


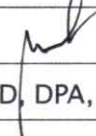
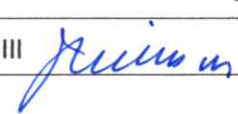


Philippine Children's Medical Center  
Institutional Research – Ethics Committee (IR-EC)  
**SOP 3.0 Structure and Composition  
of the IR-EC Membership**

Effective Date:  
**JUN 25 2021**

## PCMC IR-EC SOP 3.0: Structure and Composition of the IR-EC Membership

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Supersedes:	PCMC IRB-EC SOP 01.0, V. 3.0
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Effective Date:	
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### **3.0 STRUCTURE AND COMPOSITION OF THE IR-EC**

#### **3.1 Policy Statement**

The IR-EC shall comply with national and international guidelines regarding research ethics committee composition policy. The IR-EC shall have at least 9 members that includes 6 medical (5 pediatricians and 1 non-pediatrician), 3 non-medical/non-scientist and at least 1 non-affiliated member.

The IR-EC shall select and appoint alternate members with the same qualifications as the regular members.

While the IR-EC is now directly under the authority of the Deputy Executive Director for Education, Training and Research Services, it shall maintain its independence and develop its competence related to decision making in research ethics review as defined in international and national guidelines.

The IR-EC shall report to the DEDETRS administrative-wise for its project procurement management plan, financial audit and performance governance system breakthroughs.

As an independent committee in terms of its mandate as ethical reviewer, the IR-EC will hold its own office, distinct from the Deputy Executive Director for Education, Training and Research Services (DEDETRS) as well as the Clinical Research Division (CRD). In the hospital organizational structure, the IR-EC is represented with a broken line under the DEDETRS to emphasize its independence as an office. All communication to and from the IR-EC with regard to ethical review, monitoring reports, research data privacy and confidentiality as well as investigator / subject queries shall not pass thru the DEDETRS and the CRD.

#### **3.2 Purpose of the Activity**

To ensure that the membership has the appropriate expertise and the composition is adherent to the National Ethical Guidelines.

#### **3.2 Scope**

This SOP includes the procedures in outlining the structure and composition of the IR-EC that begins from defining the composition of the IR-EC membership of the and ends with the recommendation and submission of the list of potential members and set of Officers to the Deputy Executive Director for Education, Training and Research Services for endorsement.



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### 3.4 Process Flow/Steps for the Structure and Composition of the IR-EC

NO.	ACTIVITY	PERSON/S RESPONSIBLE
1	Defining the composition of the IR-EC membership	IR-EC Chair, Member-Secretary, IR-EC Members
2	Opening the nomination for potential new IR-EC Members	IR-EC Chair, IR-EC Members
3	Submission of names of potential members to the Chair	IR-EC Members, Department Managers, Division Heads, Section Heads
4	Discussion of nominated potential members and Officers at full board meeting	IR-EC Chair, IR-EC Members
5	Recommendation and submission of the list of potential members and set of Officers to the Deputy Executive Director for Education, Training and Research Services for endorsement	IR-EC Chair

### 3.5 Detailed Instructions

#### 3.5.1 Defining the composition of the IR-EC membership

**3.5.1.1** The Chair shall discuss the qualifications of the additional members with the existing members of the IR-EC.

**3.5.1.2** The IR-EC shall be composed of at least nine (9) Members. Its membership shall be multidisciplinary and multi-sectoral. The IR-EC Members should have diverse background and experience to foster a comprehensive and efficient review of research activities commonly conducted by the PCMC staff and non-affiliated organizations.

**3.5.1.3** The membership shall include persons whose primary concerns are in medical science; at least one member who is a non-pediatrician; at least one member who is in a non-medical/non-scientific field; and at least one member who is non-affiliated with PCMC.

The types of membership are as follows:

- a. Medical – a professional who has a medical degree
- b. Non-Medical – a person who has no medical degree
- c. Scientist – professional with advanced training and expertise in the medical or non-medical areas of science
- d. Non-Scientist – a person with no background in the medical or non-medical areas of science
- e. Non-Institutional/ Non-Affiliated – a person who is not an employee nor affiliated with the institution and its services



