknowledgement of queries and complaints and ends with the logging of the response and inclusion in the agenda of the EACRERC meeting.

28.4. Workflow

Process Flow	Activity	Responsibility	TIMELINE
Step 1	Receipt, logging, and acknowledgement of queries and complaints (SOP #24 Managing EACRERC Incoming and Outgoing Communications)	EACRERC Staff	1 working day
Step 2	Referral of query or complaint to appropriate authority. 2.1 Referral of protocol-related query to primary reviewers.	EACRERC Staff	1-2 working days

	2.2. Referral of all complaints to the EACRERC Chair		
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	EACRERC Staff	1 working day
Step 4	Communication of response (SOP # 23 Communicating EACRERC Decisions)	EACRERC Staff	1 working day
Step 5	Logging of the response (SOP on Managing EACRERC Incoming and Outgoing Communications (SOP # 24)) and inclusion in the agenda of the EACRERC meeting (SOP on Preparing the Meeting Agenda (SOP # 20))	EACRERC Staff	1 working day

28.5. Description of Procedures

Step 1 – **Receipt, logging, and acknowledgement of queries and complaints:** The EACRERC receives the letter of query and/or complaints and logs it in the database. The database includes the date, time, name of the concerned party, specific study, and nature of the query or complaint.

Step 2 – **Referral of query or complaint to appropriate authority:** The EACRERC Chair directs the queries or complaints to the concerned party in the Committee. Queries related to specific protocols are directed to the primary reviewers, while all complaints are directed to the EACRERC Chair who then determines the level of risk affected by the issue. Complaints with minimal risks are directed to the reviewer/s of the concerned protocol, on the other hand, complaints with more than minimal risks are referred to the Committee by calling for a special meeting within forty-eight (48) hours. The EACRERC staff notifies the concerned primary

reviewers that they will head the discussion, and related materials are sent their way to be used as reference.

Step 3 – **Formulation of response:** For queries, the reviewer/s accomplish Form 9A: Query and Complaints Form.

For minimal risk complaints, the reviewer/s accomplish Form 9A: Query and Complaints Form.

For more than minimal risk complaints, the committee may choose any of the following options:

3.3.1. Constitute a site visiting team to gather more information, verification and clarification regarding the source and cause/s of the complaint for its early resolution.

3.3.2. Designate the primary reviewers to meet with the complainants and the researcher (preferably separately) for clarification of issues and obtain suggestions for resolution.

3.3.3. Formulate recommendation if satisfied with the adequacy of information –

- request for explanation/justification from researcher
- accept request/demand of participant
- suspension of further recruitment
- amendment of protocol and re-consent of participants
- others

Step 4 – **Communication of response:** The EACRERC staff prepares the responses to the complainant and sign by the EACRERC Chair.

Step 5 – **Logging of response and inclusion in the agenda of the EACRERC meeting:** The EACRERC staff logs the response and include the query and/or complaints in the agenda of the next meeting.

28.6. Glossary

Query – the act of asking for information or clarification about a study.

Complaint – the act of expressing discontent or unease about certain events or arrangements in connection with a study.

28.7. Forms

EACRER Form 9 (A): Query/Complaint Form

28.8. History of SOP

Version No.	Date	Authors	Main Change
1	10 October 2025	EACRERC Members 2025	First Draft

28.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

29.1. Policy Statement

The EACRERC shall periodically review its SOPs to determine the need for revisions in order to maintain its relevance and effectiveness to its operations.

29.2. Objective of the Activity

Writing and revising SOPs ensures continuing quality assurance of EACRERC function.

29.3. Scope

This SOP is specifically applied to all EACRERC activities that are involved with the development, revisions, publications, and dissemination of its SOPs to the institution. It begins with the proposal and approval for the revision or writing of new SOPs and ends with the inclusion of the new or revised SOP in the SOP Manual and its dissemination.

29.4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Proposal for Revision of an SOP or a New SOP	EACRERC Member
Step 2: Deliberation of the Proposed Revision or Constitution of New SOPs	EACRERC Chair
Step 3: Drafting of the Revision or New SOP	EACRERC Members
Step 4: Review and Finalization of SOP	EACRERC Members
Step 5: Submission of the SOP to the Research Director for Approval	EACRERC Chair and EACRERC Members
Step 6: Inclusion of the New or Revised SOP in the SOP Manual and its Dissemination	EACRERC Staff

29.5 Description of Procedures

Step 1 – **Proposal for Revision of an SOP or a New SOP**: Any member of the committee may propose to amend old SOPs or suggest new SOPs for review. This proposal is presented formally during a meeting where members evaluate the merits of the proposal.

Step 2 – **Deliberation of the Proposed Revision or Constitution of New SOPs**: If the proposal is evaluated to be beneficial by all members of the committee. Approval to revise or constitute new SOPs shall be decided by a majority vote.

Step 3 – **Drafting of the Revision or New SOP:** The proponent/s shall draft the proposed amendment or the new SOPs and present them to the EACRERC Chair. The chair then distributes the drafts to the Committee for comments. In writing the draft, the following template is recommended:

(a) Title, which is descriptive of contents
(b) Policy statement
(c) Objective/s of the activity, which defines the purpose and intended outcome
(d) Scope, which defines the extent of coverage of the SOP and its limitation
(e) Workflow provides a graphic representation of the essential steps to implement the SOP and the responsible person for each step
(f) Description of Procedures, which elaborate on the steps listed in the workflow
(g) Glossary, acronyms and terms which need to be defined
(h) Forms, documents to be accomplished by different parties as required by the SOP, document history, which tabulates the different versions (from draft to final versions) of the document by author, version, date, and description of the main changes
(i) References, which lists the instruments used to draft the Guidelines such as other SOPs, guidelines, or policies

Step 4 – **Review and Finalization of SOP:** The Chair shall present the draft to the Committee for final review and deliberation. If approved, the staff is asked to prepare the draft for official publication and endorsement to the Research Director.

Step 5 – Submission of the SOP to the Research Director for Approval: The finalized SOP is formally submitted by the RERC Chair and members to the Research Director for review and official approval before implementation.

Step 6 – **Inclusion of the New or Revised SOP in the SOP Manual and its Dissemination**: Amended or newly constituted SOPs shall be disseminated within thirty (30) days of approval of the Research Director and will be disseminated as a hard copy.

29.6. Glossary

SOP (Standard Operating Procedure) – These are the step-by-step descriptions of the different procedures done to accomplish the objective of an activity. They consist of for the conduct of ethical reviews to ensure quality and consistency

Deliberation – A formal discussion and evaluation of a proposal before making a decision.

Proponent – A member who proposes a new SOP or revision of an existing one.

Revision – The process of updating or modifying an existing SOP to maintain its relevance and effectiveness.

29.7. Forms

29.8. History of SOP

Version No.	Date	Authors	Main Change
1	10 October 2025	EACRERC Members 2025	First draft

29.9. References

Philippine Health Research Ethics Board Standard Operating Procedures 2020
National Ethical Guidelines for Health and Health-related Research 2020

Glossary

Active Study – is an ongoing study, implementation of which is within the period covered by ethics clearance. Archiving- is the systematic keeping of proposal files in storage after the studies have been completed with final reports accepted or terminated or declared inactive.

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

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

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

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”.

Amendment – Any change or revision in the protocol made after its approval.

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

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

Coding - a unique number assigned to a protocol indicating the year and series it was received.

Complaint – the act of expressing discontent or unease about certain events or arrangements in connection with a study.

Confidentiality - duty to not freely disclose private/research information entrusted to an individual or organization.

Confidentiality of Documents – pertains to the recognition and awareness that certain documents that have been entrusted or submitted to the EACRERC must not be freely shared or disclosed.

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.

Conforme – acceptance of or agreement to an assignment or designation.

Controlled document – pertains to the document that have been entrusted or submitted to the EACRERC that must not be freely shared or disclosed such that it is appropriately tagged, and its distribution carefully tracked, monitored and appropriately recorded

Database – a collection of information (e.g. regarding a protocol/s) that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

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

Deliberation – A formal discussion and evaluation of a proposal before making a decision.

Draft Meeting Agenda – the order of business that includes the list of topics or items recommended for discussion in a meeting. This is endorsed to the EACRERC Chair for his/her approval.

Draft Meeting Minutes – Proceedings of the meeting prepared by the Panel Secretary.

EACRERC SOP - Emilio Aguinaldo College Research Ethics Committee Standard Operating Procedure

Early Termination - refers to the decision of the researcher, principal investigator, the institution, or sponsor to end the implementation of a study before its completion.

Exempt from Review - a decision made by the EACRERC Chair or designated member of the committee regarding a submitted study proposal based on criteria in the NEGHHR 2022 The Ethics Review Process Guideline 47-48.3. This means that the protocol will not undergo an expedited nor a full review.

Expedited Review - is the ethical evaluation of a research proposal and other protocol- related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.

Expert – a person who is specially qualified and trained in a particular field.

Expertise - a proficiency, skill or know-how possessed by experts in a certain academic or Professional field.

Final Meeting Agenda - is the order of business that includes the list of topics or items approved for discussion in a meeting by the EACRERC Members in a regular or special meeting.

Final Meeting Minutes – Proceedings of the meeting that have been approved by the Panel members.

Final Report – is a summary of the outputs and outcomes of the study upon its completion. The EACRERC requires the accomplishment of the Final Report form within a reasonable period after the end of the study.

10th FLOOR, BLDG 7, 1113-1117 SAN MARCELINO ST., PACO, MANILA
EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph
TEL. NO.: (632) 8521 2710 local 5388

Full Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.

Inactive Study – a study whose proponent has not communicated with the EACRERC with regard to issues pertaining to the approval or implementation of the study – within a period of time required by the EACRERC.

Incoming Communications – are documents which are directed to and received at the EACRERC office.

Independent consultants – whose presence is called upon to provide expert opinion on the protocol under review. They are member of the EACRERC.

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

Majority rule – is a policy based on the principle that the decision made by the greater number should be carried/accepted.

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

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

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

Non-affiliated – are regular members who are not in the roster of personnel or staff of the Institution. They are not employees of the institution, nor do they receive regular salary or stipend from the institution.

Non-medical – are individuals without academic degrees in the medical profession nor a master's degree in the nursing profession.

Non-scientific – are individuals whose primary interest is not in any of the natural, physical and Social sciences and whose highest formal education is a bachelor's degree.

Outgoing Communications – are documents generated within the EACRERC office intended for individuals or offices related to the operations of the EACRERC.

10th FLOOR, BLDG 7, 1113-1117 SAN MARCELINO ST., PACO, MANILA
EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph
TEL. NO.: (632) 8521 2710 local 5388

Outgoing Communications – are documents generated within the EACRERC office intended for individuals or offices related to the operations of the EACRERC.

PI – refers to the Principal Investigator of the study. The person responsible for the study.

Preliminary review – initial evaluation of protocol package done by the EACRERC Chair to determine the type of review appropriate for the study.

Primary reviewer – is a member of the EACRERC who is assigned to do an in-depth evaluation of research related documents using technical and ethical criteria established by the committee.

Progress Report – description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Form 4B. The frequency of submission at least once a year or as requested by the EACRERC.

Proponent – A member who proposes a new SOP or revision of an existing one.

Protocol database - a collection of information (e.g. regarding protocols) that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

Protocol Deviation – non-compliance with the approved protocol that does not increase risk or decrease benefit to participants or does not significantly affect their rights, safety or welfare or the integrity of data. Example: missed visit, non-submission of a food diary on time.

Protocol File/Folder – is an organized compilation of all documents (in physical or electronic form) related to a study.

