Eastern Visayas Health Research and Development Consortium- Ethics Review Committee (EVHRDC-ERC) STANDARD OPERATING PROCEDURE CHAPTER 2: INITIAL REVIEW PROCEDURES		
EXPEDITED REVIEW	SOP No.	07
	Version No.	05
	Version Date	04-25-2023
	Effective Date	04-30-2023

1. STATEMENT OF POLICY

The EVHRDC ERC adheres to the principle of protection of dignity and safety of human research participants. There is an ethical review of all health-related research protocols involving human participants.

An expedited review shall be conducted for study protocols that (1) do not entail more than minimal risk to the study participants, (2) do not have study participants belonging to a vulnerable group, and (3) the study procedures do not generate vulnerability. The result of initial review shall be presented and discussed during the Expedited Primary Reviewer Review Meeting. Approved protocol that underwent expedited review shall be reported in the subsequent Full Board Review Meeting.

Expedited primary review meeting occurs on the last Tuesday of the month. Expedited review refers to the number of ERC members doing the initial review rather than the length of time it requires.

Criteria for protocols to be initially classified as subject to Expedited Review are as follows:

1. The study does not entail more than minimal risk to the study participants:
    - Protocol that will not likely harm the status or interests of the study participants and not likely to offend the sensibilities nor cause psychological stress of the people involved.
    - Protocol that involves collection of anonymized personal data, anonymized biological specimens for research purposes by non-invasive means (e.g. collection of small amounts of blood, body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner).
    - Protocol that deals with data or documents involving anonymized human data, biological specimens that have been already collected or will be collected for ongoing medical treatments or diagnosis
2. The study does not have participants belonging to a vulnerable group:
    - Protocol that will not deal with: patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency

situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent.

3. The study procedures do not generate vulnerability:
    - Protocols that are non-confidential in nature defined as; not dealing with private character such as sexual preference, etc.
    - Not dealing with sensitive issues that may cause social stigma.

Criteria for study protocols to be subject to Expedited Review, after initial approval:

1. Protocols initially classified for Expedited review, even if with major modifications recommended, will still undergo expedited review upon resubmission as long as minimal risk is not elevated.
2. Protocols discussed in the full board with minor modifications will undergo expedited review.
3. All post-approval amendments, deviations, violations, off-site SAEs/SUSARs shall be subject to Expedited Review, regardless of initial review classification if the study protocols satisfy any of the following criteria:
    - Administrative revisions, such as correction of typing error
    - Addition or deletion of non-procedural items, such as the addition of study personnel names, laboratories, etc.
    - Minor protocol amendments, deviations, violations on the study and related documents that do not impact on the potential risk/benefits to the participant and no substantial change in the study population, methodology and consent that will impact on the integrity of the research
4. Progress Reports and Continuing Review Applications will be subject to Expedited Review if initial classification of study protocol was likewise expedited.
5. All Final Reports, regardless of type of initial classification of review, will be subject to Full Board Review. However, in the event that a PI decides not to continue the application for ethics review, the PI must write a letter requesting for withdrawal of study protocol from the ERC. All requests for withdrawal will be discussed during the Full Board Review Meetings regardless of initial review classification.

It is the responsibility of assigned Primary Reviewers to review any protocol qualified for the expedited process. The same assessment forms used for full board review should be used to evaluate the scientific and ethical merits of the protocol.

Only complete protocols submitted on or before the cut-off (15^{th} day of the month) shall be included in the agenda for the expedited review meeting.

The conduct of meetings is governed by ***SOP No. 22 Preparing for an ERC Meeting*** whether the review will be a virtual meeting, face-to-face meeting, or a hybrid meeting. The ERC Chair will decide on the type of platform to be used.

2. OBJECTIVE/S OF THE ACTIVITY

The activity aims to standardize procedures for expedited review, ensure consistency in reviewing protocols that entail minimal risk to participants, and maintain quality assurance of the review process

3. SCOPE/APPLICABILITY

This applies to health related researches that entail minimal risk to be conducted in member institutions.

4. ROLES AND RESPONSIBILITIES

Compliance is the responsibility of the ERC Chair, ERC Staff Secretary, and Reviewers and Proponent.

ERC Chair - assigns review to members on deck; dialogues with reviewer/s regarding reviewer's decision; communicates result of review to the Principal Investigator.

