TITLE	MANAGEMENT OF PROTOCOL DEVIATION AND VIOLATION REPORT
POLICY STATEMENT	*Researchers shall report protocol deviations and violations in the conduct of approved researches within a week from the detection of the protocol violation/deviation. Major protocol violations undergo full review.*
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.*
SCOPE	*This SOP applies to the review of reports of protocol deviations or violations in the conduct of previously approved studies. This begins with the receipt and documentation of the report of protocol violations and deviations in the logbook and ends with the filing of all related documents* and update of the *database*.

Workflow

STEP	ACTIVITIES	RESPONSIBILITY	TIMELINE	INTERFACE
1	Receipt and documentation of report of protocol violations and deviations in the logbook	STAFF SECRETARY	within 1 working day	
	↓			
2	Retrieval of pertinent protocol file	STAFF SECRETARY	within 1 working day	
	↓			
3	Notification of Chair and Primary Reviewers	MEMBER SECRETARY	within 2 working days after retrieval	
	↓			
4	Determination of type of review: expedited or full review	CHAIR AND PRIMARY REVIEWER		SOP 4 ON EXPEDITED REVIEW SOP 5 ON FULL REVIEW
	↓			

5	Actual Review: Expedited or Full		
	↓		
6	Inclusion of report in the agenda of the next REC regular meeting	CHAIR	SOP 18 on Preparing the Meeting Agenda SOP 19 on Conduct of Meeting
	↓		
7	Communication of decision to the Principal Investigator/Researcher	MEMBER SECRETARY OR CHAIR	SOP 21 on Communication REC Decisions
	↓		
8	Filing of Amendments and Decision Letter and Update of the protocol database	STAFF SECRETARY	SOP 23 on Management of Active Files

Description of Procedures

Step 1 - Receipt and documentation of report of protocol violations and deviations in the logbook/database: *The Staff Secretary, within 1 working day, receives the report on protocol deviation or violation in the appropriate report form (F05-01) and records this in the logbook for incoming documents.*

Step 2 - Retrieval of pertinent protocol file. *The Staff Secretary, within 1 working day, retrieves the approved protocol and checks the identity of the primary reviewers for reference and guidance of the Chair in the selection/ designation of reviewers.*

Step 3 - Notification of Chair and primary reviewers. *The Member Secretary, within 2 working days after retrieval, notifies and sends the protocol deviation or violation report and together with the retrieved pertinent documents to the Chair and the primary reviewers.*

Step 4 - Determination of type of review: expedited or full review: *The Chair and primary reviewers determine the type of review such that major protocol violations undergo full review. Otherwise, the protocol deviation undergoes expedited review. See SOP 04: Expedited Review and SOP 05: Full Review.*

Step 5 - Actual Review: Expedited or Full

Step 6 - Inclusion of report in the agenda of the next REC regular meeting. *The 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 7 - Communication of Decision to the Principal Investigator/researcher: *The Member Secretary 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, (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 8 - Filing of all related documents and update of the protocol database. *The Staff Secretary collates and files the retrieved protocol documents, the report on protocol deviation and violation and the decision letter in the appropriate protocol file and updates the protocol database with the relevant information.*

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.

Principal Investigator- the lead person selected by the sponsor to be primarily responsible for the implementation of a sponsor-initiated clinical drug trial.

Researcher- is the individual primarily responsible for the conceptualization, planning and implementation of a study.

Sponsored Clinical Trials – are clinical studies on investigational drugs.

Clinical Monitor- an individual who oversees the progress of a clinical trial.

Clinical Auditor – an individual who systematically and independently examines trial related activities and documents at a particular period.

Regular Meeting – a periodically scheduled assembly of the REC.

Drug or device – health product used for diagnosis or treatment.

Protocol File – is an organized physical or electronic compilation of all documents related to a Protocol

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 REC 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 REC with the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the REC.

Forms

Form F05-01 Protocol Deviation/Violation Report Form
Form C01-01 Decision Letter Template

History of SOP

Version No.	***Date***	***Authors***	***Main Change***
1	*2025 May 6*	*Marianne R. Edulan* *Dr. Nueva Joy Perucho*	*First Draft*

References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)?

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
National Ethical Guidelines for Research Involving Human Participants 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020