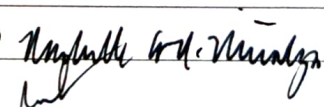

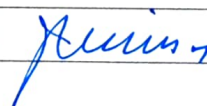




Philippine Children's Medical Center
Institutional Research – Ethics Committee (IR-EC)
SOP 1.0 Writing Standard Operating Procedures (SOPs)

Effective Date:
JUN 25 2021

PCMC IR-EC SOP 01.0: Writing SOP

Supersedes:	PCMC IRB-EC SOP 01.0, V. 3.0
Authored by:	SOP Team / PCMC IR-EC Members
Effective Date:	
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Approval Date:	

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1.0 WRITING SOP

1.1 Policy Statement

The PCMC IR-EC shall prepare new standard operating procedures (SOPs) based on need as recommended by Members.

1.2 Purpose of the Activity

The SOP aims to simplify the procedures of the PCMC IR-EC to ensure consistency and efficiency.

1.3 Scope

This SOP includes the procedure in writing SOPs that begins with the identification of the proposed new SOP and ends with the archiving of the superseded SOP.

1.4 Process Flow/Steps for Writing SOP

NO.	ACTIVITY	PERSON/S RESPONSIBLE
1	Proposal for new SOP/s	IR-EC Members
2	Deliberation of the new SOP/s in a special meeting	IR-EC Members
3	Submission of the new SOP/s to the Executive Director for approval	Executive Director
4	Receipt of the approved new SOP/s	IR-EC Secretariat
5	Filing and distribution of the approved new SOP/s	IR-EC Secretariat
6	Archiving of the superseded SOP	IR-EC Secretariat

1.5 Detailed Instructions

1.5.1 Proposal for new SOP/s

1.5.1.1 The IR-EC Member/s shall submit a proposed SOP with a justification using the Standard Operating Procedures (SOPs) Template Form (Form 1.1 V. 3.0). The IR-EC Member/s shall be referred to as *proponent*.

1.5.1.2 The layout of the SOP shall be based on the following standard format:

- Number and version
- Title
- Policy Statement – describes the acceptable methods or actions to be used by the committee



- d. Purpose of the Activity – summarizes and explains the objectives of the undertaking
- e. Scope – identifies the range of activities that the SOP refers to
- f. Process Flow / Steps – enumerates the order of the procedures in a short and simplified manner
- g. Detailed Instructions – explains thoroughly each step of the process flow
- h. Forms – simplify details using formatted documents
- i. Glossary
- j. References

1.5.2 Deliberation of the new SOP/s in a special meeting

- 1.5.2.1** The Chair shall schedule a special meeting (See SOP 24: *Preparing for a Meeting*).
- 1.5.2.2** During the special meeting, the proponent presents the nature of the SOP and the reasons/justifications why it is necessary.
- 1.5.2.3** The Chair leads the discussion and the Members deliberate on the relevance of the SOP and any relationship or association with other SOPs. Consistency of intra-SOP and inter-SOP shall be verified.
- 1.5.2.4** The Committee shall approve the provisional SOP/s by consensus.

1.5.3 Submission of the provisional SOP/s to the Executive Director for approval

- 1.5.3.1** Upon approval of the provisional SOP/s by the IR-EC, the Chair shall submit the same to the Deputy Executive Director for Education, Training and Research Services for endorsement.
- 1.5.3.2** Upon endorsement, the provisional SOP shall be forwarded to the Executive Director for approval.

1.5.4 Receipt of the approved new SOP/s

- 1.5.4.1** The Secretariat shall receive the approved new SOP/s from the Office of the Executive Director.

1.5.5 Filing and distribution of the approved new SOP/s

- 1.5.5.1** The approved new SOP/s shall be in harmony with the rest of the current SOPs.
- 1.5.5.2** The Secretariat shall forward copies of the new SOP/s to the IR-EC Members as well as the Executive Director, Deputy Executive Director for Education, Training and Research Services and the Clinical Research Division.



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1.5.5.3 The Secretariat shall send an electronic copy of the approved new SOP/s to the hospital information system for uploading in the PCMC website.

1.5.5.4 The Secretariat shall retain one complete originally signed SOP copy.

1.5.6 Archiving of the superseded SOP

1.5.6.1 The superseded SOP shall be archived properly.

1.6 Forms

Form 1.1 V.3.0 Standard Operating Procedures (SOPs) Template

Form 2.1 V.1.0 Proposal for Standard Operating Procedures (SOPs)

1.7 Glossary

Consensus – a general agreement among the members in attendance to finalize a decision

Proponent – member/s who will introduce a proposal for deliberation

ANNEXES

ANNEX 1: Standard Operating Procedures Template

ANNEX 2: Document History

ANNEX 3: Log of SOP Recipients



ANNEX 1. STANDARD OPERATING PROCEDURES (SOPs) TEMPLATE

TITLE PAGE

- **HEADER**
 - Institutional seal or logo – located on the left upper portion
 - Name of institution – typeset as header at the center
 - SOP identifier – typeset below the header and expressed as **IR-EC SOP XX.X** where *XX.X* is a three-digit number corresponding to the SOP number and section in the manual where the SOP is found
 - SOP title – typeset after the SOP identifier
 - Effective date – typeset on the right upper portion
- **FOOTER**
 - Year and Version number – expressed as IR-EC SOP Year V.1
 - Page number

Supersedes:	
Authored by:	
Effective Date:	
Prepared by:	
Endorsed by:	
Approved by:	
Approval Date:	

MAIN TEXT/ CONTENTS

- Policy Statement – describes the acceptable methods or actions to be used by the committee
- Purpose of the Activity – summarizes and explains the objectives of the undertaking
- Scope – identifies the range of activities that the SOP refers to
- Process Flow / Steps – enumerates the order of the procedures in a short and simplified manner
- Detailed Instructions – explains thoroughly each step of the process flow
- Annex, if applicable – document that explains further or complex descriptions



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ANNEX 2. DOCUMENT HISTORY

REVIEW NO.	REVISED BY	REVISION NO.	REASON FOR REVISION	DATE REVISED	APPROVED BY	EFFECTIVE DATE	DESCRIBE THE MAIN CHANGES
1	SOP Team and IR-EC Members	1					



Philippine Children's Medical Center
Institutional Research – Ethics Committee (IR-EC)
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ANNEX 3. LOG OF SOP RECIPIENTS

Name of Recipient	SOPs	No. of copies	Signature	Date
1.	PCMC IRB-EC SOP 2015 V.1	1		
2.				
3.				
4.				