ERC Staff Secretary – delivers relevant documents to the reviewer/s, files all communications, decisions and protocols; and includes expedited protocol in the next meeting's agenda for confirmation and information of committee members.

Primary Reviewers - conducts review; fills out the forms; submits accomplished checklist to the ERC chair; and dialogues with the Chair when necessary.

Principal Investigator – submits complete protocol package for initial submission; complies with recommendations of the ERC.

5. WORKFLOW

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Assignment of Primary Reviewers and/or Independent Consultants	ERC Chair	3 days from cut-off
Step 2: Send Protocol Package to the Primary Reviewers and/or Independent Consultant and provision of study documents and protocol assessment forms	ERC Staff Secretary	7 days
Step 3: Review of protocol and complete the protocol and ICF evaluation form	Primary Reviewers	day of the meeting
Step 4: Return accomplished evaluation form and ICF evaluation form	Primary Reviewers	day of the meeting

Step 5: Decision forwarded to the ERC Chair for inclusion of the agenda in the regular meeting	ERC Chair, ERC Staff Secretary	7 days
Step 6: Decision is communicated to the Primary Investigator	ERC Staff Secretary	
Step 7: Filing of protocol-related documents and updating of the Protocol Database	ERC Staff Secretary	7 days

6. DESCRIPTION OF PROCEDURES

6.1 Assignment of Primary Reviewers and/or Independent Consultants

The ERC chair or Vice-chair shall conduct Preliminary review to go over the submitted protocol to decide on the type of review to be applied. Once decided that the study satisfied any of the criteria to be classified for Expedited Review, the ERC Chair assigns at least two (2) ERC members to be the Primary Reviewer for expedited review. Assigned primary reviewers should preferably be composed of a scientific member with related expertise to review the protocol and a non-scientific member to review the informed consent. If there are no ERC members with a field of expertise to adequately review the scientific aspect of the study protocol, an Independent Consultant may be invited to join the protocol review.

The ERC chair or Vice-chair then shall return the protocol with the decision to the staff secretary to facilitate distribution to the primary reviewers.

6.2 Send Protocol Package to the Primary Reviewers and/or Independent Consultant and provision of study documents and protocol assessment forms

The staff secretary sends the protocol package to the reviewers. The staff secretary gathers the pertinent documents; for initial submissions: the complete protocol package; for post approval submissions: the pertinent information from the retrieved protocol and the report itself. The ERC staff secretary prepares copies of the protocol and/or protocol-related documents and assessment forms for delivery, either through manual delivery or through electronic mail, to the primary reviewers and/or independent consultants, if any, at least seven (7) working days prior to the next scheduled ERC Expedited Review meeting.

6.3 Review of protocol and complete the protocol and ICF evaluation form

The assigned Primary Reviewers meet on the last Tuesday of the month. The Primary Reviewers shall carry out the expedited review of the protocol and related documents (patient information sheet, consent form, advertisements,

etc.). This process must be completed with an accomplished **Form 12.1 Protocol Evaluation and Form 12.2 Informed Consent Evaluation**. If a primary reviewer cannot attend the meeting, the ERC Chair exercises his/her prerogative to take over the role of the primary reviewer so that the meeting can proceed.

6.4 Return accomplished evaluation form and ICF evaluation form

The Primary Reviewers submit the accomplished forms on the same day of the review and return the protocol package to the ERC member secretary through the ERC Staff Secretary.

Evaluation forms may be submitted in hard copies, duly signed and dated by the Primary Reviewers and/or Independent Consultant. Electronic copy of the assessment forms may likewise be submitted bearing the e-signature of the Primary Reviewers and/or Independent Consultant. The Electronic copy will be printed by the ERC Staff secretary.

6.5 Decision forwarded to the ERC Chair for inclusion of the agenda in the regular meeting

The ERC Chair will consolidate and finalize the review results. In case of differing opinions between the Primary Reviewers, the ERC Chair may mediate to reach an agreement, and may have the final say. In case of considerable difference and consensus cannot be reached, the ERC Chair may refer the protocol for full board review.

Only approved protocols under expedited review will be reported in the regular full board meeting. One of the primary reviewers will present the decision made during the expedited review during the full board review.

6.6 Decision is communicated to the Primary Investigator

The decision is communicated to the PI. It shall follow ***SOP No. 27 Communicating the ERC Decision***. As soon as the decision of Primary Reviewers is reached, the decision is communicated to the principal investigators within seven (7) working days from the scheduled ERC Expedited Primary Review meeting.