Protocol package – refers to the set of pertinent documents (protocol and forms) submitted to the EACRERC for review.

Protocol Violation - non-compliance with the approved protocol that increases risk or decreases benefit to participants or significantly affects their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.

Protocol-related Documents - consist of all other documents aside from the proposal/proposal itself that are required to be submitted for review, e.g., Informed Consent Form, Survey Questionnaire, CV of proponent, etc.

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

Provisional Meeting Agenda – is the order of business that includes the list of topics or items approved for discussion in a meeting by the EACRERC Chair.

10th FLOOR, BLDG 7, 1113-1117 SAN MARCELINO ST., PACO, MANILA
EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph
TEL. NO.: (632) 8521 2710 local 5388

Provisional Meeting Minutes – Proceedings of the meeting that have been noted or approved by the Presiding officer.

Query – the act of asking for information or clarification about a study.

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

Regular Meeting - a periodically scheduled assembly of the EACRERC

EACRERC – Emilio Aguinaldo College Research Ethics Review Committee

Resubmission – the revised study proposal that is re-forwarded to the EACRERC following the recommendations from the initial review.

Revision – The process of updating or modifying an existing SOP to maintain its relevance and effectiveness.

Room-use Restriction – the rule that limits the use of a document within the designated premises

SAE (Serious Adverse Events) – is an event observed during the implementation of a study where the outcome is any of the following

Site Visit – is an activity of the EACRERC where an assigned team goes to the research site or office for specific monitoring purposes.

SOP (Standard Operating Procedure) – These are the step-by-step descriptions of the different procedures done to accomplish the objective of an activity. They consist of for the conduct of ethical reviews to ensure quality and consistency

Special meeting – an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like selection of officer, approval of a revised or new SOP, report of critical research problem that requires immediate action.

Study Documents – include all materials (protocol and forms) pertinent to a research proposal that have to be submitted to the EACRERC for a comprehensive review.

Study File Index - is a chronological record of the documents in the proposal file. The proposal index is in table form indicating the date of filing, the nature of the document filed, the name and signature of the person who filed and an extra column to record any movement of the document. The index is pasted inside the cover page of the proposal file/folder for easy reference and checking.

SUSAR (Suspected Unexpected Serious Adverse Reactions)- is a noxious response to a drug that is

10th FLOOR, BLDG 7, 1113-1117 SAN MARCELINO ST., PACO, MANILA
EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph
TEL. NO.: (632) 8521 2710 local 5388

Termination package - refers to the entitlements of study participants in the event of discontinuance of the study, which can come in the form of access to the study intervention, treatment, or information, for purposes of adherence to the principle of fairness for all concerned.

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

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

10th FLOOR, BLDG 7, 1113-1117 SAN MARCELINO ST., PACO, MANILA
EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph
TEL. NO.: (632) 8521 2710 local 5388

GROUP A

EMILIO AGUINALDO COLLEGE
1113-1117 San Marcelino St., Paco, Manila 1007, Philippines www.eac.edu.ph (02) 8521-2710
VIRTUE ♦ EXCELLENCE ♦ SERVICE
EAC RESEARCH ETHICS REVIEW (RER) COMMITTEE
EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph

CURRICULUM VITAE

(For EACRERC Reviewer Applicants)

_____
COMPLETE NAME & Academic/Professional Title

[School/Affiliation]

ROLE AND DESIGNATION IN THE INSTITUTION

- ❖
- ❖

Field of Expertise and Specialization:

- ❖
- ❖

Eligibility:

- ❖
- ❖

Educational Background:

- ❖
- ❖
- ❖

Research Publications

- ❖
- ❖

Research Ethics Relevant Trainings/Seminar attended

- ❖
- ❖

Achievements and Awards

- ❖
- ❖

I hereby declare that all information stated are accurate and true

_____
Signature over printed name
Date Signed:

10th FLOOR, BLDG 7, 1113-1117 SAN MARCELINO ST., PACO, MANILA
EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph
TEL. NO.: (632) 8521 2710 local 5388

GROUP B

EMILIO AGUINALDO COLLEGE
1113-1117 San Marcelino St., Paco, Manila 1007, Philippines www.eac.edu.ph (02) 8521-2710
VIRTUE ♦ EXCELLENCE ♦ SERVICE
EAC RESEARCH ETHICS REVIEW (RER) COMMITTEE
EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph

APPOINTMENT LETTER

[DATE]

FOR:

SUBJECT: **APPOINTMENT LETTER** AS **[DESIGNATION]** of the **RESEARCH ETHICS REVIEW (RER) COMMITTEE**

This is to formalize your appointment as **[DESIGNATION]** of the **RESEARCH ETHICS REVIEW COMMITTEE of EMILIO AGUINALDO COLLEGE-MANILA** effective **[DATE EFFECTIVE]** unless sooner terminated for cause.
With this appointment, you are expected to perform your duties with competence and adherence to the International and National Guidelines and Regulations in Research and compliance with the EAC Standard Operating Procedures (SOP) in the responsible conduct of research.

[NAME OF VP FOR ACADEMIC AFFAIRS]
Vice President for Academic Affairs

[NAME OF VP FOR ADMINISTRATION]
Vice President for Administration

[NAME OF INSTITUTION PRESIDENT]
President

CONFORME

(signature)
[NAME OF EACRERC MEMBER]
Date:

ENDORSED BY:

(signature)
[NAME OF RESEARCH DIRECTOR]
Research Director

10th FLOOR, BLDG 7, 1113-1117 SAN MARCELINO ST., PACO, MANILA
EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph
TEL. NO.: (632) 8521 2710 local 5388

GROUP C

Communication No. **<NO.>** S <YYYY>
EAC Research Ethics Review Committee

DECISION LETTER

<DATE>

TO: **MS./MR. <NAME OF PRINCIPAL INVESTIGATOR>**
Principal Investigator
<School>
<Institution>

RE: **{TITLE OF PROJECT/STUDY}**
PROTOCOL CODE:

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

Dear Ms./Mr. <Name>,

This is to acknowledge receipt of your request and the following supporting documents submitted on **<Date Submitted>:**

-
-
-

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

(List of findings)

(List of recommendations)

(Specific instructions to the proponent, if any)

Best regards,

(Signature)

(Name)

Chair

EACRER FORM 5 (B) 2025: Research Ethics Clearance

We are pleased to inform you that your study protocol has undergone a thorough review and has been granted approval for implementation by the **EMILIO AGUINALDO COLLEGE RESEARCH ETHICS REVIEW** Committee.

Your study has been assigned the protocol code **<e.g. EACRER 2024-001>,** which should be referenced in all correspondence related to this research. Please note that this research ethics clearance is valid until <**mm/dd/yyyy**>.

RESEARCH ETHICS CLEARANCE	
Study Protocol Title	
Name of Principal Investigator (PI)	**<Name, Surname>**
School/Department/Affiliation/	
Funding Agency (if applicable)	

JUSTIFICATION FOR APPROVAL

The following documents have been approved for use in the study.

1. <Expedited or Full Board> protocol approved on < **mm/dd/yyyy>**
2. Informed consent <English/Tagalog Version> approved on <**mm/dd/yyyy>**
3. Assent form (if applicable) approved on <**mm/dd/yyyy>**
4. Resubmitted protocol form (if applicable) approved on <**mm/dd/yyyy>**
5. Protocol amended protocol (if applicable) approved on <**mm/dd/yyyy>**
6. Continuing review application (if applicable) approved on <**mm/dd/yyyy>**

Apart from the above-mentioned documents, the following technical documents were included in the screening on which this approval was based:

1. Letter of Intent
2. Technical Evaluation and plagiarism score indicating compliance with the acceptable standards for originality
3. Curriculum vitae of the principal investigator

RESPONSIBILITIES OF PRINCIPAL INVESTIGATOR WHILE STUDY IS IN PROGRESS

While the study is in progress, we request you to submit to us the following documents:

1. Progress Report Form 4(B)
2. Any changes in the protocol, especially those that may adversely affect the safety of the participants. If there changes in the protocol during the study, kindly submit Protocol Amendment Application Form 3(A).

3. Kindly submit Protocol Amendment Application Form 2(J) if there are revisions or changes made in the informed consent.
4. If there are reports of adverse events, kindly submit Unanticipated Adverse Report Form 4(A).
5. Notice of early termination of the study.
6. Any event which may have ethical significance.
7. Any information which is needed by the EACRER to do ongoing review.
8. Notice of completion of the study. Kindly submit the Final Report Form 4 (C) not later than sixty (60) days after the end of the study.
9. Application for renewal of ethical clearance thirty (30) days before the expiration date of approval through submission of Continuing Review Application Form 3(B).

_____
Signature of EACRER Chair over printed name

EACRER FORM 5 (A) 2025: CERTIFICATION OF EXEMPTION FROM ETHICS REVIEW

The **EMILIO AGUINALDO COLLEGE RESEARCH ETHICS REVIEW (EACRER)** committee has processed your request for **EXEMPTION FROM ETHICAL REVIEW** for the following study protocol and related documents which has been reviewed with following conditions and considerations:

CERTIFICATION OF EXEMPTION FROM ETHICAL REVIEW

EACRER PROTOCOL CODE	**<to be accomplished by the RER** committee>
Study Protocol Title	
Name of Principal Investigator (PI)	**<Name, Surname>**
School/Department/Affiliation/	
Funding Agency (if applicable)	
Submission Date	**<dd/mm/yyyy>**
Date of Action	**<dd/mm/yyyy>**

JUSTIFICATION FOR THIS CERTIFICATION

1. **< FOR QUALIFIED RESEARCHES WITH CRITERIA FOR EXEMPTION>:**
   The study protocol qualified with the criteria for exemption as stipulated in the National Ethical Guidelines for Research Involving Human Participants (2022), since the study **<indicate criteria for exemption>**

2. **<FOR RESEARCHES WITH NO STUDY PROTOCOL AND DOES NOT CONSTITUTE HUMAN HEALTH RESEARCH>:**
   This activity does not constitute human health research and will not involve collection of individual identifiable data. Furthermore, the National Ethical Guidelines for Research Involving Human Participants (2022) states that research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior, **< "if the information obtained is recorded by the investigator in such a manner that the identity of the participant cannot be ascertained", is considered exempt from ethical review>**

RESPONSIBILITIES OF PRINCIPAL INVESTIGATOR WHILE STUDY IS IN PROGRESS

1. Continuing compliance with the exemption criteria of the National Ethical Guidelines for Research Involving Human Participants (2022) in the duration of the study;
2. No substantial changes in research design, methodology and subject population from the protocol submitted for exemption. Modifications that significantly affect previous risk-benefits assessment or qualification for exemption may be submitted as new protocol for initial review.
3. Notice of termination of the study using Final Report Form.

_____
Signature of EACRER Chair over printed name

10th FLOOR, BLDG 7, 1113-1117 SAN MARCELINO ST., PACO, MANILA
EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph
TEL. NO.: (632) 8521 2710 local 5388

GROUP D

CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENT

Know all Men by these Presents:

Given the appointment as **<POSITION>, <NAME OF MEMBER>, <AFFILIATION>** hereinafter referred to as the *Undersigned*, and

Whereas:
The *Undersigned* has been asked to assess research studies and protocols involving human subjects to ensure that the same is conducted humanely and ethically, with the highest standards of care according to the applied national and local laws and regulations, institutional policies, and guidelines.

The appointment of the Undersigned as an <**POSITION**> of the EAC-RER committee is based on individual merits and neither as an advocate or representative of a home province/territory/community nor as the delegate of any organization or private interest.

