Eastern Visayas Health Research and Development Consortium- Ethics Review Committee (EVHRDC-ERC) STANDARD OPERATING PROCEDURE CHAPTER 2: INITIAL REVIEW PROCEDURES		
FULL REVIEW	SOP No.	06
	Version No.	05
	Version Date	07-10-2023
	Effective Date	07-17-2023

1. STATEMENT OF POLICY

Full review process is systematic, organized, confidential, collegial, competent, efficient, interactive, impartial, independent, and comprehensive. Full review is conducted on the second Friday of every other month. If the second Friday falls on a holiday, the full review occurs on the third Friday. Research protocols in which the procedure/methodology is more than minimal risk is reviewed in a full review of protocols. Because of the assessment of risk, this review is decided in a panel meeting subject to quorum requirement.

The following are types of protocols that should be reviewed at a convened full review meeting:

1.1 Phase 4 intervention research involving drugs, biologics or device
1.2 Protocols including questionnaires and social interventions that are confidential in nature (about private behavior, e.g. related to sexual preferences etc.; or about sensitive issues that may cause social stigma, psychological, legal, economic and other forms of social harm)
1.3 Intervention protocols involving vulnerable subjects (patients with incurable diseases, persons in nursing homes, patients in emergency situations, ethnic minority groups, homeless persons, refugees, minors and those incapable of giving consent) that require additional protection from the ERC during review
1.4 Protocols that involve collection of identifiable biological specimens from vulnerable groups, etc.
1.5 Resubmitted protocols reviewed in a previous full review with major modifications.
1.6 Protocol and ICF amendments that involve major changes
1.7 Progress reports of ongoing studies that involve medium to high risk procedures to human participants.
1.8 Final Reports previously reviewed in a full review
1.9 Study Protocol Noncompliance.
1.10 Expedited review results which decision was not attained.
1.11 RNEs and Early Termination Application are all subject to Full Board Review regardless of initial review classification.

1.12 Progress Reports and Continuing Review Applications will be subject to Full Board Review if the initial classification of the study protocol was likewise full review.

2. OBJECTIVE/S OF THE ACTIVITY

This activity aims to standardize procedures for full review and ensure consistency in the review of protocols that entail medium to high risk to participants, in order to maintain quality assurance of the review process.

3. SCOPE / APPLICABILITY

This activity guides the officers and members, and other persons who may be involved in the conduct of Full Review.

4. ROLES AND RESPONSIBILITIES

Compliance is the responsibility of the officers and members, and other persons who may be involved in the conduct of a full review.

ERC Chair - sets the agenda, determines the need for resource person(s)/ expert(s) and other invitees based on the agenda and instructs the ERC Staff Secretary to prepare the invitation letter/s accordingly.

ERC Member Secretary-supervises the ERC Staff Secretary in confirming attendance to the meeting and preparing for the meeting.

Primary Reviewers – scientist and non-scientist member. Initially reviews the protocol specifically the technical and ethical soundness and fill out the protocol assessment forms and present the research protocol to the committee members

5. WORKFLOW

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Assignment of reviewers or independent consultant/s	ERC Chair	3 days from cut-off
Step 2: Notification of Primary Reviewers and Independent Consultant and provision of study documents and assessment forms to the Primary Reviewers, Independent Consultant and the rest of the committee members	ERC Staff Secretary	10 days

Step 3: Review of Protocol and Informed Consent Form	Primary Reviewers and Independent Consultants (if applicable)	10 days
Step 4: Presentation of review findings and recommendations during the meeting	Primary Reviewers	1 day prior to meeting
Step 5: Discussion of the technical and ethical issues	Primary Reviewers, ERC Members	day of the meeting
Step 6: Summary of issues of all Member Reviewers	Primary Reviewers	day of the meeting
Step 7: Summary of the ERC Chair and Discussion on Committee Action and Recommendation.	ERC Chair	day of the meeting
Step 8: Documentation of Committee deliberation and action	ERC Member Secretary, ERC Staff Secretary	day of the meeting
Step 9: Communication of Committee Action to the researcher	ERC Staff Secretary	7 days
Step 10: Filing of protocol-related documents and Updating of the Protocol Database	ERC Staff Secretary	7 days

6. DESCRIPTION OF PROCEDURES

6.1 Assignment of reviewers or independent consultant/s

Once decided that the study satisfied any of the criteria to be classified for Full Review, the ERC Chair assigns at least two (2) ERC members to be the Primary Reviewers. The reviewers, at a minimum, should preferably be composed of a scientist member with related expertise to review the protocol and a non-scientist 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 (***see SOP No. 03 Appointment of Independent Consultants***).

6.2 Notification of Primary Reviewers and Independent Consultant and provision of study documents and assessment forms to the Primary Reviewers, Independent Consultant and the rest of the committee members

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 staff secretary prepares copies of the protocol and/or protocol-related documents and evaluation forms for delivery, either manually or through electronic mail, to the primary reviewers and/or independent consultants, if any, as well as the rest of the committee members, at least ten (10) working days prior to the next scheduled ERC Full Board Review meeting.

6.3 Review of Protocol and Informed Consent Form

The assigned Primary Reviewers and Independent Consultants (if applicable) are given ten (10 days) to review the protocol and ICF.

