



STANDARD OPERATING PROCEDURE	Effective Date:
SOP No: 21	6/5/25
Version No: 2025-01	Revision No: 1
Date of Approval:	

TITLE	COMMUNICATING REB DECISIONS
POLICY STATEMENT	The REB shall communicate its decisions to the researcher not later than six weeks after the receipt of a 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 REB and signed by the chair. All communications will be made through the REB’s official webpage and email.
OBJECTIVE OF THE ACTIVITY	The management of communicating REB decisions ensures that all stakeholders are appropriately, accurately and promptly informed of the results of deliberations of the REB.
SCOPE	This SOP covers REB actions related to the communicating REB decisions either a Notification Form or an Approval Form to summarize required modifications in the protocol or to its approval respectively. 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.

Workflow

STEP	ACTIVITIES	RESPONSIBILITY	TIMELINE	INTERFACE
1	Finalization of recommendations of the committee (in case of full review) or reviewers (in case of expedited review)	CHAIR		SOP5 ON FULL REVIEW SOP4 EXPEDITED REVIEW
	↓			
2	Transfer of information from meeting minutes to REB decision forms or templates	MEMBER SECRETARY	Within 2 working days	
	↓			
3	Approval of the REB decision document	CHAIR	Within 1 working day	
	↓			
4	Filing of the decision document in the protocol file and Update of the Protocol Database	STAFF SECRETARY		SOP23 ON MANAGING ACTIVE FILES

Description of Procedures

Step 1 - Finalization of recommendations of the committee (in case of full review) or reviewers (in case of expedited review): For the finalization of Committee's Recommendations will be done by the Chair following SOP 05 on Full Review or for finalization of Reviewers' Recommendations, following SOP 04 Expedited Review).

Step 2 - Transfer of information from meeting minutes to REB decision forms or templates: Upon approval of the draft minutes, or finalization of the reviewers' recommendations, REB will provide an Approval Letter or Notification Letter to send to the researcher. The REB Secretary will draft the letter and the process overseen by either a designated member of REB or the vice chair before having it approved by the chair.

Step 3 - Approval of the REB decision document: The REB Chair will review and approve the decision documents. The Chair will affix his/her signature signifying its approval.

Step 4 - Transmittal of REB decision to researcher: Transmittal of REB decisions to researchers will be done by the REB secretary, and this process will be overseen by the Vice Chair or a designated REB member. The researchers will be provided with an email, they can opt to pick up a printed copy at the REB office.

Step 5 - Filing of the decision document in the protocol file and Update of the Protocol Database: A protocol folder will be provided where REB will keep all protocol related decisions or actions to facilitate retrieval. A Database will be provided along with this folder containing The action should also be noted in the protocol database. The REB Secretary will file the decision document in the protocol folder and regularly update the Protocol Database. This step is in relation to SOP23 ON MANAGING ACTIVE FILES

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.

Protocol Index - is a chronological record of the documents in the protocol file. The protocol 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 protocol file/folder for easy reference and checking,

Protocol Database - a collection of information about protocols 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.

Active Files - are documents pertaining to protocols which are currently being assessed, managed or monitored by the REC.

Forms

Form C01-01 Decision Form/Letter

History of SOP

Version No.	Date	Authors	Main Change
1	2025 April 20	Umpad, Jean	First draft

References

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