The fundamental duty of an RER member is to independently review both scientific and ethical aspects of research protocols involving human subjects and decide on the best possible objective recommendations, based on the merits thereof under review; and

The EAC-RER must meet the highest ethical standards to merit the trust and confidence of the communities in protecting the rights and well-being of human subjects.

The following terms and conditions covering Confidentiality and Conflict of interest arising in the discharge of said appointed RER member.

Functions are hereby stipulated in this Agreement to ensure the same high standards of ethical behavior necessary for the RER to carry out its mandate.

Confidentiality

This Agreement thus encompasses any information deemed Confidential. Privileged or Proprietary provided to and/or otherwise received by the Undersigned in conjunction with and/or during the performance of his/her duties as a member/Independent Consultant of the EAC-RER.

Any written information provided to the Undersigned that is of a Confidential. Privileged or Proprietary shall be identified accordingly. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the RER.

As such, the Undersigned agrees to hold in trust and confidence all Confidential, Privileged, or Proprietary information, including trade secrets and other intellectual property rights (hereinafter collectively referred to as the "information"). Moreover, the Undersigned agrees that the information shall be used only for contemplated purposes and none other. Neither shall the said information be disclosed to any third party.

The Undersigned further agrees not to disclose or utilize, directly or indirectly, any information belonging to a third party, in fulfilling this agreement. Furthermore, the Undersigned confirms that her performance of this agreement is consistent with EAC policies, and any contractual obligations owed to third parties.

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist; however, there is concomitant faith in the ability of the RER to manage these conflict issues, if any, in such a way that the outcome of the protection of human subjects remains.

It is the policy of the RER that no member/consultant may participate in the review, comment, or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the RER. The Undersigned will immediately disclose to the Chair of the EAC-RER any actual or potential conflict of interest that he/she may have about any particular proposal submitted for review by the RER and abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that an RER member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chair. The request must contain evidence that substantiates the claim that a conflict exists with the RER member(s) in question. The RER may elect to investigate the applicant's claim of the potential conflict.

When a member/consultant has a conflict of interest, the member should notify the Chairperson and may not participate in the RER review or approval except to provide information requested by the Committee.

Examples of conflict-of-interest cases may include but are not limited to any of the following:

- A member/consultant is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's/consultant's personal biases may interfere with his or her impartial judgment.

Agreement on Confidentiality and Conflict of Interest

To the Undersigned: Please sign and date this Agreement if you agree with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the EAC-RER. A copy will be given to you for your records.

During my activities as a <**POSITION**> of the EAC-RER, I will be provided with confidential information and documentation (which we will refer to as "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information, subject to applicable legislation, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chair or Committee upon termination of my functions as an RER member.

Whenever I have a conflict of interest, I shall immediately inform the Chair or Committee not to count me toward a quorum for voting.

I have read and accept the terms and conditions as explained in this Agreement.

_____ Date: _____

<NAME OF MEMBER>
<POSITION>

EMILIO AGUINALDO COLLEGE
1113-1117 San Marcelino St., Paco, Manila 1007, Philippines www.eac.edu.ph (02) 8521-2710
VIRTUE ♦ EXCELLENCE ♦ SERVICE
EAC RESEARCH ETHICS REVIEW (RER)COMMITTEE
EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph

Reference Code	<.....> *(To be filled out by EACCRP Staff)*
Protocol Code	<.....> *(To be filled out by EACCRP Staff)*

EACRER FORM 6 (A) 2025: DISCLOSURE OF CONFLICT OF INTEREST AGREEMENT
(FOR MEMBERS AND CONSULTANTS)

In general, *Conflict of Interest* occurs when there is conflict (actual, potential or perceived) between an individual's duties and his/her personal or private interest. *Conflict of Interest* impairs one's abilities to exercise objectivity in the performance of official duties.

The Members (including the Chair) of the EAC Research Ethics Review Committee and its consultants shall sign this agreement to disclose any *Conflict of Interest* that they may have in the review of research protocols and other related documents.

The following can be used as a guide to determining whether he/she has *Conflict of Interest.*

INSTRUCTIONS TO EACRERC MEMBERS AND/OR CONSULTANTS
Before affixing your signature below, please consider each of the following statements in relation to: 1.) all your past and current official positions; and 2.) all your immediate family members, especially spouse and children. Then, check (✓) your answer in the 'yes' or 'no' column.

STATEMENTS	YES	NO
• I/My family have owned stocks and shares in the proponent organization(s).		
• I/My family have received a salary, an honorarium, a compensation, concessions and gifts from the proponents organization(s).		
• I/My family have served as an officer, director, advisor, trustee, consultant or an active participant in the activities of the proponent organization(s).		
• I/My family/my other organizations have had research work experience with the principal investigator(s).		
• I/My family/my other organizations have a long-standing issue against the principal investigator(s), the proponent organization(s), or the funding agency.		
• I/My family have regular social activities, such as parties, home visits, and sport events, with the principal investigator(s).		
• I/My family/my other organizations have an interest in or an ownership issue against the proposed topic.		

As a member/consultant of the EAC Research Ethics Review Committee (EACRERC) I shall disclose any conflict of interest that I may have in connection with the review of specific research protocols and related documents.

I shall do this before or during any deliberations so that I may not participate in the decision regarding the said protocol.

_____ _____
SIGNATURE OVER PRINTED NAME **DATE**

_____
INSTITUTIONAL AFFILIATION

_____
ADDRESS

10th FLOOR, BLDG 7, 1113-1117 SAN MARCELINO ST., PACO, MANILA
EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph
TEL. NO.: (632) 8521 2710 local 5388

GROUP E

EAC RESEARCH ETHICS REVIEW (RER) COMMITTEE
EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph

Reference Code	<.....> (To be filled out by EACCRP Staff)
Protocol Code	<.....> (To be filled out by EACCRP Secretariat)

EACRER FORM 2(A): APPLICATION FOR RESEARCH ETHICS CLEARANCE

Please utilize this form to submit your application for research studies involving human participants. Fill in all the information needed regarding your form.

A. **GENERAL INFORMATION** *To be filled out by the Principal Investigator*

Research Study Protocol Title	
Principal Investigator (PI)	
Position/Designation	**<faculty, undergraduate/graduate learner, staff, dean>**
Institution	
School/Department	
Student ID/Employee number	
Email Address	
Contact number	
Research Advisor (if PI is a learner)	
Email of Research Advisor	
Research Advisor Contact No.	
Date submitted by the PI	
PI Signature	

B. PROTOCOL INFORMATION

Research Study Protocol Title	
Type of Study	*(Check only that apply)* [ ] Academic Requirement [ ] Collaborative Research Project [ ] Independent Research Work/Project [ ] Community Research Work [ ] Other (specify):

Funding Source	*(Check only that apply)* [ ] Self-funded [ ] Institution-funded [ ] Government-funded [ ] Consortium/External Organization funded Specify the name of the organization: [ ] Business/Industry-funded Specify the name of the funding agency:
Brief Description of the Research Study Protocol	< 1. Describe the **objective of the study** > < 2. Describe the **procedure** of the study > < 3. How long will the participants be involved in this research study? (ex. The number of sessions, and the duration of each session) > < 4. Where will this study take place? >
Duration of the entire study	**<start>** **<end>**
Number of participants	
Has the research study passed the technical review?	[ ] YES (attach EAC-CRP Form 1.2 or 1.3 or any valid proof) [ ] NO
Has the research study passed the acceptable score for plagiarism?	[ ] YES (attach EAC-CRP Form 1.2 or 1.3 or any valid proof) [ ] NO

C. ETHICAL CONSIDERATION	
A. Confidentiality and Privacy	1. Aside from research data, indicate the identifiable information you will collect or access in this study. *(Select all that apply)* [ ] Name (first & last name) [ ] Home/Residence Address [ ] Email Address [ ] Birthdate [ ] Contact Numbers [ ] Any valid government ID numbers [ ] Financial account [ ] Full-face photo or video [ ] Other unique identifier: _____ Briefly explain or justify why you will collect or access this information: 2. Describe the measures you will take to maintain the confidentiality of the identifiable information. *(Select all the apply)* [ ] Use of identification code (ex. code numbers, pseudonyms) [ ] Password-protected computer files or web-based storage [ ] Locked file cabinets [ ] Locked offices [ ] Other: Briefly explain how participants' privacy will be maintained during the data collection process. 3. What will happen to the research data when the study has been completed? *(Choose only one)* [ ] Destroyed immediately. [ ] Stored for a specific length of time. Specify the no. days/months/years. Briefly explain why the data must be stored.

B. Vulnerability of the Participants	*(Choose all categories of participants who will be involved in this research study)* [ ] Healthy adults [ ] Children-individuals under the age of 18 [ ] Prisoners [ ] Women who may be pregnant or have childbearing potential. [ ] Patients receiving medical treatment. [ ] Individuals with a mental or decisional impairment [ ] Individuals residing in government facilities, homes or centers [ ] Fetuses, neonates, fetal material in vitro fertilization [ ] HIV-positive individuals [ ] Indigenous groups [ ] Indigent persons (ex. low socioeconomic status) [ ] Senior citizens [ ] EAC learners [ ] Elementary [ ] High School [ ] College [ ] Others: Specify Are there specific inclusion criteria for participating in the study? [ ] **YES,** please specify: [ ] **NO** Are there specific exclusion criteria for participating in the study? [ ] **YES,** please specify: [ ] **NO**
C. Discomfort and Risks	1. Will medical, psychological, or other reparative measures be provided for participants who may require it because they participated in the study? [ ] **YES** (if yes, describe the source of medical or psychological care and provide the institution & contact information). [ ] **NO** 2. Does this research possibly involve greater than minimal risk to the participants (e.g., Risks greater than they normatively face in daily life)? [ ] **YES,** (if yes, describe the steps taken to minimize risk to participants throughout the study. [ ] **NO**

D. Benefits of the Study	1. What are the potential direct or indirect benefits of the study? 2. Explain how the benefits outweigh the risks of the study.
E. Payment for the Participants	Will compensation be given to the participants? [ ] **YES**, (if yes, how, and when will compensation/honorarium or gift be given to the participants? [ ] Compensation will **NOT** be offered.
F. Informed Consent Process	What type of consent will be obtained? [ ] Active signed consent (participants will sign a consent form) [ ] Active consent (participant will click a link signifying consent in an online survey) [ ] Active verbal consent (participant gives active consent verbally like in-person, online, or telephone interview) [ ] Others, specify:
G. Recruitment	Indicate the type of recruitment that will be done for this research. [ ] Letters/Emails/Telephone calls to potential participants [ ] Websites or media outlets [ ] Flyers, posters, brochures [ ] Face-to-face approach [ ] Others, explain:

H. Data Collection Methods/Sources of Data	Identify all the data collection methods or data sources that will be used in this study. Kindly attach a copy of all instruments/measures, interviews, and focus group topics/questions. [ ] Survey or questionnaires [ ] face-to-face [ ] online [ ] Psychological tests [ ] Cognitive/educational/achievement tests [ ] Individual interview [ ] face-to-face [ ] online [ ] Focus group discussion [ ] face-to-face [ ] online [ ] Behavior observations [ ] Photograph/audio/ video recordings [ ] Existing secondary data/records [ ] Existing biological specimens [ ] Collected biological specimens (e.g. urine, blood & other human-derived samples) *Will genetic data be derived from these samples? [ ] **YES** [ ] **NO** [ ] Biomedical devices (e.g. EEG, EKG, MRI, X-Ray) *Is the device registered? [ ] **YES** [ ] **NO** [ ] Physical testing measures (e.g. height, weight, BMI, Bp) [ ] Other, specify:
I. Other Biomedical Procedures	1. Will participants be asked to undergo diagnostic procedures? [ ] **YES** [ ]**NO** 2. Will participants undergo drug testing procedures? [ ] **YES** [ ]**NO** 3. Will participants undergo alcohol testing procedures? [ ] **YES** [ ]**NO** [ ] Other, specify:

For the use of EACRER Chair (Do not fill out)

Upon preliminary review of the study, this application is classified for:
[ ] Exempt [ ] Expedited [ ] Full Review

_____
EACRER Chair

Date:_____

J. ASSURANCES

As the Principal Investigator on this research study, I assure you that….

