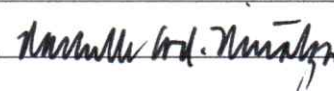
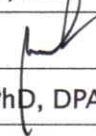





Philippine Children's Medical Center
Institutional Research – Ethics Committee (IR-EC)
SOP 5.0 Appointment of Independent Consultants

Effective Date:
JUN 25 2021

PCMC IR-EC SOP 5.0: Appointment of Independent Consultants

Supersedes:	PCMC IRB-EC SOP 01.0, V. 3.0
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Effective Date:	
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5.0 APPOINTMENT OF INDEPENDENT CONSULTANTS

5.1 Policy Statement

The IR-EC shall have independent consultants who shall be chosen from among the PCMC medical staff and whose appointment shall be renewable on a yearly basis.

The PCMC Executive Director shall be responsible for the formal appointment of the Independent Consultants through a Memorandum Order after endorsement from the Deputy Executive Director for Education, Training and Research Services.

5.2 Purpose of the Activity

To ensure that the IR-EC has a pool of independent consultants to address the gap in expertise which may be necessary in the review of protocols.

5.3 Scope

This SOP includes the procedures in appointing Consultants that begins from assessing the need for Independent Consultants and seeking approval for contracting their services and ends with the organizing and completing the documents in the Independent Consultant Files.

5.4 Process Flow/Steps for the Appointment of the Independent Consultants

NO.	ACTIVITY	PERSON/S RESPONSIBLE
1	Assessing the need for Independent Consultants and seeking approval for contracting their services	Chair, IR-EC Members
2	Recruitment of Independent Consultant	Chair, IR-EC Members, Department Chairs, Division Heads, Section Heads
3	Appointment of Independent Consultant	Executive Director
4	Organizing and completing the documents in the Independent Consultant Files	Secretariat

5.5 Detailed Instructions

5.5.1 Assessing the need for Independent Consultants and seek approval for contracting their services



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- 5.5.1.1** Considering the field/specialty of the protocol for review, the Chair and the IR-EC Members shall identify the expertise needed by the IR-EC membership.
- 5.5.1.2** The Chair and the IR-EC Members shall nominate Independent Consultants to help with the review of the types of research where the IR-EC lacks expertise. Each specialty section of the hospital shall also be asked to nominate candidates for Independent Consultants.

5.5.2 Recruitment of Independent Consultant

- 5.5.2.1** The IR-EC Secretariat shall compile the list of potential Independent Consultants from the IR-EC Members, Department Chairs, Division Heads and Section Heads.
- 5.5.2.2** The IR-EC Chair shall conduct a qualification review of the prospective Independent Consultants.
- 5.5.2.3** The Chair shall submit the names of possible Independent Consultants to the Deputy Executive Director for Education, Training and Research Services for endorsement to the Executive Director
- 5.5.2.4** The Chair shall request for corresponding honoraria the Independent Consultants who are tasked to help the IR-EC with protocol review.

5.5.3 Appointment of Independent Consultant

- 5.5.3.1** Upon endorsement of the Deputy Executive Director for Education, Training and Research Services, the Executive Director shall approve the appointment of Independent Consultants to the IR-EC.
- 5.5.3.2** Once appointed by the Executive Director, the Chair shall request the Independent Consultants to sign the Appointment Letter that includes the following:
 - a. Terms of Reference (TOR) with duration of consultancy of three (3) years and general overview of deliverables (Form 5.1)
 - b. Request for a copy of the consultant's curriculum vitae (CV)
- 5.5.3.3** The IR-EC Secretariat shall send the letter to the Independent Consultant after it is signed by the Chair together with the duplicate copies of the Confidentiality and Conflict of Interest Declaration (Form 4.3) for the consultant's signature.
- 5.5.3.4** The IR-EC Secretariat staff shall ask the Independent Consultant to sign and date his/her acceptance of the TOR of the appointment. The responsibilities of the Independent Consultant shall include the following:
 - a. Attendance to the IR-EC meeting to review the assigned protocol.
 - b. Participate in the discussion but without the right to vote.
 - c. Completion of the Assessment Form of the protocol to be reviewed



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5.5.3.5 The IR-EC Secretariat shall collect the signed and dated Confidentiality and Conflict of Interest Agreement, and the signed and dated updated CV using the prescribed format.

5.5.4 Organizing and completing the documents in the Independent Consultant Files

5.5.4.1 The Independent Consultant Files shall contain the following:

- a. IR-EC Appointment of Independent Consultant signed and dated by the IR-EC Chair
- b. Updated curriculum vitae that is signed and dated by the Independent Consultant. The CV is updated every time the appointment is renewed.
- c. Training Record and photocopy of Training Certificates of relevant trainings
- d. Confidentiality and Disclosure of Conflict of Interest Agreement signed and dated by the Independent Consultant.

5.5.4.2 The IR-EC Secretariat shall create one file for each Independent Consultant.

5.6 Forms

Form 4.3 V.1.0 Confidentiality and Conflict of Interest Declaration

Form 5.1 V.1.0 Appointment Letter of Independent Consultants

5.7 Glossary