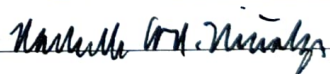






Philippine Children's Medical Center  
Institutional Research – Ethics Committee (IR-EC)  
**SOP 12.0 Management of Resubmission**

Effective Date:  
**JUN 25 2021**

## PCMC IR-EC SOP 12.0: Management of Resubmission

Supersedes:	PCMC IRB-EC SOP 01.0, V. 3.0
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Effective Date:	
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## **12.0 MANAGEMENT OF RESUBMISSION**

### **12.1 Policy Statement**

Submission of the recommended revisions shall be accepted within 15 working days after receipt of decision letter. The IR-EC shall classify protocol resubmissions beyond the deadline as inactive, hence, shall require reapplication.

### **12.2 Purpose of the Activity**

To ensure efficiency of IR-EC actions and orderliness in the protocol files.

### **12.3 Scope**

This SOP includes the procedures for the management of resubmission of protocols that begins from the receipt of the resubmitted protocol package and ends with preparation of protocol folder.

### **12.4 Process Flow/Steps for Management of Resubmission**

<b>NO.</b>	<b>ACTIVITY</b>	<b>PERSON/S RESPONSIBLE</b>
1	Receipt of the Resubmitted Protocol Package	IR-EC Secretariat
2	Distribution of Protocol Documents to Primary Reviewers	IR-EC Secretariat
3	Review of Resubmitted Protocol Documents	Primary Reviewers
4	Full Review of Resubmitted Protocols with Major Modifications	IR-EC Secretariat
5	Notify PI of IR-EC Decision	IR-EC Secretariat
6	Preparation of Protocol Folder	IR-EC Secretariat

### **12.5 Detailed Instructions**

#### **12.5.1 Receipt of the Resubmitted Protocol Package**

**12.5.1.1** The PI shall fill up and submit the Protocol Resubmission Form (Form 12.1) with the appropriate documents.

**12.5.1.2** The IR-EC Secretariat shall receive the resubmitted protocol documents from the PI.



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**12.5.2 Distribution of Protocol Documents to Primary Reviewers**

- 12.5.2.1** The IR-EC Secretariat shall send the package to the designated Primary Reviewers.
- 12.5.2.2** The Secretariat shall log the protocol documents in the Log for Outgoing Documents.

**12.5.3 Review of Resubmitted Protocol Documents**

- 12.5.3.1** The Primary Reviewers shall review resubmitted protocol with minor protocol revisions and assess compliance with the requirements for revision.

**12.5.4 Full Review of Resubmitted Protocols with Major Modifications**

- 12.5.4.1** The Primary Reviewers shall present protocols with major modifications during a full board meeting and shall make a recommendation for approval.
- 12.5.4.2** The IR-EC Members shall vote to endorse or not to endorse the recommendation for approval.

**12.5.5 Notify PI of IR-EC Decision**

- 12.5.5.1** For approved resubmitted protocols, the IR-EC Secretariat shall prepare the Decision Letter and Notice of Research Protocol Approval (Forms 27.1 and 10.3) to be signed by the Chair.
- 12.5.5.2** The IR-EC decision shall be communicated to the PI.

**12.5.6 Preparation of Protocol Folder**

- 12.5.6.1** The IR-EC Secretariat shall file copies of the approved documents in the protocol file folder.
- 12.5.6.2** The IR-EC Secretariat shall update the protocol file index of the protocol file folder.
- 12.5.6.3** The IR-EC Secretariat shall update the protocol database.

**12.6 Forms**

Form 10.3 V.3.0 Notice of Research Protocol Approval  
Form 12.1 V.1.0 Protocol Resubmission Form  
Form 27.1 V.3.0 Decision Letter of IR-EC