1. This application accurately reflects all procedures involving human participants and the nature and extent of their proposed involvement in my study.

2. I am familiar with and will comply with pertinent institutional and national regulations and policies regarding research ethics with human participants. I will inform the EACRER if need support or advice regarding an ethical concern.

3. I will notify the EACRER within one (1) week regarding any significant unexpected problems and/or unexpected adverse events that impact my human participants.

4. All research personnel listed on this form possess the requisite competencies and have been adequately trained in research and ethical behavior towards human participants.

5. Any individual associated with or responsible for the design, conduct, or reporting of this research will comply with Emilio Aguinaldo College rules and regulations.

_____ _____
Printed name & signature of the Principal Investigator Date

I hereby confirm that I have read this application, and my signature denotes the accuracy of the information provided. I confirm that I will supervise the learner or co-investigators as we conduct the study, and monitor that ethical standards and practices are maintained in the study.

_____ _____
Printed name & signature of Research Advisor Date
(Required if PI is a leaner)

I hereby confirm that I have read and noted this application. To the best of my knowledge, the information in the application relating to researchers of the is accurate.

_____ _____
Printed name & signature of Department/Unit Head Date
(Required if PI is a faculty/research professional)

To be filled out by EACRER Secretariat

Protocol Code	<.....>

EACRER FORM 2 (B): INFORMED CONSENT FORM IN ENGLISH
**Use this form as a guide and template for creating the Informed Consent Form.*

Research Study Protocol Title	
Name of Funder/Grant-Provider (if applicable)	
Name of Principal Investigator (PI)	
Email Address	
Contact Number	
Research Advisor (if PI is a learner)	
Email of Research Advisor	
Research Advisor Contact No.	

INTRODUCTION

I am **<Name>** and we are researching **<title of research study>**

This form provides you with information and invites you to be part of this research study. You may discuss the research with anyone you are comfortable with before deciding to participate or not.

This form may contain certain words that you do not clearly understand. Please do not hesitate to inquire from me/us at any point if you have any questions or need clarification. If any questions/doubts arise at a later time, you may inquire form me/us at any time during this research.

DESCRIPTION AND PURPOSE OF THE RESEARCH
Indicate a simple, accurate explanation of the purpose of the study.

The purpose of the study is to <.....>

PROCEDURES OF RESEARCH
Give a concise description of the procedures in the exact order or a step-by-step manner. Provide information on the assessment, tests, and measurements that will be performed. Indicate which procedures are routine and which are experimental or descriptive. Participants should clearly understand what to expect and what is expected of them.

PARTICIPANT SELECTION AND VOLUNTARY *Describe briefly how the participants are selected, where will the study take place and why they were selected.*
You are being asked to join this study because <.....>
DURATION *Explain how much time the subject will need to commit in terms of hours, days, weeks, months, and years.*
The study will take place over a period of <.....> The session will last approximately <.....>
POTENTIAL RISKS/HAZARDS/DISCOMFORTS *If there are any risks/hazards/discomforts involved in the research study, mention it all. It should also state what measures have been implemented within the study to minimize the possibility of occurrence of such risks.*
BENEFITS *Indicate benefits to the participants and/or community and/or society. Compensation for participation in the study is not considered a benefit.*
RESEARCH RELATED HARM/INJURY *Describe what care or treatment will be provided for research-related harm/injury that directly results from participation in the research.*

COMPENSATION
If the participants are compensated either monetary or in kind. If no compensation, please mention it as well.

CONFIDENTIALITY AND ANONYMITY
Explain how confidentiality will be maintained in this study. Be specific about how records will be secured to protect the identity of the subject. Explain how the subject will be pseudo-anonymized; e.g. will code numbers will be used?

RIGHT TO REFUSE OR WITHDRAW
Simply and directly tell the subject there are no negative consequences should they choose not to participate.

<You may choose to join the study, or you may choose not to join the study. Your participation is voluntary. There is no penalty if you choose not to join the research study>

<You can stop your participation in the research study and withdraw your data at any time even after it has started. There is no penalty or loss of benefits if you decide to do so.>

WHOM TO CONTACT
Provide contact information of ALL researchers/investigators that should be contacted if the participants have questions about the study.

<If you have questions or concerns regarding the study and your participation in it, contact the Principal Investigator and the co-investigators>

1. Name of PI: <.....>
   Institution: <.....>
   Contact number: <.....>
   Email address: <.....>

2. Name of Co-investigators: <.....>
   Institution: <.....>
   Contact number: <.....>
   Email address: <.....>

<If a member of the research team cannot be reached or you want to speak to someone other than those working on the study, you may contact the EAC Research Ethics Review (RER) Committee Office (RER Office) at the Emilio Aguinaldo College at 02 8521 2710 local 5388.

CERTIFICATE OF CONSENT
This section is mandatory and should be written in first-person language. Fill in the blanks with the appropriate information.

I have been invited to participate in a study about <**title of the study**>. In the study, I am asked to <.....>

I have read the information about the study, or it has been read to me. I have had the opportunity to ask questions about it and they have been answered to my satisfaction.

I consent voluntarily to be a participant in this study.

I was given a copy of the informed consent I have signed.

_____ Date:
Signature of the Participant Over Printed Name

[If the participant is unable to sign, or conditions justify that the participant did not sign to protect their identity, then a literate witness must sign on behalf of the participant. This person should be selected by the participant and have no connection to the research team.]

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

_____ Date:
Signature of the Participant Over Printed Name

STATEMENT BY THE RESEARCHER/PERSON OBTAINING CONSENT
This section is mandatory and to be filled out by the investigator

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability.

I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this document has been provided to the participant.

_____
Signature of Researcher/Person taking the consent Over Printed Name

Date: _____

To be filled out by EACRER Secretariat

Protocol Code	<.....>

EACRER FORM 2 (C): PORMULARYO NG MAY-KABATIRANG PAHINTULOT (INFORMED CONSENT)

Pamagat ng Pananaliksik	
Pangalan ng tagapondo	
Pangalan ng Pangunahing Mananaliksik (PM)	
Email Address ng PM	
Numero ng telepono	
Pangalan ng gurong tagapayo (kinakailangan kung ang PM ay isang mag-aaral)	
Email Address ng gurong tagapayo	
Numero ng telepono	

PANIMULA

Ako ay si **<pangalan>** at kami ay nanaliksik tungkol sa pag-aaral na may pamagat na <.....>

Inaanyayahan kang makilahok sa isang pananaliksik. Boluntaryo and pakikilahok mo, na nag ibig sabihin, Malaya kang makapili kung lalahok ka ng aba o hindi. Sakaling mapagpapasiyahan mong hindi lumahok, walang ipapataw na anumang parusa o negatibing ibubunga.

Huwag lalagda o sasang-ayong lalahok kung hindi ka tiyak o mayroon ka pang mga tanong. Mangyaring hilingin mo sa mananaliksik na ipaliwanag ang anumang hindi malinaw para s aiyo, pati na nag alinmang salita na nasa pormularyong ito. Kung mapagpapasiyahan mong lumahok, hihilingin sa iyo na lagdaaan ang pormularyong ito at ibibigay s iyo ang isang kopya o record ng pagpapahintulot pati na ang impormasyon hinggil sa pag-aaral.

LAYUNIN NG PANANALIKSIK
Maghayag ng isang payak at tumpak na paliwanag ng layunin ng pag-aaral

Nilalayon ng pananaliksik na ito na mapag-aralan pa ang tungkol sa <.....>

PAMAMARAAN NG PANANALIKSIK *Magbigay ng batayang pagkakasunod-sunod ng mga gagawin ng kalahok sa isang payak at di- teknikal na wika. Alalahaning ipaliwanag nang malinaw ang anumang proseso sap ag-eeksperimento.*
PAGPILI AT BULUNTARYO NG KALAHOK *Ipaliwanag kung bakit angkop na anyayahan ang kalahok sa pananaliksik.*
Inaanyayahan kang makilahok sa pananaliksik na ito dahil <…….>
TAGAL NG PANANALIKSIK *Ipaliwanag kung gaano katagal ang pananaliksik*
Magaganap ang pananaliksik sa loob ng <..... > Inaasahan na tatagal nang <.....> ang sesyon.
POSIBLENG PANGANIB *Ipahayag ng malinaw sa kalahok ang lahat ng maari o inaasahang di-kaginhawaan o panganib, anupaman ang antas ng mga ito.*
BENEPISYO *Isaad ang mga benepisyo para sa kalahok at/o sa kominidad at/o sa Lipunan sa kabuoan. Hindi itinuturing na isang benepisyo ang bayd sa paglahok sa pananaliksik.*

PANANALIKSIK NA MAY KAUGNAY NA PANGANIB *Ilarawan kung anong pag-aalaga o pagpapagamot ang maaaring maibigay para sa mga sakit/pinsalang tuwirang idinulot ng paglahok sa pag-aaral, pati na ang anumang limistasyon para sa ganitong pag-aalaga o pagpapagamot o anumang hakbang bilang kabayaran.*
BAYAD PARA SA PARTISIPASYON *Paglalarawan ng anumang kompensasyon, salapi o anupaman (halimbawa, food pack, gift certificate), kung bibigyan ng kompensasyon ang mga kalahok para sa kanilang oras, pagsisikap, at pagbibiyahe.*
KUMPIDEBSYAL AT ANONYMITY *Ipaliwang kung paano mapapanatili ang kumpidensiyalidad sa pananaliksik.*
<Kumpidensiyal ang impormasyong ibibigay mo. Hindi lalabas and buong pangalan mo sa alinman sa mga kuwestiyonaryo, at ang mga impormasyong makapagbubunyag sa identidad mo ay hindi lalabas sa alinman sa mga ulat o publikasyon ng pananaliksik na ito. Tanging ang pangunahing mananaliksik ang makaaalam sa identidad na may kaugnayan sa mga impormasyong nakolejta sap ag-aaral, at hindi nila ito isisiwalat kaninuman>
KARAPATAN NA TUMANGGI O WITHDRAW *Payak at tuwirang sabihin sa mga kalahok na walng anuman negatibong ibubunga ang hindi nila pagpili ng lumahok.*
<Maari mong piliing lumahok o hindi lumahok sa pananaliksik. Walang anumang kaparusahan kung hind imo piniling lumahok sa pananaliksik. Hindi mamasamain ng iyong ang magiging desisyon mo> <Maaaring bumitiw ka sa paglahok sa pananaliksik at mababawi mo ang mga datos na ibinigay mo kahit nagsimula na ang pag-aaral. Walang parusa o pagkawala ng benepisyo kapag napagpasiyahan mo ito.>
SINO ANG MATATAWAGAN PARA SA KATANUNGAN TUNGKOL SA PANANALIKSIK
<Kung may mga tanong tanong o paglilinaw hinggil sa pananaliksik at sa paglahok mo dito, makipag ugnayan sa Pangunahing Mananaliksik na nakatala sa unang pahina ng pormularyong ito>. < Kung hindi maabot ang isa sa mga miyembro ng pangkat mananaliksik o kung ibig mong makipag-usap sa iba pang kasama sa pag-aaral na ito, maaaring makipag-ugnayan sa EAC Research Ethics Review (RER) Committee Office (RER Office) ng Emilio Aguinaldo College sa mga numerong 02 8521 2710 local 5388 para sa anumang paglilinaw, o reklamo kaugnay ng iyong mga Karapatan bilang kalahok sap ag-aaral.

