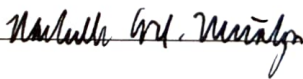






Philippine Children's Medical Center  
Institutional Research – Ethics Committee (IR-EC)  
**SOP 26.0 Conduct of Meetings**

Effective Date:  
**JUN 25 2021**

## PCMC IR-EC SOP 26.0: Conduct of Meetings

Supersedes:	PCMC IRB-EC SOP 01.0, V. 3.0
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Effective Date:	
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## 26.0 CONDUCT OF MEETINGS

### 26.1 Policy Statement

The IR-EC shall conduct a meeting according to agenda and that the quorum shall be established at the start of the meeting.

A quorum shall be determined at the beginning of the meeting. And is defined as at least 5 Members including at least 1 non-medical and 1 non-institutional who may be the same person. The Chair or the Vice Chair, in the absence of the Chair, shall preside over the meeting.

The decision shall be made by consensus or by secret ballot if consensus cannot be generated.

### 26.2 Purpose of the Activity

To provide an opportunity for discussion and deliberation on protocol-related and administrative matters that require action from the IR-EC and for information of the Committee.

### 26.3 Scope

This SOP includes the procedures for conducting full board meetings that begins from the calling the meeting to order and ends with the adjournment of the meeting.

### 26.4 Process Flow/Steps for Conduct of Meetings

NO.	ACTIVITY	PERSON/S RESPONSIBLE
1	Calling the Meeting to Order	IR-EC Chair
2	Declaration of Quorum	IR-EC Chair
3	Declaration Conflict of Interest	IR-EC Members
4	Approval of the Minutes of the previous Full Board Meeting and Discussion of Business arising from the Minutes	IR-EC Members
5	Approval or modification the agenda	IR-EC Members
6	Deliberation of protocols for initial review	Primary Reviewers IR-EC Members
7	Deliberation of protocol document resubmission	Primary Reviewers IR-EC Members



Philippine Children's Medical Center  
Institutional Research – Ethics Committee (IR-EC)  
**SOP 26.0 Conduct of Meetings**

Effective Date:  
**JUN 25 2021**

8	Deliberation on protocol amendments	Primary Reviewers/Chair IR-EC Members
9	Deliberation on after-approval reports	Primary Reviewers/Chair IR-EC Members
10	Reporting Expedited Review Results	IR-EC Chair
11	Discussion of Other Matters	IR-EC Members
12	Adjournment	IR-EC Chair

## **26.5 Detailed Instructions**

### **26.5.1 Calling the Meeting to Order**

**25.5.1.1** The Chair shall declare the formal opening of the Meeting at the appointed time and place once majority of the members are present

### **26.5.2 Declaration of Quorum**

**26.5.2.1** The Chair shall check and report if the quorum requirements are met to enable the meeting to start. IR-EC quorum requirements should comply with national and international requirements and as defined in these SOPs. Quorum shall be maintained throughout the duration of the meeting when members are required to vote to arrive at a decision. The following shall be met to constitute quorum in a full board meeting of IRB-EC:

- a. 50%+ 1 of panel membership but not less than five (5)
- b. presence of medical/ scientific and non-medical/ non-scientific members
- c. presence of non-affiliated member

**26.5.2.2** If there is a quorum, the Chair shall proceed but, if there is none, the Chair shall declare an adjournment.

### **26.5.3 Declaration Conflict of Interest**

**26.5.3.1** The Chair shall ask the IR-EC members to declare their conflict of interest related to any protocols to be discussed.

**26.5.3.2** Conflict of interest shall be present when a PCMC IR-EC member has affiliation with a Principal Investigator or institute which will undermine his/her ability to make a free and independent evaluation.

**26.5.3.3** The IR-EC members shall check the agenda and declare their COI related to any protocol to be reviewed. They shall be asked to leave the room during the discussion of such protocols, unless they are asked to reply to questions for clarification. Quorum should be maintained when conflicted members leave the room. They shall return to the room after discussion of their protocol.



Philippine Children's Medical Center  
Institutional Research – Ethics Committee (IR-EC)  
**SOP 26.0 Conduct of Meetings**

Effective Date:  
**JUN 25 2021**

**26.5.4 Approval of the Minutes of the previous Full Board Meeting and Discussion of Business arising from the Minutes**

**26.5.4.1** The Minutes of the previous meeting should have been sent to all members before the meeting for comments. The Chair shall ask the members to approve the Minutes of the last meeting and shall ask the members to voice out their comments, if any.

**26.5.4.2** The Chair shall also ask the members to comment about issues arising from the Minutes and the discussions shall be recorded in the current Minutes by the Member Secretary / designated Member.

**26.5.5 Approval or modification the agenda**

**26.5.5.1** The Chair shall ask the Members to examine and approve the items in the Meeting Agenda.

**26.5.5.2** IR-EC members may suggest additional items for discussion and the meeting agenda may be modified to include additional items for discussion.

