



STANDARD OPERATING PROCEDURE	Effective Date:
SOP No: 15	6/5/25
Version No: 2025-01	Revision No: 1
Date of Approval:	

TITLE	MANAGEMENT OF APPEALS
POLICY STATEMENT	The REB shall consider the perspective of the researcher regarding the feasibility and acceptability of REC recommendations including its disapproval. Appeals of researchers shall undergo full review and shall be resolved within six weeks (30 working days) upon receipt of the fully documented appeal
OBJECTIVE OF THE ACTIVITY	Management of appeals ensures fairness, transparency and comprehensiveness of ethics review that takes into consideration the perspective of the researcher.
SCOPE	The SOP on Management of Appeals covers procedures that begin with the receipt of the appeal and ends with communicating the board’s action to the researcher and updating of the protocol.

Workflow

STEP	ACTIVITIES	RESPONSIBILITY	INTERFACE
1	Receipt of an appeal	STAFF SECRETARY	
	↓		
2	Retrieval of pertinent protocol file	MEMBER SECRETARY	
	↓		
3	Notification of Chair and Primary Reviewer/s	MEMBER SECRETARY	
	↓		
4	Inclusion in Agenda of the next regular meeting	CHAIR and PRIMARY REVIEWER	
	↓		
5	Discussion of and deliberation on the appeal	CHAIR and REB Members	
	↓		
6	Communication of committee action	CHAIR	SOP 21 on Communication REB Decisions

7

Filing of documents and updating
of the protocol database

STAFF SECRETARY

Description of Procedures

Step 1 - Receipt of an Appeal: *The Staff Secretary receives the letter of appeal and enters the pertinent information into the logbook.*

Step 2: Retrieval of pertinent protocol file: *The Member Secretary retrieves the pertinent file for reference in the review. The file includes the initially submitted protocol, ICF, research tools and other related documents.*

Step 3: Notification of Chair and Primary reviewers: *The Member Secretary notifies the Chair and the primary reviewers about the letter of appeal and awaits further instructions.*

Step 4. Inclusion in the Agenda of the next regular meeting: *The Chair instructs the Member Secretary to include the appeal in the agenda of the next meeting, to ensure that the retrieved protocol and related documents are available during the meeting and to inform the researcher to be available on the scheduled meeting in case there is a need for further clarification.*

Step 5: Discussion of and Deliberation on the Appeal: *The primary reviewer summarizes the protocol and the previous discussion of the issues in the protocol as background to the appeal. The Chair presents the contents of the appeal and leads discussion. The researcher may be called in for further clarification of issues. The researcher is asked to step out after the committee has taken up the issues for clarification. The committee then decides (by voting) whether to accept any or all of the points raised in the appeal.*

Step 6: Communication of Committee Action: *Based on the deliberations, the Chair summarizes the decision points and instructs the Member Secretary to prepare the draft decision letter (Form C01-01 Decision Letter Template) for his/her finalization and forwarding to the researcher. (SOP 21 Communicating REB Decisions):*

Step 7: Filing of Documents and Update of Protocol Database: *The Staff Secretary files all the documents into the appropriate folder and updates the protocol database accordingly.*

Glossary

Appeal - a request of a researcher/ investigator for a reconsideration of the REC recommendation.

Primary reviewer - is a member of the REC who is assigned to do an in-depth evaluation of research-related documents using technical and ethical criteria established by the committee.

Protocol File/Folder - is an organized compilation of all documents (in physical or electronic form) related to a study.

Protocol database - a collection of information (e.g. regarding protocols) that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

Forms

Form C01-01 Decision Letter Template

History

Version No.	Date	Authors	Main Change
1	2025 April	Dr. JM Daguipa	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 Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020