KATIBAYAN NG PAGPAPAHINTULOT
Kahingian ang bahaging ito at kailangang maisulat sa unang panauhan. Punan ang mga patlang ng mga angkop na impormasyon.

Naanyayahan akong lumahok sa isang pananaliksik tungkol sa **<pamagat ng pananaliksik>.** Sa pag-aaral, hinihingi sa akin na <.....>

Nabasa ko ang mga impormasyon hinggil sa pananaliksik o binasa ang mga ito sa akin. Nagkaroon ako ng pagkakataon para magtanong tungkol dito at sapat ding nasagot ang mga ito.

Boluntaryng sinasang-ayunan ko ang paglahok ko sa pag-aaral na ito.

Nabigyan ako ng kopya ng pormularyo ng may-kabatirang pahintulot (informed consent) na aking nilagdaan.

_____
Lagda ng Kalahok

_____ _____
Pangalan ng Kalahok Petsa (buwan/araw/taon)

[Kung hindi makalalagda ang kalahok, o kung mapangangatwiranan ng mga kondisyon na hindi dapat lumagda ang kalahok upang protektahan ang kaniyang identidad, kinakailangang lumagda ang isang nakasusulat na saksi sa ngalan ng kalahok. Ang taong ito ay dapat na pinili mismo ng kalahok at walang relasyon ni anuman sa pangkat mananaliksik.]

Nasaksihan ko ang wastong pagbasa ng pormularyo sa pagpapahintulot sa potensiyal na kalahok, at nagkaroon din ang indibidwal na ito ng pagkakataong makapagtanong. Pinatutunayan kong malayang nagbigay ng pahintulot ang kalahok na ito.

_____
Lagda ng Kalahok

_____ _____
Pangalan ng Kalahok Petsa (buwan/araw/taon)

PAHAYAG NG MANANALIKSIK
Kahingian ang bahaging ito.

Pinatutunayan kong nabigyan ng pagkakataon ang kalahok na magtanong tungkol sa panalaliksik at ang lahat ng tanong ay nasagot nang tama at sa abot ng aking kakayahan.

Pinatutunayan ko rin na ang indibidwal na ito ay hindi pinilit upang magbigay ng kaniyang pahintulot, at ang pahintulot na ito ay ipinagkaloob nang malaya at boluntaryo.

Isa kopya ng dokumentong ito ang naibigay sa kalahok.

_____
Lagda ng Mananaliksing/taong humihingi ng pahintulot

_____
Pangalan ng Mananliksik/taong humihingi ng pahintulot

Petsa: _____
(buwan/araw/taon)

To be filled out by EACRER Secretariat

Protocol Code	<.....>

EACRER FORM 2 (D): *ASSENT FORM FOR CHILDREN*

STUDY PROTOCOL INFORMATION	
Research Study Protocol Title	
Name of Principal Investigator (PI)	
Email Address	
Contact Number	
Affiliation/Company	
EAC Research Ethics Review (RER) Office Contact Information	

We want to tell you about a research study we are doing and see if you want to take part in it. Research is a way to learn more about something. This is the way we find out information that can help us.

<**The title of this study is**..... >

<**The researchers are**..... >

It is okay to ask questions about what we are telling you. You can circle or highlight things on this paper you want to know more about. If you do not understand something, just ask us. We want you to ask questions anytime.

We are working to <find out/learn more about..... >

You are being asked to be in this research study because **< write a simple reason for inclusion>**

To be part of this study, you and your parent (or guardian) must agree first by signing this assent form. It is your parent or guardian responsibility to make sure this study is okay for you. However, even if your parents or guardian allow you to participate in this study, you always have the right to refuse and there is no penalty if you choose not to join the research study.

If you decide to be in this study and your parent or guardian agrees,

< We will ask you to..... >
<We will have you do..... >
<We will look at your (e.g. school records).....>
<This research will take (state how long will the study be conducted).....>

There will be a time that during the research you could feel <uncomfortable& afraid>. We will help you with these feelings of discomforts. However, you can stop at any time if you want. You do not have to answer all the questions and nobody will get mad at you, just tell the researcher or your parents/guardian if you want to stop any time.

I have read this form or someone has read it for me. If I do not understand something I can always ask the researcher to explain it to me. I will also be given a copy of the informed consent I have signed.

Please check one box
[ ] YES, I want to join in this study and I can stop anytime I want without anyone getting mad at me.

[ ] NO, I do not want to join this study.

_____ _____
Child's Name Child's Signature

Date signed:

Child's Birthdate: Age in Years:

_____
Signature over Printed Name of Parents/Legal Guardian

_____
Date signed by the Legal Guardian

If the child agrees to join in this study, the researcher should tick the appropriate box below. Check all the apply.

[ ] The child is capable of reading and understanding the assent form and has signed to take part in this study.
[ ] This child is NOT capable of reading the assent form, but the information was verbally explained to him/her and the child signed this assent form to participate in this study.
[ ] The child was given ample time to ask questions and all her/his questions were answered.

_____
Signature of Person Obtaining Agreement

_____
Printed Name of Person Obtaining Agreement Date Signed:

EMILIO AGUINALDO COLLEGE
1113-1117 San Marcelino St., Paco, Manila 1007, Philippines www.eac.edu.ph (02) 8521-2710
Virtue ♦ Excellence ♦ Service
EAC RESEARCH ETHICS REVIEW (RER) COMMITTEE
EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph

Reference Code	<.....> (To be filled out by EACCRP Staff)
Protocol Code	<.....> (To be filled out by EACCRP Secretariat)

EACRER FORM 2 (E): INFORMED CONSENT ASSESSMENT FORM
**This form is to be issued upon initial processing by EACRER*

Research Study Protocol Title	
Name of Principal Investigator (PI)	**<Name, Surname>**
Email Address/Contact number	
ICF Submission Date	**<dd/mm/yyyy>**

INSTRUCTIONS

*To the Principal Investigator

Please indicate in the space provided below whether the specified element is addressed by the informed consent form (ICF). To facilitate the evaluation of the assessment point, indicate the page and paragraph where this information can be found.

*To the Primary Reviewer

Please evaluate how the elements outlined below have appropriately addressed by the main informed consent form (ICF) and any additional ICFs, as applicable. Indicate, for each item, which ICF the comment is referring to and by confirming the submitted information and putting your comments in the space provided under "REVIEWER COMMENTS". In your comments, ensure that vulnerability, recruitment process, and process of obtaining informed consent are always assessed in the context of the study protocol and the participants. Finalize your review by indicating your conclusions under "RECOMMENDED ACTION" and signing in space provided for the primary reviewer.

ESSENTIAL ELEMENTS (as applicable to the study)	To be filled out by the Principal Investigator			**To be filled out by the Primary Reviewer**
	Indicate if the ICF has the specified element		Page & paragraph where element is found	REVIEWER COMMENTS
	YES	**N/A**		
1. Statement that the study involved research.				
2. Statement describing the purpose of the study				
3. Study-related treatments and probability for random assignment				
4. Study procedures including all invasive procedures				
5. Responsibilities of the participant				

6. Expected duration of participation in the study				
7. Approximate number of participants in the study.				
8. Study aspects that are experimental				
9. Foreseeable risks to participant/embryo/ fetus/nursing infant; including pain, discomfort, or inconvenience associated with participation including risks to spouse or partner				
10. Risks from allowable use of placebo (as applicable)				
11. Reasonably expected benefits; or absence of direct benefit to participants, as applicable				
12. Expected benefits to the community or to society, or contributions to scientific knowledge				
13. Description of post-study access to the study product or intervention that have been proven safe and effective				
14. Alternative procedures or treatment available to participant				
15. Compensation or insurance or treatment entitlements of the participant in case of study-related injury				
16. Anticipated payment, if any, to the participant during the study; whether money or other forms of material goods, and if so, the kind and amount				
17. Compensation (or no plans of compensation) for the participant or the participant's family or dependents in case of disability or death resulting from study-related injuries.				
18. Anticipated expenses, if any to the participant during the study				
19. Statement that participation is voluntary, and that participant may withdraw anytime without penalty or loss of benefit to which the participant is entitled				
20. Statement that the study monitor(s), auditor(s), the VRH-IRB Ethics Review Panel, and regulatory authorities will be granted direct access to participant's medical				

records for purposes ONLY of verification of clinical trial procedures and data				
21. Statement that the records identifying the participant will be kept confidential and will not be made publicly available, to the extent permitted by law; and that the identity of the participant will remain confidential in the event the study results are published; including limitations to the investigator's ability to guarantee confidentiality				
22. Description of policy regarding the use of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of results to immediate family relative or to others without consent of the participant				
23. Possible direct or secondary use of participant's medical records and biological specimens taken during clinical care or during this study				
24. Plans to destroy collected biological specimen at the end of the study; if not, details about storage (duration, type of storage facility, location, access information) and possible future use; affirming participant's right to refuse future use, refuse storage, or have the materials destroyed				
25. Plans to develop commercial products from biological specimens and whether the participant will receive monetary or other benefit from such development				
26. Statement that the participant or participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to willingness of the participant to continue to participation				
27. Statement describing access of participant to the result of the study				
28. Statement describing extent of participant's right to access his/her records (or lack thereof vis a vis pending request for approval of non				

or partial disclosure)				
29. Foreseeable circumstances and reasons under which participation in the study may be determined				
30. Sponsor, institutional affiliation of the investigators, and nature and sources of funds				
31. Statement whether the investigator is serving only as an investigator or as both investigator and the participant's healthcare provider				
32. Person(s) to contact in the study team for further information regarding the study and whom to contact in the event of study-related injury				
33. Statement that the EACRER committee (specify) has approved the study, and may be reached through the following contact for information regarding rights of study participants, including grievances and complaints: Name of EACRER Chair: Address: Email: Contact no:				

RECOMMENDED ACTION:

[ ] APPROVED
[ ] MINOR MODIFICATIONS
[ ] MAJOR MODIFICATIONS
[ ] DISAPPROVED <indicate the reason for disapproval>

_____ _____
Signature of PRIMARY REVIEWER over Printed Name Date

Reference Code	<.....> (To be filled out by EACCRP Staff)
Protocol Code	<.....> (To be filled out by EACCRP Secretariat)

EACRER FORM 2 (F): PROTOCOL TEMPLATE
**Use this template as a guide for creating the research protocol*

Research Study Protocol Title	
Name of Principal Investigator (PI)	

RESEARCH OBJECTIVES

This study aims to <.....>

SIGNIFICANCE
**Please limit to 500 words*

BRIEF LITERATURE REVIEW/CONCEPTUAL FRAMEWORK
**If your submission is for Validation of Exemption or Expedited Review, please limit to 1000 words.*

METHODS
**The subsections below are the minimum requirements, feel free to add more.*

Sampling design *(Describe the identity, nature, and size of the sample population)*

Setting *(Describe the site/location where the intervention will be carried out. Describe the facilities and equipment is necessary).*

Recruitment *(Describe in detail how the prospective participants will be contacted and asked to participate in the study, including who will recruit and what media will be used. Include all pertinent materials such as script, spiels, posters, etc. in your submission.)*

Inclusion and Exclusion Criteria *(State the inclusion and exclusion criteria for recruitment, e.g. what characteristics will render prospective participants eligible for participation in the study. If none, write N/A.)*

Procedure *(Describe in detail the procedure, particularly the intervention that will involve human participants. Identify the specific type of data that will be derived from the participants. Include statistical analysis that will be utilized in the procedures.)*

ETHICAL CONSIDERATION

**Discuss possible ethical issues, including but not limited to informed consent, voluntariness, benefits and risks, compensation, vulnerability, confidentiality, conflicts of interest, etc.*

RESEARCH BUDGET

**Include only items for matters pertinent to ethical considerations. For self-funded research study, write N/A.*

LITERATURE CITED

**Use APA style of referencing and citations.*

EAC RESEARCH ETHICS REVIEW (RER) COMMITTEE

EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph

Reference Code	<.....> (To be filled out by EACCRP Staff)
Protocol Code	<.....> (To be filled out by EACCRP Secretariat)

EACRER FORM 2 (G): PROTOCOL ASSESSMENT FORM

Research Study Protocol Title	
Name of Principal Investigator (PI)	**<Name, Surname>**
Email Address/Contact number	
ICF Submission Date	**<dd/mm/yyyy>**

INSTRUCTIONS

*To the Principal Investigator

Please indicate in the space provided below whether the specified assessment point is addressed by your study protocol. To facilitate the evaluation of the assessment point, indicate the page and paragraph where this information can be found.