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- 3.5.1.4** Relevant expertise may include medicine and research, social or behavioral science, law, philosophy, environmental science and public health. It is recommended that the IR-EC should include a person who will represent the interest and concerns of the community.
  - 3.5.1.5** The IR-EC shall aim for adequate representation of both men and women members in order to promote gender sensitivity in its review procedures.
  - 3.5.1.6** The IR-EC shall have representatives from both the older and younger generations.
  - 3.5.1.7** The IR-EC shall invite members who shall be tasked primarily to attend an IR-EC meeting to substitute for a Regular Member, and shall be designated as an *Alternate Member*.
  - 3.5.1.8** During review board meetings, the IR-EC shall adhere to quorum requirements according to 21 CFR 56.108C: Quorum will be declared if majority (defined as 50% + 1) of the PCMC IR-EC Members are present but should not be less than five (5). Moreover, there should be at least one (1) member who is non-medical and one (1) non-institutional. When reviewing clinical trials involving children or pediatric patients, a pediatrician or child development specialist shall be present during its review board meeting.
  - 3.5.1.9** The IR-EC shall invite Independent Consultants, whenever necessary, to provide expert opinion related to protocols under review.
- 3.5.2 Opening the nomination for potential new IR-EC Members**
- 3.5.2.1** The nomination process for IR-EC Membership shall be announced to the IR-EC Members and opened to the, hospital Department Chairs, Division Heads and Section Heads.
  - 3.5.2.2** Current IR-EC Members shall nominate candidates for new members. Each department, division and section shall also be asked to nominate candidates for new members.
- 3.5.3 Submission of names of potential members to the Chair**
- 3.5.3.1** The current IR-EC Members, Department Managers, Division Heads and Section Heads shall submit the names of candidates for new membership to the IR-EC Chair.
  - 3.5.3.2** The Secretariat shall prepare the list of nominees for new membership for full board discussion.
- 3.5.4 Discussion of nominated potential members and Officers at full board meeting**
- 3.5.4.1** The Chair shall discuss the list of nominees during a full board meeting.
  - 3.5.4.2** The Chair shall present the credentials of the nominees for new membership.



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**3.5.4.3 Qualifications for selection of new members**

The IR-EC Members shall discuss the qualifications of the nominees at during a full board meeting. Members are selected based on -

- a. Good moral character and personal capacities; their scientific expertise and knowledge of ethical principles.
- b. Willingness to volunteer their time and effort to perform their functions in the IR-EC.
- c. Preferably have prior training in research ethics, research methodology, and Good Clinical Practice or should be willing to undergo continuing

**3.5.4.4** The IR-EC Members shall discuss and decide by consensus on the final list of nominees to be submitted to the Executive Director. Potential conflict of interest issues of the nominees shall also be discussed.

**3.5.4.5** The IR-EC Members shall also discuss whether the potential new member can be a Regular Member or an Alternate Member.

**3.5.5 Recommendation and submission of the list of potential members and set of Officers to the Deputy Executive Director for Education, Training and Research Services for endorsement**

**3.5.5.1 Selecting Members**

**3.5.5.1.1** The Chair shall recommend and submit the list of potential new members of the IR-EC to the Deputy Executive Director for Education, Training and Research Services for endorsement.

**3.5.5.1.2** The IR-EC shall adopt some mechanism to enable participation of new members with fresh outlook and approaches, but it shall also strive to ensure continuity-, as well as development skills and expertise.

**3.5.5.2 Selecting Officers**

**3.5.5.2.1** The IR-EC Chair, Vice Chair and Member-Secretary shall be nominated by the Members of the IR-EC. They should be highly-respected individuals within or outside the institution, fully capable of managing the IR-EC and ensuring fairness and impartially in dealing with matters brought the IR-EC. They should have the following qualifications:

- a. Good personal character and reputation
- b. Have training on Basic Research Ethics, Good Clinical Practice in Research and preferably advanced courses on Research Ethics in the past 3 years Recommend further action, specify
- c. Have been a member of an Ethics Review Committee for at least 3 years



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**3.5.5.2.2** The election of Officers shall be conducted during full board meeting. If a Member of the IR-EC is absent during the election, he/she will be given the list of nominees by the Secretariat and allowed to cast his/her vote. Once all the votes have been cast, the Secretariat shall tally the votes.

**3.5.5.2.3** The Chair shall present to the full board the result of the election for approval. The list of elected IR-EC Officers shall be submitted by the Chair to the Deputy Executive Director for Education, Training and Research Services for endorsement.

**3.5.5.3** Upon endorsement, the Deputy Executive Director for Education, Training and Research Services shall transmit the list of potential new members and set of Officers to the Executive Director for approval.

### **3.6 Forms**

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

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

### **3.7 Glossary**

*Alternate Member* – a member of the IR-EC who shall be tasked primarily to attend an IR-EC meeting to substitute for a Regular Member

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

*Medical* – a professional who has a medical degree

*Non-Medical* – a person who has no medical degree

*Non-Institutional/Non-Affiliated* – a person who is not an employee nor affiliated with the institution and its services

*Non-Scientist* – a person with no background in the medical or non – medical areas of science

*Quorum* – the number of present members required to act on any motion presented for action during a full board meeting, in addition to types of members required to be present based on international and national guidelines and regulations

*Regular Member* – a member of the IR-EC who fulfilled qualifications with official appointment tasked to do ethical review on researches

*Scientist* – a professional with advanced training and expertise in the medical or non – medical areas of science

## **ANNEXES**

### **ANNEX 4: ORGANIZATIONAL STRUCTURE**