6.4 Presentation of review findings and recommendations during the meeting

The primary reviewers submit the electronic copies of their findings and recommendations **(Form 12.1 Protocol Evaluation and Form 12.2 Informed Consent Evaluation)** to the ERC Chair one (1) day before the meeting and present these during the actual meeting ***(see SOP No. 24 Conduct of Meetings)***. The staff secretary prints the electronic copies. 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. Evaluation forms may be submitted in hard copies or soft copies, duly signed and dated by the Primary Reviewers and Independent Consultant and the rest of the committee members. The assigned primary reviewers will present their assigned research protocols and provide their comments and recommendations. If deemed necessary, the Primary Reviewers may call for a clarificatory meeting or dialogue with the Principal Investigator to request for additional information.

6.5 Discussion of the technical and ethical issues

The ERC Primary Reviewers lead the discussion of the technical and ethical issues using **Form 12.1 Protocol Evaluation and Form 12.2 Informed Consent Evaluation** for an orderly exchange of ideas.

Some major points to be considered during the discussion are the following:

- The protocol manifests scientific validity and contains all the standard sections to ensure scientific soundness. This would include statistical design, sample size, methodology etc.
- In assessing the degree of risk against the benefit, determine whether the risks are reasonable in relation to anticipated benefits; and/or if the risk can be minimized.
- Study participants are selected equitably especially if randomization is not to be used

- Study participant's information sheet should be clear, complete and written in understandable language.
- There is voluntary, non-coercive recruitment of study participants.
- The informed consent is adequate, easy to understand and properly documented.
- There should be a translation of the Informed Consent document into the local dialect which should be comprehensible by the general public.
- The procedure for getting the informed consent is clear and unbiased.
- The persons who are responsible for getting the informed consent are named and they introduce themselves to the study participants.
- The research plan makes adequate provision for monitoring data collection to ensure the safety of study participants, where appropriate.
- There are adequate provisions to protect the privacy of study participants and to maintain the confidentiality of data, where appropriate.
- There is provision for compensation to study participants. There should be reasonable provision for medical/psychosocial support; treatment for study related injuries, as well as compensation for participation to cover expenses like transport and lost wages because of participation.
- There are appropriate safeguards included to protect vulnerable study participants.
- Contact persons with address and phone numbers are included in the informed consent.
- There is clear justification for the use of biological materials and a separate consent form for future use of biological specimens.
- There are appropriate contracts or memoranda of understanding especially in collaborative studies.
- Examine community involvement and impact/benefit of the study to the community and/or the institution. If relevant, the reviewer looks for the following in the protocol.
    - Community consultation should be described and planned with community leaders.
    - Involvement of local researchers and institutions in the protocol design, analysis and publication of the results.
    - Contribution to development of local capacity for research and treatment in benefit to local communities.
    - Sharing of study results with the participants/community should be described and discussed.

6.6 Summary of issues of all Member Reviewers

The ERC Primary Reviewers summarize 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.

6.7 Summary of the ERC Chair and Discussion on Committee Action and Recommendation.

The ERC 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**
- **For Modification**
- **Disapproved**

Decision of the committee is arrived at by voting and the majority decision is arrived at and is adopted ***(See SOP No. 24 Conduct of Meetings)***.

6.8 Documentation of Committee deliberation and action

See SOP No. 26 Preparing the Minutes of the Meeting.

6.9 Communication of Committee Action to the researcher *(See SOP No. 27 Communicating the ERC Decision)*

As soon as a committee decision is reached, the decision is communicated to the principal investigators within seven (7) working days from the scheduled ERC full review meeting.

- The reviewers recommend approval if there are no issues. **Form 27.3 Notification of ERC Decision** and **Form 27.1 Approval Letter** are issued to the Principal Investigator.
- If there are findings, reviewers shall recommend revisions. **Form 27.3 Notification of ERC Decision** and **Form 27.2 Letter of Modification** are issued to the Principal Investigator.
- In the case of disapproval, the principal investigator may appeal the decision if deemed necessary ***(See SOP No. 19 Management of Appeals).*** Principal Investigator will receive the **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 to the procedure to be done.
  - Revisions that will not impact risk-benefit (example: additional related literature requested).

  Major modification – a recommended revision applying to protocols found to have significant findings 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.

6.10 Filing of protocol-related documents and Updating of the Protocol Database
See SOP No. 29 Management of Active Files (Administrative and Study Files).

TIMELINE FOR FULL 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.
10 working days prior to the full board meeting	ERC Staff Secretary	Send out study documents and assessment forms to reviewers
2nd Friday of every other month	Full board review	
7 working days after ERC meeting	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	12/05/2019	ERC	Updates on procedures and policy.
3	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.
4	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	Updated statement of policy and added timeline in the Workflow
5	07/10/2023	Dr. Jane R. Borrinaga Ms. Sarah B. Delorino Engr. Florentino L. Quiñones Ms. Noreen S. Buhat Fr. Charles Gingco	Included ICF amendments that involve major changes as an additional

		Dr. Jose Carlo K. Del Pilar Ms. Erleta S. Piñero Atty. Alma Sonia Q. Sanchez-Danday Mr. Ricky T. Serrano Mr. Raymond G. Campo	type of protocol that should be reviewed in a full review process and added additional steps in the description of procedures.

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: 07-10-2023	Date: 07-10-2023	Date: 07-10-2023