*To the Primary Reviewer

Please evaluate how the assessment points outlined below have been appropriately addressed by the study protocol, as applicable, by confirming the submitted information and putting your comments in the space provided under "REVIEWER COMMENTS." Finalize your review by indicating your conclusions under "RECOMMENDED ACTION" and signing in space provided for the primary reviewer.

ESSENTIAL ELEMENTS (as applicable to the study)	To be filled out by the Principal Investigator			**To be filled out by the Primary Reviewer**
	Indicate if the study protocol contains the specified assessment point		Page & paragraph where element is found	REVIEWER COMMENTS
	YES	**N/A**		
1. SOCIAL VALUE				
Review of relevance of the study to an existing social or health problem such that the results are expected to bring about a better understanding of related issues, or contribute to the promotion of well-being of individuals, their families, and communities.				

2. SCIENTIFIC DESIGN				
2.1.Objectives *Review of viability of expected output*				
2.2. Literature review *Review of results of previous animal/human studies showing known risks and benefits of intervention, including known adverse drug effects, in case of drug trials*				
2.3.Research design *Review of appropriateness of design in view of objectives*				
2.4. Sampling design *Review of appropriateness of sampling methods and techniques*				
2.5. Sample size *Review of computation of sample size*				
2.6. Statistical Analysis Plan (SAP) *Review of appropriateness of statistical methods to be used and how participant data will be summarized.*				
2.7. Data Analysis Plan *Review of appropriateness of statistical and non-statistical methods of data analysis and how participant data will be summarized*				
2.8. Inclusion Criteria *Review of precision of criteria both for scientific merit and safety concerns; and of equitable selection*				
2.9. Exclusion Criteria *Review of criteria precision both for scientific merit and safety concerns; and of justified exclusion*				
2.10. Withdrawal Criteria *Review of criteria precision both for scientific merit and safety concerns*				

3. CONDUCT OF STUDY				
3.1. Data Collection Plan *Review of appropriateness of data collection, including description of personal data to be collected. For studies involving use of database, review of database management and role of personal data collector, as well as authority of investigator to access database.*				
3.2. Specimen Handling *Review of specimen storage, access, disposal, and terms of use*				
3.3. PI Qualifications *Review of CV and relevant certifications to ascertain capability to manage study related risks*				
3.4. Suitability of Site *Review of adequacy of qualified staff and infrastructures.*				
3.5. Duration *Review of length/extent of human participant involvement in the study*				
4. ETHICAL CONSIDERATION				
4.1. Transparency and Conflict of Interest *Review of management of conflict arising from financial, familial, or proprietary considerations of the PI, sponsor, or the study site*				
4.2. Privacy and Confidentiality *Review of measures or guarantees to protect privacy and confidentiality of participant information as indicated by data collection methods including data protection plans*				
4.3. Informed Consent Process *Review of application of the principle of respect for*				

persons, who may solicit consent, how and when it will be done; who may give consent especially in case of special populations like minors and those who are not legally competent to give consent, or indigenous people which require additional clearances				
4.4. Justification for the involvement of Vulnerable Participants *Review of involvement of vulnerable study populations and impact on informed consent (see 3.3). Vulnerable groups include children, the elderly, ethnic and racial minority groups, the homeless, prisoners, people with incurable disease, people who are politically powerless, or junior members of a hierarchical group*				
4.5.Recruitment *Review of manner of recruitment including appropriateness of identified recruiting parties*				
4.6. Assent *Review of feasibility of obtaining assent vis à vis incompetence to consent; Review of applicability of the assent age brackets in children:* *0-under 7: No assent* *7-under 12: Verbal Assent* *12-under15: Simplified Assent Form 15-under18: Co-sign informed consent form with parents*				
4.7. Risks *Review of level of risk and measures to mitigate these risks (including physical, psychological, social, economic), including plans for adverse event management; Review of justification for allowable use of placebo as detailed in the Declaration of Helsinki (as applicable)*				
4.8. Benefits *Review of potential direct*				

benefit to participants; the potential to yield generalizable knowledge about the participants' condition/problem; nonmaterial compensation to participant (health education or other creative benefits), where no clear, direct benefit from the project will be received by the participant				
4.9. *Incentives or Compensation* *Review of amount and method of compensations, financial incentives, or reimbursement*				
4.10. *Community Considerations* *Review of impact of the research on the community where the research occurs and/or to whom findings can be linked; including issues like stigma or draining of local capacity; sensitivity to cultural traditions, and involvement of the community in decisions about the conduct of study.*				
4.11. Collaborative Study Terms of Reference *Review of terms of collaborative study especially in case of multi-country/multi-institutional studies, including intellectual property rights, publication rights, information and responsibility sharing, transparency, and capacity building*				

RECOMMENDED ACTION:

[ ] APPROVED
[ ] MINOR MODIFICATIONS
[ ] MAJOR MODIFICATIONS
[ ] DISAPPROVED <indicate the reason for disapproval>

SUMMARY OF RECOMMENDATIONS:

1.
2.
3.
4.
5.

JUSTIFICATION FOR RECOMMENDED ACTION:

Overall Risk Benefits Assessment:

[ ] Favorable
[ ] Unfavorable

_____ _____

Signature of **PRIMARY REVIEWER** over Printed Name Date

Reference Code	<.....> *(To be filled out by EACCRP Staff)*
Protocol Code	<.....> *(To be filled out by EACRER Secretariat)*

EACRER FORM 2 (H): PROTOCOL APPLICATION CHECKLIST ACKNOWLEDGEMENT

The EACRER secretariat checks whether the following requirements for research ethics clearance application have been submitted by the applicant. Required documents must be complete for the review process to begin. Submit all soft copies of document as SEPARATE PDF FILES, each labeled with the appropriate file name.

The applicant is encouraged to submit any additional relevant documents as requested by the ethics committee to support their application throughout the review process. One copy of this form is given to the applicant, the other copy is kept by the CRP & EACRER office.

GENERAL DOCUMENTS

[ ] EACCRP Form 1 (A)	Letter of Intent
[ ] EACCRP Form 1 (B)	Technical Evaluation of Thesis/Dissertation Proposal (required for undergraduate and graduate students)
[ ] EACCRP Form 1 (C)	Technical Evaluation of Research Project Proposal for Grant/Funding (if applicable)
[ ] EACCRP Form 1 (D)	Curriculum Vitae (CV) of the Principal Investigator Template

INITIAL STUDY PROTOCOL REVIEW DOCUMENTS

[ ] EACCRP Form 2 (A)	Application for Research Ethics Clearance
[ ] EACCRP Form 2 (B)	Informed Consent Form in English
[ ] EACCRP Form 2 (C)	Informed Consent Form in Local Language (if applicable)
[ ] EACCRP Form 2 (D)	Assent Form for Children (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
[ ] EACRER Form 2 (E)	Informed Consent Assessment Form
[ ] EACRER Form 2 (F)	Protocol Template
[ ] EACRER Form 2 (G)	Protocol Assessment Form

ACKNOWLEDGEMENT

This is to acknowledge that the EACRER office has received the complete research ethics clearance application of:

_____
Signature of **PRINCIPAL INVESTIGATOR** over Printed Name

Research Study Protocol Title:

_____ _____
Signature of EACRER Staff over Printed Name Date Received

Reference Code	**<.....>** *(To be filled out by EACCRP Staff)*
Protocol Code	**<.....>** *(To be filled out by EACRER Secretariat)*

EACRER FORM 2 (I): REVIEW OF RESUBMITTED PROTOCOL FORM

Research Study Protocol Title	
Name of Principal Investigator (PI)	**<Name, Surname>**
Email Address/ Contact number	
Date of Initial Submission	**<dd/mm/yyyy>**
Resubmitted Protocol Submission Date	**<dd/mm/yyyy>**
Initial Review Date	**<dd/mm/yyyy>**
Last Review Date	**<dd/mm/yyyy>**

RECOMMENDATIONS FROM LAST REVIEW	**To be filled out by the Principal Investigator**			**To be filled out by the Primary Reviewer**
	Indicate if the study protocol contains the specified assessment point		Page & paragraph where element is found	Were the recommendations met (YES/NO)? Explain
	YES	**N/A**		
<1. Protocol-related issues> 1.1. 1.2. <2. Ethical-related issues> 2.1. 2.2. <3. Informed consent-related issues> 3.1. 3.2. <4. Changes that were not part of the initial review> 4.1. 4.2.				

_____
Signature of **PRINCIPAL INVESTIGATOR** over Printed Name

RECOMMENDATION OF PRIMARY REVIEWER	JUSTIFICATION FOR RECOMMENDED ACTION:
[] APPROVED [] MINOR MODIFICATION [] MAJOR MODIFICATION [] DISAPPROVED	

RECOMMENDED ACTION:

[] APPROVED
[] MINOR MODIFICATIONS
[] MAJOR MODIFICATIONS
[] DISAPPROVED < indicate the reason for disapproval>

SUMMARY OF RECOMMENDATIONS:
1.
2.
3.
4.
5.

_____ _____
Signature of **PRIMARY REVIEWER** over Printed Name Date

EAC RESEARCH ETHICS REVIEW (RER) COMMITTEE

EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph

Reference Code	<.....> (To be filled out by EACCRP Staff)
Protocol Code	<.....> (To be filled out by EACCRP Secretariat)

EACRER FORM 3 (A): PROTOCOL AMENDMENTS APPLICATION

Instructions to the Principal Investigator
A research protocol amendment is a written description of changes to or formal clarification of a protocol and/or informed consent documents. Amendments that should be submitted for approval are generally those that have implications for the considerations of risks and benefits of the study to its human participants.

Complete all requested information and submit the form plus relevant attachments in softcopies as separate PDF files to research.ethics@eac.edu.ph and research.center@eac.edu.ph.

Research Study Protocol Title	
Name of Principal Investigator (PI)	
Study Protocol Ethics Approval Date	
Email and Contact number	
School/Department/Affiliation	
Study Site (s) if applicable	
Name of Funding Source/ Email Address & Contact Information (if applicable)	

AMENDMENTS TO REPORT:

In a Separate Document:
(1) Enumerate, (2) Describe, and (3) Justify the protocol amendments with reference to how these have changed or differ from the approved protocol. Attach relevant supporting document as such as new instruments, new ICF, etc.

