

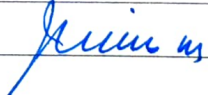




Philippine Children's Medical Center
Institutional Research – Ethics Committee (IR-EC)
SOP 13.0 Management of Appeals

Effective Date:
JUN 25 2021

PCMC IR-EC SOP 13.0: Management of Appeals

Supersedes:	PCMC IRB-EC SOP 01.0, V. 3.0
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13.0 MANAGEMENT OF APPEALS

13.1 Policy Statement

The IR-EC shall accept appeals regarding protocol revisions or disapproval. Appeals shall undergo full review and shall be resolved within 25 working days upon receipt of the request.

13.2 Purpose of the Activity

To ensure fairness, transparency, and comprehensiveness of ethics review in consideration of the PI's perspective.

13.3 Scope

This SOP includes the procedures for the management of appeals of protocols with prior decisions that begins from the receipt of the letter of appeal and ends with filing of documents and updating protocol database.

13.4 Process Flow/Steps for Management of Appeals

NO.	ACTIVITY	PERSON/S RESPONSIBLE
1	Receipt of Letter of Appeal	IR-EC Secretariat
2	Retrieval of Protocol File	IR-EC Secretariat
3	Notification of Chair/Primary Reviewers	IR-EC Secretariat
4	Inclusion in Full Board Agenda	IR-EC Secretariat
5	Discussion and Deliberation on the Appeal	IR-EC Members
6	Notify PI of Decision	IR-EC Secretariat
7	Filing of Documents and Updating Protocol Database	IR-EC Secretariat

13.5 Detailed Instructions

13.5.1 Receipt of the Letter of Appeal

13.5.1.1 The Secretariat shall receive the Letter of Appeal and shall enter pertinent information such as title of the protocol, name of PI, date of receipt of letter in the logbook.

13.5.2 Retrieval of Protocol File

13.5.2.1 The Secretariat shall retrieve the initial protocol package submitted.



13.5.3 Notification of Chair/Primary Reviewers

- 13.5.3.1** The Secretariat shall notify the Chair / Primary Reviewers about the Letter of Appeal.

13.5.4 Inclusion in Full Board Agenda

- 13.5.4.1** The Chair shall schedule discussion of the appeal and shall instruct the Secretariat to include the appeal in the agenda of the next meeting.
- 13.5.4.2** The Secretariat shall ensure that the retrieved protocol and related documents are available as reference during the meeting.
- 13.5.4.3** The PI and supervising investigator shall be available on the scheduled meeting in case further clarification is needed.

13.5.5 Discussion and Deliberation on the Appeal

- 13.5.5.1** The Primary Reviewer shall summarize the protocol and previous discussion of the issues in the protocol as background to the appeal.
- 13.5.5.2** The Chair shall present contents of the appeal and shall lead the discussion on the rationale and supporting information/material that will aid in the review of the appeal.
- 13.5.5.3** The PI and the supervising investigator shall be called in for further clarification of issues.
- 13.5.5.4** The PI and supervising investigator shall step out after the IR-EC Members have taken up the issues for clarification.
- 13.5.5.5** The IR-EC Members shall decide by consensus whether to accept the points raised in the appeal.

13.5.6 Notify PI of Decision

- 13.5.6.1** The Secretariat shall communicate the Decision Letter (Form 27.1) from the IR-EC to the PI.

13.5.7 Filing of Documents and Updating Protocol Database

- 13.5.7.1** The Secretariat shall file all the documents into appropriate protocol folder and shall update the database accordingly.

13.6 Forms

Form 27.1 V.3.0 Decision Letter of IR-EC



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13.7 Glossary

Appeal - a written request submitted by the investigators regarding IR-EC decisions that are in contention, including IR-EC decisions to disapprove, suspend, terminate, or stipulate modifications to submitted protocols and associated submission materials, including informed consent forms.

Additional Reference:

<https://www.uth.edu/cphs/policies/appeals-to-irb.htm>