Eastern Visayas Health Research and Development Consortium-
Ethics Review Committee (EVHRDC-ERC)
STANDARD OPERATING PROCEDURE

CHAPTER 3: POST APPROVAL PROCEDURES

SITE VISIT	SOP No.	20
	Version No.	05
	Version Date	07-10-2023
	Effective Date	07-17-2023

1. STATEMENT OF POLICY

Site visit is standardized, actual and takes effect upon recommendation of the ERC and proper communication between parties involved. The site visit is conducted to check compliance with ERC approved protocol and related documents, and national and international standards. The ERC 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 and (e) multiple studies conducted by a researcher.

2. OBJECTIVE/S OF THE ACTIVITY

The site visit of the on-going research process aims to ensure compliance with the protocol and protection and security of subjects (especially in high risk studies) and smooth implementation of the study. The following are the specific objectives of this activity:

2.1 To monitor the number of Serious Adverse Events (SAE) for studies involving human subjects.
2.2 To promote compliance with the study protocol.
2.3 To determine the progress of the approved protocol

3. SCOPE/ APPLICABILITY

This applies to any visits made on any study site on behalf of the ERC, to check compliance with ERC approved protocols and related documents.

4. ROLES AND RESPONSIBILITIES

Compliance is the responsibility of the ERC members and researchers.

ERC Chair – determines the need for an onsite/ actual site visit, identifies visiting committee members, and decides on the needed actions regarding the result of the monitoring and evaluation.
ERC Staff Secretary – communicates to the PI, coordinates with the ERC chair and the ERC members or reviewers, and files all communications, decisions and protocols.

Site Visiting Team – conducts monitoring and evaluation through Actual Site visit and submits report to the ERC chair.

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

5. WORKFLOW

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Selection of study site to visit	ERC Members	NA
Step 2: Creation of study site visit team	ERC Chair	7 days
Step 3: Preparation of the Study Site Visit Plan	Study Site Visit Team	7 days
Step 4: Notice of Site Visit to Principal Investigator	ERC Staff Secretary	7 days
Step 5: Conduct of Site Visit	Study Site Visit Team	1 day
Step 6: Submission of Site Visit Report	Study Site Visit Team	7 days
Step 7: Presentation of findings during full board meeting	Study Site Visit Team	Next Full Meeting Schedule
Step 8: ERC Staff Secretary communicates the results to the Primary Investigator	ERC Staff Secretary	7 days
Step 9: Filing of protocol-related documents and updating of the Protocol Database	ERC Staff Secretary	7 days

6. DESCRIPTION OF PROCEDURES:

6.1 Selection of study site to visit

The ERC members may recommend to visit study sites for any of the following reasons: frequent occurrence of SAE, protocol violations, failure to submit progress reports, complaints about PI performance. Visits may also be conducted to monitor implementation of risky protocols, PI with many ongoing studies or inexperienced PIs. Study site visit may be conducted upon recommendation of Primary Reviewers.

6.2 Creation of study site visit team

ERC will create a study site visit team. The ERC Chair selects members of the site visit team. The team will be constituted with at least 2 ERC members. The team leader should be the Primary Reviewers of the protocol for site visit. The visiting team member receives **Form 20.1 Notice of Site Visit to Members of the Site Visit Team** together with **Form 14.2 Progress Report,** if applicable**,** in preparation for the site visit. The site visit team returns the signed conforme included in the **Form 20.1 Notice of Site Visit to Members of the Site Visit Team**, seven (7) working days upon receipt.

6.3 Preparation of the Study Site Visit Plan

The Study Site Visit Team prepares the Study Site Visit Plan that includes the following:

- Date and time of the planned visit
- Members of the Study Site Visit Team
- Objectives of the Visit
- Documents to be reviewed
- Persons to be interviewed

The Study Site Visiting Team, in consultation with the ERC Chair, is given access to documents in the protocol file folder of a study for monitoring. The Team may also photocopy some parts of the files (like advertisement materials, the informed consent form (ICF), case report form) for comparison with the documents used in the study site.

6.4 Notice of Site Visit to Principal Investigator

A letter will be sent to the PI using **Form 20.2 Notice of Site Visit to Principal Investigator** at least 2 weeks before the conduct of the site visit, stating the nature and date of the site visit. The Principal Investigator will then have to reply within seven (7) working days upon receipt.

6.5 Conduct of Site Visit

The Site Visiting Team conducts the site visit as per the Study Visit Plan. The Site visit Team is required to accomplish **Form 20.3 Site Visit Report**. Decisions are reached through a majority vote. In case of a tie, the members will have another discussion and voting until the body arrives at a majority decision. The ERC Staff Secretary includes the presentation of the study site visit report in the next meeting agenda. During the visit, the designated site visit team shall:

- Review the study protocol
- Review the informed consent documents and verify if the site is using the most recently approved version.
- Ask the PI or any member of the team to explain the informed consent process.
- Review the post-approval documents and verify if the site is using the most recently approved version.
- Ensure and document that the documents are being filed properly, securely and with confidentiality at the study site.
- Make an overall resolution of the protection of the rights, safety, and welfare of human participants in the study.
- At the end of the visit, the Site Visit Team will discuss the findings with the research team and solicit feedback.
- Conduct debriefing at the end of the site visit

6.6 Submission of Site Visit Report

The site visit team submits **Form 20.3 Site Visit Report** to the ERC Staff Secretary within seven (7) working days after the visit.

6.7 Presentation of findings during full board meeting

The site visiting team presents the report during the full review. The ERC makes a determination whether the rights, safety and welfare of the research participants were compromised and appropriate recommendations are given to the PI, if any.

6.8 ERC Staff Secretary communicates the results to the Primary Investigator

The decision of the committee is communicated to the researcher within seven (7) working days after the final deliberation.

- For submitted request with major/ minor modifications, the ERC Staff Secretary sends **Form 27.2 Letter of Modification**;
- For an approved application, the ERC Staff Secretary sends **Form 27.1 Approval Letter**.

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

The ERC Staff Secretary then logs the date of decision of the application and stores the documents in the study protocol file folder.

7. FORMS AND TOOLS

Form 14.2	Progress Report
Form 20.1	Notice of Site Visit to Members of the Site Visit Team
Form 20.2	Notice of Site Visit to Principal Investigator
Form 20.3	Site Visit Report
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	10/23/2015	ERC	First draft
2	12/05/2019	ERC	Updates on Procedures
3	11/18/2022	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	Revised description of procedures

		Atty. Alma Sonia Q. Sanchez-Danday Mr. Ricky T. Serrano Mr. Raymond G. Campo	
5	07/10/2023	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	Included timelines 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: 07-10-2023	Date: 07-10-2023	Date: 07-10-2023