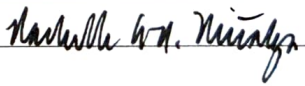

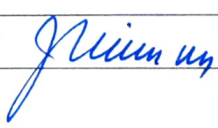




Philippine Children's Medical Center  
Institutional Research – Ethics Committee (IR-EC)  
**SOP 23.0 Review of Final Reports**

Effective Date:  
**JUN 25 2021**

## PCMC IR-EC SOP 23.0: Review of Final Reports

Supersedes:	PCMC IRB-EC SOP 01.0, V. 3.0
Authored by:	SOP Team / PCMC IR-EC Members
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## **23.0 REVIEW OF FINAL REPORTS**

### **23.1 Policy Statement**

The IR-EC shall require submission of final report within twenty (20) working days after the end of the study.

### **23.2 Purpose of the Activity**

To ensure adherence to the study protocol and the efficient management of protocol records.

### **23.3 Scope**

This SOP includes the procedures in reviewing final reports that begins from the receipt of the progress report package and ends with the filing of pertinent documents and updating protocol file index and protocol database.

### **23.4 Process Flow/Steps for Review of Final Reports**

<b>NO.</b>	<b>ACTIVITY</b>	<b>PERSON/S RESPONSIBLE</b>
1	Receipt of the progress report package	IR-EC Secretariat
2	Forwarding the Final Report for review	IR-EC Secretariat
3	Deliberating on the Final Closure report during IR-EC full board meeting	IR-EC Members
4	Communicating the IR-EC decision to the PI	IR-EC Secretariat, IR-EC Chair
5	Filing of pertinent documents and updating protocol file index and protocol database	IR-EC Secretariat

### **23.5 Detailed Instructions**

#### **23.5.1 Receipt of the progress report package**

**23.5.1.1** The submission shall include the accomplished Progress Report (Form 17.1) and the Final Report (Form 23.1) forms, protocol summary of approved research and the abstract of finished paper.

**23.5.1.2** The IR-EC Secretariat shall verify the completeness of the submission and whether the Protocol Code No. and the forms used are correct.



Philippine Children's Medical Center  
Institutional Research – Ethics Committee (IR-EC)  
**SOP 23.0 Review of Final Reports**

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**23.5.2 Forwarding the Final Report for review**

- 23.5.2.1** The IR-EC Secretariat shall identify the Primary Reviewer of the protocol from the protocol database.
- 23.5.2.2** The IR-EC Secretariat shall record the Closure/Final Report package together with the Notice of Review and a copy of the latest version of the protocol in the Log of Outgoing Documents.
- 23.5.2.3** The Closure or Final Report package shall be forwarded to the Primary Reviewer/s or Chair for review at least 7 days before the full board meeting.
- 23.5.2.4** The review is accomplished by commenting and recommending appropriate action on the Closure / Final Report (Form 23.1).
- 23.5.2.5** Primary Reviewer shall accomplish the form and return the Closure / Final Report package to the IR-EC Secretariat.

**23.5.3 Deliberating on the Final Closure report during IR-EC full board meeting**

- 23.5.3.1** The Primary Reviewer or Chair shall present the results of the review.
- 23.5.3.2** The IR-EC decision can be any of the following:
  - a. Acknowledged / Accepted
  - b. Request for further information, specify
  - c. Recommend further action, specify

**23.5.4 Communicating the IR-EC decision to the PI**

- 23.5.4.1** The Secretariat shall take note of the decision and/or discussion during the board meeting in the meeting minutes and shall communicate with the PI if further action is required.
- 23.5.4.2** The IR-EC Secretariat shall prepare the Notification of the IR-EC Decision Review of Closure/Final Report for signature of the IR-EC Chair.
- 23.5.4.3** The IR-EC Secretariat shall send the notification to the PI.

**23.5.5 Filing pertinent documents and updating the protocol file index and protocol database**

- 23.5.5.1** The IR-EC Secretariat shall file the accomplished, signed and dated Closure / Final Report and other related document in the protocol file folder and shall update the protocol file index.
- 23.5.5.2** Upon approval of the Closure / Final Report, the study protocol shall be classified as inactive, the Protocol Code No. shall be updated and the protocol file folder shall be re-labeled and transferred to the storage cabinet for inactive files.
- 23.5.5.3** The IR-EC Secretariat shall update the protocol file index and protocol database.



Philippine Children's Medical Center  
Institutional Research – Ethics Committee (IR-EC)  
**SOP 23.0 Review of Final Reports**

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### **23.6 Forms**

Form 17.1 V.1.1 Progress Report Form  
Form 23.1 V.3.0 Final Report Form

### **23.7 Glossary**