**26.5.6 Deliberation of protocols for initial review**

The list of protocols for initial review shall be discussed according to the following procedures:

**26.5.6.1** The primary medical reviewer shall summarize the protocol to enable the members to understand it.

**26.5.6.2** He/she shall use the assessment form to comment on the technical and ethical issues in the protocol and shall make recommendations about clarification, modification or approval. He/she also shall comment on the qualifications of the researchers and the sites.

**26.5.6.3** The Chair shall open the protocol for discussion of IR-EC members taking note of additional and contradictory comments.

**26.5.6.4** The non-medical/ non-scientific reviewer shall presents his/her assessment of the Patient Information Sheet and Informed Consent Form making use of the ICF Assessment Form. The comments should note the discrepancies between the protocol and the information sheet, the correct consent or assent is enclosed, and provisions for proper signatures in the form.

**26.5.6.5** The PI shall be called to enter the room to answer questions and clarify certain protocol related matters, after which, he/she is asked to leave the room.

**26.5.6.6** The Chair shall summarize the points raised and shall note different views among members that should be resolved. The Chair shall ask the members to vote by consensus based on the decision points in the SOPs:



Philippine Children's Medical Center  
Institutional Research – Ethics Committee (IR-EC)  
**SOP 26.0 Conduct of Meetings**

Effective Date:  
**JUN 25 2021**

- a. Approval (no further revision of the documents is required)
- b. Minor Modification
- c. Major Modification,
- d. Disapproval

**26.5.6.7** The Chair/Member Secretary shall take note of decision by consensus and shall include them in the Minutes of the meeting.

**26.5.6.8** Once the protocol documents are approved, the IR-EC shall agree on the frequency of continuing review.

**26.5.7 Deliberation of protocol document resubmission**

**26.5.7.1** The Secretariat shall include in the Meeting Agenda resubmissions required for Major Modification for full board discussion.

**26.5.7.2** The Primary Reviewers shall check if the researchers complied with the IR-EC requirements and recommends appropriate decision. The IR-EC members shall decide to approve the resubmission.

**26.5.8 Deliberation on protocol amendments**

**25.5.8.1** The Chair shall screen amendments to determine Major Protocol Amendments that require full board review and to ensure inclusion in the Meeting Agenda.

**25.5.8.2** The Chair/Primary reviewer shall review the amendment and presents their assessment to full board.

**25.5.8.3** The IR-EC members shall vote to approve the Major Amendment.

**26.5.9 Deliberation on after-approval reports**

**26.5.9.1** Discuss and decide on Progress Reports for full board review.

**26.5.9.2** Approve Final Reports.

**26.5.9.3** Discuss Protocol Deviation/ Violation Reports for appropriate action.

**26.5.9.3.1** The Chair/Primary Reviewers shall review the Reports and shall present their assessment and recommendation for appropriate action to full board.

**26.5.9.3.2** The IR-EC members shall decide by consensus to take corresponding action on the Protocol Deviation/ Violation Reports

**26.5.9.4** Report Onsite SAEs for appropriate action

**26.5.9.4.1** The IR-EC Secretariat shall prepare a list of Onsite SAEs/ SUSARs and submits them to full board for appropriate action.

**26.5.9.4.2** The SAE Reviewer / Chair shall review the Onsite SAE/SUSAR Reports and shall present their assessment and recommendation for appropriate action to full board.

**26.5.9.4.3** The IR-EC members shall decide by consensus to take corresponding action on the Onsite SAE / SUSAR Reports.



Philippine Children's Medical Center  
Institutional Research – Ethics Committee (IR-EC)  
**SOP 26.0 Conduct of Meetings**

Effective Date:  
**JUN 25 2021**

**26.5.10 Reporting Expedited Review Results**

**26.5.10.1** The IR-EC Secretariat shall prepare a list of all Expedited Review results approved by the Chair and shall submit them to full board to inform the IR-EC members.

**26.5.10.2** IR-EC Members may comment on the reports.

**26.5.11 Discussion of Other Matters**

**26.5.11.1** The Chair / Member-Secretary or any IR-EC Member may suggest items or other matters for the information or discussion by full board.

**26.5.11.2** The Chair/Member-Secretary or any IR-EC Members may report queries and complaints that may need board discussion for appropriate action.

**26.5.12 Adjournment**

**26.5.12.1** The Chair shall formally close the full board meeting after determination that all the Meeting Agenda items have been discussed.

**26.5.12.2** Confirmation of the date of the next regular meeting shall be done before adjournment of the meeting.

**26.6 Forms**

Form 25.1 V.20 Minutes of the Meeting Form

Form 26.1 V.2.0 Notice of the Meeting

**26.7 Glossary**

***Conflict of Interest*** - conditions in which professional judgment concerning a primary interest (such as patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)