Type of Review (Check one that is subject to RER review)

[ ] EXPEDITED REVIEW, for amendments that:

- Do not involve substantial changes in study populations
- Do not involve the collection of (new/additional) private information that may place participants at substantial risk if identities are revealed
- Do not substantially change approved use of anonymized or archived samples
- Involve study protocols previously classified under expedited or regular review
- Are administrative in nature
- Do not materially affect the risk-benefit ratio of the approved protocol or increase risk to study participants

[ ] FULL REVIEW, for any amendments not cited under expedited review and proposed for submissions

_____

Signature of PRINCIPAL INVESTIGATOR over Printed Name

Amendment Submission Date:

EAC RESEARCH ETHICS REVIEW (RER) COMMITTEE
EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph

Reference Code	<.....> (To be filled out by EACCRP Staff)
Protocol Code	<.....> (To be filled out by EACCRP Secretariat)

EACRER FORM 3 (B): CONTINUING REVIEW APPLICATION FORM

Instructions to the Principal Investigator
Ethical clearance or approval is granted for a specific period, typically one year, as indicated in your ethics approval letter. A continuing review and approval is necessary if interaction with human participants goes beyond the period of the initial or previous ethics approval. If a continuing ethics approval application is not submitted, the protocol will be rendered inactive and interactions with participants must stop as per university policies and national ethics regulations. The P.I. is advised to submit this form 45 days prior to the expiry date of the original approval.

Complete all requested information. If the item is not applicable to your protocol, write "NA". Submit this form through email at research.ethics@eac.edu.ph and research.center@eac.edu.ph and a hard copy with your signature.

Research Study Protocol Title	
Name of Principal Investigator (PI)	**<Name, Surname>**
Study Protocol Ethics Approval Date	
Email and Contact Number	
School/Department/Affiliation	
Study Site(s) if applicable	
Name of Funding Source/Email Address & Contact Information (if applicable)	
Study Protocol Approval Date(s)	
Study Protocol Expiration Date(s)	
Date(s) of Continuing Review	

1. **SUMMARY OF STUDY AIMS:**
2. **STUDY SITE(S)** if applicable
3. **START DATE:**
4. **TARGET COMPLETION DATE:**

5. STATUS OF THE RESEARCH (check all that apply)
[ ] Research has not begun <explain your reason>
[ ] Research was initiated but on hold <reason>
[ ] Data collection has begun and is ongoing
[ ] Data analysis in ongoing
[ ] Other reason

6. REPORT ON RESEARCH PARTICIPANTS
6.1. Target number of participants approved by EACRER
6.2. New participants accrued since last approval
6.3. Total participants accrued since study began
6.4. Participants still involved in the study
6.5. Participants who discontinued or withdrawn from the study
6.6. Participants who have completed the study

7. Have there been any changes or deviation to your approved study protocol?
[ ] NO, all procedures are in compliance with the EACRER approved protocols.

[ ] YES, <explain the changes or deviations, state if changes may be in study population, sites, selection criteria, data collection methods, new instrument, new personnel, new data collected and other changes that materially increase risk to the participants> Kindly attach or submit also the protocol amendment form that was Previously submitted to EACRER.

8. Have there been changes in the informed consent process since the approval?
[ ] NO
[ ] YES, (complete Protocol Amendment Form and Submit revised ICFs)

9. Has there any new information about the risks of methods currently being applied?
[ ] NO
[ ] YES <explain briefly>

10. Have there been UNANTICIPATED, ADVERSE, or SERIOUS EVENT[1] documented during the study?
[ ] NO problems or adverse events have been observed or recorded during the study.
[ ] YES <describe the problem> Kindly submit Unanticipated Adverse Event Report Form 4 (A)

11. Are identifiable data being used, collected, and stored for this study?
[ ] YES, but treatment of identifiable data is complaint with EACRER approval protocol.
[ ] NO, data is anonymous
[ ] Others, treatment of identifiable data requires EACRER approval. Kindly submit Protocol Amendment Form 3 (A)

DECLARATION

[ ] I confirm that the study and its principal investigator and research personnel continue to abide by the ethics

[ ] I confirm that, if necessary, I will submit the relevant, requisite forms and reports (e.g. Protocol Amendment For, Continuing Ethics Review Application

_____ **Signature of PRINCIPAL INVESTIGATOR over Printed Name**
Amendment Submission Date:

EAC RESEARCH ETHICS REVIEW (RER)COMMITTEE

EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph

Reference Code	**<……>** *(To be filled out by EACCRP Staff)*
Protocol Code	**<……>** *(To be filled out by EACRER Secretariat)*

EACRER FORM 4 (A): UNANTICIPATED ADVERSE EVENT REPORT FORM

Instruction to the Principal Investigator

This form should be submitted to the EAC-RER Office as promptly as possible. Unanticipated problems that are serious adverse events should be reported within one week of the investigator becoming aware of the event.

Complete all the requested information. If the item is not applicable to your protocol, write "NA". Submit this form through email at researchethics@eac.edu.ph and research.center@eac.edu.ph and a hard copy with your signature.

Research Study Protocol Title	
Name of Principal Investigator (PI)	**<Name, Surname>**
Email and Contact number	
School/Department/Affiliation	
Study Site (s) if applicable	
Name of Funding Source/ Email Address & Contact Information (if applicable)	
Study Protocol Approval Date(s)	
Indicate the Continuing Review Approval Date (s), if applicable	

1.SUMMARY OF STUDY AIMS:

2. STUDY SITE (S) if applicable

3. ONSET DATE OF UNANTICIPATED PROBLEM/ADVERSE EVENT

4. DATE THE STUDY TEAM HAD KNOWLEDGE OF THE ADVERSE EVENT:

5. THE EVENT MEETS THE CRITERIA OF AN UNANTICIPATED PROBLEM BECAUSE:

(choose all that apply)

[] The event is **unexpected** in terms of severity or frequency, compared to what was indicated in the previously approved protocol and informed consent form.
[] The event is **unexpected** for the population being studied
[] The event places the participants at greater risk for harm (including physical, psychological, economic, or social harm) than was previously known or recognized
[] The event has already resulted in harm to the participants or others

Note: *The event has to meet at least 3 criteria indicated above to be considered an unanticipated problem.*

6. Is the UNANTICIPATED problem an ADVERSE event[1]?
[] NO, not a SERIOUS ADVERSE Event
[] YES, it is a SERIOUS ADVERSE Event
If yes, <provide detailed description of the UNANTICPATED problem and attach relevant supporting document>

7. Provide a description of corrective or mitigating actions and plan to prevent the problem from recurring. Attach new materials or informed consent form if necessary.

8. Have any of the corrective or mitigating actions been applied prior to this report?
[] YES, <provide reasons for implementing changes prior to RER approval>
[] NO

DECLARATION
[] I confirm that the unanticipated problem has been fully and accurately described in this report.

[] I confirm that the study team will await the official response and recommendations of the EAC-RER committee with respect to the proposed corrective or mitigating actions, except for actions that need to be immediately implemented to prevent further harm or risk to participants

Signature of **PRINCIPAL INVESTIGATOR** over Printed Name

Unanticipated Problem Report Submission Date: <mm/dd/yyyy>

RECOMMENDATIONS (for RER committee use only)

Comments of Primary Reviewer(s*):*

Recommended Action
[] Approve proposed corrective/mitigating actions
[] Major modifications required to proposed corrective/mitigating actions
[] Minor modifications required to proposed corrective/mitigating actions
[] Disapprove proposed corrective/mitigating actions and recommend other action

Details of Recommended Action:

Signature of **PRIMARY REVIEWER** over Printed Name
Signature of **RER CHAIR** over Printed Name
Date:

Endnotes

[1] Adverse events include any event meeting the following definition: Any untoward or unfavorable medical occurrence in a human participant, including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

Serious adverse events are those temporally associated with the individual's participation in the study that meets any of the following criteria:
- results in death;
- is life-threatening;
- requires inpatient hospitalization or prolongation of existing hospitalization;
- results in persistent or significant disability or incapacity;
- results in a congenital anomaly/birth defect; or
- any adverse event that, based on appropriate medical judgment, may jeopardize the participant's health and may require medical or surgical intervention to prevent any of the aforementioned outcomes

Reference Code	**<.....>** *(To be filled out by EACCRP Staff)*
Protocol Code	**<.....>** *(To be filled out by EACRER Secretariat)*

EACRER FORM 4 (B): PROGRESS REPORT FORM

Instruction to the Principal Investigator
The progress report is required by the RER committee for research projects that are evaluated as entailing greater than minimal risk to human participants or for projects the RER committee needs to monitor more closely. This form should be submitted to the CRP and RER office.

Complete all the requested information. If the item is not applicable to your protocol, write "NA". Submit this form through email at researchethics@eac.edu.ph and research.center@eac.edu.ph and a hard copy with your signature.

Research Study Protocol Title	
Name of Principal Investigator (PI)	**<Name, Surname>**
Email and Contact number	
School/Department/Affiliation	
Study Site (s) if applicable	
Name of Funding Source/ Email Address & Contact Information (if applicable)	
Effective Period of Research Ethical Clearance	**from <mm/dd/yyyy> to <mm/dd/yyyy>**

PROGRESS REPORT

1.START OF STUDY <mm/dd/yyyy>

2. EXPECTED END OF STUDY <mm/dd/yyyy>

3. NUMBER OF ENROLLED PARTICIPANTS:

4. NUMBER OF REQUIRED PARTICIPANTS:

5. NUMBER OF PARTICIPANTS WHO WITHDREW:

6. DEVIATION FROM THE APPROVED PROTOCOL

7. NEW INFORMATION THAT MAY SIGNIFICANTLY CHANGE THE RISK-BENEFITS RATIO

8. ISSUES/ PROBLEMS ENCOUNTERED
Signature of **PRINCIPAL INVESTIGATOR** over Printed Name
COMMENTS OF REVIEWER: Signature of **PRIMARY REVIEWER** over Printed Name
Signature of **RER CHAIR** over Printed Name
Date:

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1113-1117 San Marcelino St, Paco, Manila 1007, Philippines www.eac.edu.ph (02) 8521-2710
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EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph

Reference Code	
Protocol Code	

EACRER FORM 4 (C): FINAL REPORT FORM

Instruction to the Principal Investigator
The final report should be submitted to the RER office upon the completion of the study. Completion indicates that there are no further interactions with and data collection from human participants in the study, and that the data is being handled and/or stored in accordance with the EACRER approved protocol. The final report, if deemed satisfactory by the EACRER, signifies that the protocol is to be rendered inactive and archived.

Complete all the requested information. If the item is not applicable to your protocol, write "NA". Submit this form through email at researchethics@eac.edu.ph and research.center@eac.edu.ph and a hard copy with your signature.