The reviewers recommend approval if there are no issues. **Form 27.1 Approval Letter** is issued to the Principal Investigator with **Form 27.3 Notification of ERC Decision.**

If there are findings, reviewers shall recommend revisions. **Form 27.2 Letter of Modification** is issued to the Principal Investigator with **Form 27.3 Notification of ERC Decision.**

Recommended revisions may be classified as follows:

Minor modification – 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). To wit:

- Administrative corrections like typographical errors or grammar
- Minor changes on items not directly related on procedure to be done
- Revisions will not impact risk-benefit example: additional related literature requested.

Major modification – 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. To wit:

- If there will be major revisions on either the protocol or informed consent form; such as inclusion/exclusion criteria, safety issues, methodology, that may impact on the scientific validity of the protocol.
- Revision will have an impact on the risk-benefit ratio.

No protocol may be disapproved during an expedited review; only the full board has the power to disapprove. If the Primary Reviewers recommends disapproval, the protocol must be elevated to full board review for final decision. Also, in the absence of a consensus or if a member expresses a concern, the protocol is referred for full board review.

6.7 Filing of protocol-related documents and updating of the Protocol Database

The ERC Staff Secretary files copies of communications, decisions and protocols in the active protocol files and records in the logbook.

TIMELINE FOR EXPEDITED REVIEW

TIMELINE	FROM	ACTIVITY
15th day of the preceding month	Principal Investigator	Last day of submission of research protocol to ERC office for inclusion in the full review meeting.
1-3 working days after cut-off	ERC Chair	Classification of research protocol, assignment of Primary Reviewers and online transmission of complete

		protocol package to Primary Reviewers.
7 working days prior to the expedited review meeting	ERC Staff Secretary	Send out study documents and assessment forms to reviewers
Last Tuesday of the month	Expedited Review	
Last Tuesday of the month	Primary Reviewers	Submit the signed evaluation form to Member Secretary
Seven (7) working days after submission of evaluation from the Primary reviewers	ERC Member Secretary/Staff Secretary	Send out notice of ERC decision to Principal Investigator

7. FORMS AND TOOLS

Form 12.1 Protocol Evaluation
Form 12.2 Informed Consent Evaluation
Form 27.1 Approval Letter
Form 27.2 Letter of Modification
Form 27.3 Notification of ERC Decision

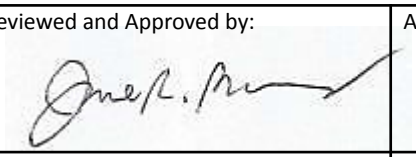
8. HISTORY

Version No.	Date (mm/dd/yyyy)	Authors	Main Change
1	01/26/2013	ERC	First draft
2	10/23/2015	ERC	Updates on Procedures
3	12/05/2019	ERC	Adopt recommendation from PHREB CSA

4	11/28/2022	Dr. Jane R. Borrinaga Ms. Sarah B. Delorino Engr. Florentino L. Quiñones Ms. Noreen S. Buhat Fr. Charles Gingco Dr. Jose Carlo K. Del Pilar Ms. Erleta S. Piñero Atty. Alma Sonia Q. Sanchez-Danday Mr. Ricky T. Serrano Mr. Raymond G. Campo	Updates on procedures and policy.
5	04/25/2023	Dr. Jane R. Borrinaga Ms. Sarah B. Delorino Engr. Florentino L. Quiñones Ms. Noreen S. Buhat Fr. Charles Gingco Dr. Jose Carlo K. Del Pilar Ms. Erleta S. Piñero Atty. Alma Sonia Q. Sanchez-Danday Mr. Ricky T. Serrano Mr. Raymond G. Campo	Revised description of procedures and added timeline in the Workflow

9. REFERENCES

- World Medical Association Declaration of Helsinki, 2013
- ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)
- WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
- International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016
- National Ethical Guidelines for Health and Health Related research 2017
- Philippine Health Research Ethics Board Standard Operating Procedures 2020
- BatMC RERC SOP 2020

Prepared by:	Reviewed and Approved by: 	Approved by: 
ETHICS REVIEW COMMITTEE	**DR. JANE R. BORRINAGA, MD, FPCP** ERC Chair	**EXUPERIA B. SABALBERINO, MD, MPH, CESe** EVHRDC Executive Committee Chair
Date: 04-25-2023	Date: 04-25-2023	Date: 04-25-2023