Research Study Protocol Title	
Name of Principal Investigator (PI)	
Email and Contact number	
School/Department/Affiliation	
Name of Funding Source/ Email Address & Contact Information (if applicable)	
Effective Period of Research Ethical Clearance	**from mm/dd/yyyy to mm/dd/yyyy**

FINAL REPORT

1.START DATE OF THE STUDY:

2. COMPLETION DATE OF THE STUDY:

3. NUMBER OF PARTICIPANTS APPROVED BY EACRER:

4. NUMBER OF PARTICIPANTS WHO WITHDREW:

5. PARTICIPANTS WHO COMPLETED THE STUDY:

6. WERE THERE ANY DEVIATION TO YOUR APPROVED PROTOCOL?
[] NO, all procedures followed the EACRER approved protocols
[] YES, protocol amendments were submitted and approved by the EACRER committee

7. WERE THERE UNANTICIPATED PROBLEMS DOCUMENTED DURING THE STUDY?
[] NO problems or adverse events arose during the study
[] YES, adverse event report were submitted to EACRER
[] Specify other reason <……>

8. SUMMARY OF BENFITS OF THE STUDY
9. ARE IDENTIFIABLE DATA WERE USED AND STORE FOR THIS STUDY? [] YES, but the treatment for identifiable data is compliant with EACRER approved protocol [] NO, data were collected anonymously
10. HAVE YOU PUBLISHED YOUR RESEARCH FINDINGS OR PRESENTED THEM IN A CONFERENCE OR FORUM? [] NO [] YES (please attach publication copy)
11. PROVIDE SUMMARY OR ABSTRACT OF RESULT OF THE STUDY
_____ Signature of **PRINCIPAL INVESTIGATOR** over Printed Name
FINAL REPORT SUBMISSION DATE: 07/16/2025
RECOMMENDATIONS (for EACRER use only)
COMMENTS OF REVIEWER: _____ Signature of **PRIMARY REVIEWER** over Printed Name
RECOMMENDED ACTION [] Satisfactory, protocol can be archived [] Request information [] Recommend further action
_____ Signature of **RER CHAIR** over Printed Name
Date:

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VIRTUE ♦ EXCELLENCE ♦ SERVICE
EAC RESEARCH ETHICS REVIEW (RER)COMMITTEE
EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph

Reference Code	<.....> *(To be filled out by EACCRP Staff)*
Protocol Code	<.....> *(To be filled out by EACCRP Staff)*

EACRER Form 7 (A): PROTOCOL VIOLATION/DEVIATION REPORT

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission of documents.

General Information	
Title of the Study	
Name of PI	
Co-researchers	
Study Site	
Telephone No.	
Mobile No.	
Email Address	
Institution	
Address of Institution	
Ethical Clearnce effectivity period	

Progress Report	
1. Start of study: Expected end of study:	
2. Number of enrolled participants: Number of required participants: Number of participants who withdrew:	
3. Deviation from the approved protocol	4. Explanation for deviation/violation
5. Impact of deviation/violation on participants' risks/harms and integrity of data	6. Actions taken to prevent future deviation/violation

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EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph

Reference Code	<.....> *(To be filled out by EACCRP Staff)*
Protocol Code	<.....> *(To be filled out by EACCRP Staff)*

EACRER Form 7 (B): REPORTABLE NEGATIVE EVENT REPORT

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission of documents.

General Information	
Title of the Study	
Name of PI	
Co-researchers	
Study Site	
Telephone No.	
Mobile No.	
Email Address	
Institution	
Address of Institution	
Ethical Clearnce effectivity period	

RNE Report	
1. Start of study: Expected end of study:	
2. Number of enrolled participants: Number of required participants:	
3. Description of Negative (harms, risks) Events a. Involving Participants b. Involving members of the Study Team c. Involving Data safety and integrity	4. Actions taken to prevent future RNEs, interventions and Outcomes
7. Recommendations	

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Reference Code	<.....> *(To be filled out by EACCRP Staff)*
Protocol Code	<.....> *(To be filled out by EACCRP Staff)*

EACRER Form 8 (A): SITE VISIT REPORT

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission of documents.

General Information	
Title of the Study	
Name of PI	
Co-researchers	
Study Site	
Telephone No.	
Mobile No.	
Email Address	
Institution	
Address	
Ethical Clearnce effectivity period	

Site Visit Report	
1. Start of study: Expected end of study:	
2. Number of enrolled participants: Number of required participants:	
3. Reasons for Site Visit	4. Person/s present during visit
5. Findings	6. Recommendations

Site Visit Team

1.

2.

3.

Report submitted by:

Name and signature

Date:

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EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph

Reference Code	<.....> *(To be filled out by EACCRP Staff)*
Protocol Code	<.....> *(To be filled out by EACCRP Staff)*

EACRER Form 8 (B): EARLY TERMINATION REPORT

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission of documents.

General Information	
Title of the Study	
Name of PI	
Co-researchers	
Study Site	
Telephone No.	
Mobile No.	
Email Address	
Institution	
Address of Institution	
Ethical Clearnce effectivity period	
Recommended by	(e.g. Sponsor, Funding Agency, etc.)

Early Termination Report

1. Start of study:
   Expected end of study:
2. Number of enrolled participants:
   Number of required participants:
3. Reason/s for termination
4. Support mechanisms/Intervention for Enrolled Participants
5. Post-Termination Actions

Name and signature of Proponent
Date:

Received by:
Date:

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EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph

Reference Code	<.....> *(To be filled out by EACCRP Staff)*
Protocol Code	<.....> *(To be filled out by EACCRP Staff)*

EACRER Form 9 (A): QUERIES AND COMPLAINTS FORM

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission of documents.

General Information	
Title of the Study	
Name of PI	
Telephone No.	
Mobile No.	
Email Address	
Involvement in the study	
Ethical Clearnce effectivity period	

Complaints/Query	**Response** *(Intended for the EACRERC use. Kindly skip this part.)*

Signature over Printed Name	
Received by:	Date Received:

Signature of Reviewer/Panel Chair over Printed Name
Date Submitted:

10th FLOOR, BLDG 7, 1113-1117 SAN MARCELINO ST., PACO, MANILA
EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph
TEL. NO.: (632) 8521 2710 local 5388

GROUP F

Communication No. **<NO.>** S <YYYY>
EAC Research Ethics Review Committee

NOTICE OF MEETING

Date of Notice:	Date of Meeting:
Venus:	Time:

Items of Discussion:

1. Full Review of New Proposals (Initial)
   1.1. Protocol Code – Title
   1.2. Protocol Code – Title
2. Report on Expedited Review of Proposals
   2.1. Protocol Code – Title
   2.2. Protocol Code – Title
3. Updates on Full Review of Proposals (Resubmission)
   3.1. Protocol Code – Title
   3.2. Protocol Code – Title
4. Updates on Expedited Review of Proposals (Resubmissions)
   4.1. Protocol Code – Title
   4.2. Protocol Code – Title
5. Updates on Approved, Ongoing Researches
   5.1. Protocol Code – Title
   5.2. Protocol Code – Title
6. Other Matters

Communication No. **<NO.>** S <YYYY>
EAC Research Ethics Review Committee

Provisional Agenda

Venue:	
Date:	Time:

1. Call to Order
2. Declaration of Quorum
3. Disclosure of Conflict of Interest
4. Approval of the Provisional Agenda
5. Review and Approval of the Minutes of the Previous Meeting
6. Business Arising
7. New Business
8. Full Review of New Proposals (Initial)
   - 8.1. Protocol Code – Title
   - 8.2. Protocol Code – Title
9. Report on Expedited Review of Proposals
   - 9.1. Protocol Code – Title
   - 9.2. Protocol Code – Title
10. Updates on Full Review of Proposals (Resubmissions)
    - 10.1. Protocol Code – Title
    - 10.2. Protocol Code – Title
11. Updates on Expedited Review of Proposals (Resubmissions)
    - 11.1. Protocol Code – Title
    - 11.2. Protocol Code – Title
12. Updates on Approved, Ongoing Researches
    - 12.1. Protocol Code – Title
    - 12.2. Protocol Code – Title
13. Other Matters
14. Adjournment

EACRER FORM 10 (A): MINUTES OF THE MEETING

Type of Meeting:
Date:
Time:
Venue:

Attendance:
Present

Name	EACRERC Designation	Office

Also Present

Name	EACRERC Designation	Office

Absent

Name	EACRERC Designation	Office

1. Call to Order
2. Declaration of Quorum
3. Disclosure of Conflict of Interest
4. Approval of the Provisional Agenda
5. Review and Approval of the Minutes of the Previous Meeting (Date)
6. Business arising from the minutes of the meeting
7. Full Review of Proposals (Initial)

7.1.

Protocol Code:	
Title:	
Researcher/s:	
Submission date:	
Reviewers:	
Discussion/Comments: **Scientific Soundness:** **Ethical Considerations** - **Social Value** - **Vulnerability issue** - **Measures to protect vulnerability population** - **Risk/benefit ratio** - **Measures to mitigate risks** - **Confidentiality and privacy** - **Informed Consent process, form and content**	
Recommendations:	
Decision:	
Decision letter date:	

8. Report on Expedited Review of Proposals (Initial)

8.1.

Protocol Code:	
Title:	
Researcher/s:	
Submission date:	
Reviewers:	
Discussion/Comments/Recommendations:	
Decision:	
Decision letter date:	

9. Updates on Full Review of Proposals (Resubmissions)

9.1.

Protocol Code:	
Title:	
Researcher/s:	
Submission date:	
Reviewers:	
Discussion/Comments/Recommendations:	
Decision:	

Decision letter date:	

10. Updates on Expedited Review of Proposals (Resubmissions)

10.1.

Protocol Code:	
Title:	
Researcher/s:	
Submission date:	
Reviewers:	
Discussion/Comments/Recommendations:	
Decision:	
Decision letter date:	

11. Updates on Approves, Ongoing Researchers

11.1.

Protocol Code:	
Title:	
Researcher/s:	
Submission date:	
Approval letter sent	
Amendment/Report submission date	
Lead Reviewers	
Discussion/Comments/Recommendations:	
Decision:	
Decision letter date:	

12. Other Matters

13. Adjournment

Prepared by:

Date:

Noted: (Chair)

Date:

10th FLOOR, BLDG 7, 1113-1117 SAN MARCELINO ST., PACO, MANILA
EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph
TEL. NO.: (632) 8521 2710 local 5388

GROUP G

EMILIO AGUINALDO COLLEGE
1115-1117 San Marcelino St., Paco, Manila 1007, Philippines www.eac.edu.ph (02) 8521-2710
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EAC RESEARCH ETHICS REVIEW (RER)COMMITTEE
EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph

YEAR: _____

LOGBOOK OF INCOMING COMMUNICATION

Date	Nature of document (Decision Letter, Approval, Invitation, Notice of Meeting, etc.)	Signatory	Addressee	Received by (Name and Signature of Recipient)	Delivered by (Name and Signature)

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1115-1117 San Marcelino St., Paco, Manila 1007, Philippines www.eac.edu.ph (02) 8521-2710
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EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph

YEAR: _____

LOGBOOK OF OUTGOING COMMUNICATION

Date	Nature of document (Decision Letter, Approval, Invitation, Notice of Meeting, etc.)	Signatory	Addressee	Received by (Name and Signature of Recipient)	Delivered by (Name and Signature)

PROTOCOL INDEX

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EMAIL: research.ethics@eac.edu.ph, research.center@eac.edu.ph

PROTOCOL INDEX

Date of Filing	Nature of document (e.g. Other study document, proposal, decision, etc)	Name of and signature of Filer	Date Document Withdrawn	Name and Signature of Staff Member-in-charge

PROTOCOL REVIEW DATABASE

PROTOCOL REVIEW																			
PROTOCOL CODE	REFERENCE CODE	Study Protocol Title	Date Issued the Protocol Application Checklist Acknowledgement	Purpose of the Study	Name of Principal Investigator	Email Address	Contact Information	School/Department/Affiliation	Category of Protocol Review	Funding Agency (if applicable)	Primary Reviewer	Date of Review or Meeting (if applicable)	Date of Notice of Panel Action/Decision	Date of Research Ethics Clearance or Approval	Due Date of Progress Report (for funded project)	Expiration Date of Research Ethics Clearance	Due Date of Final Report	Status	Additional Remarks