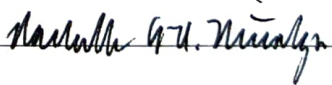

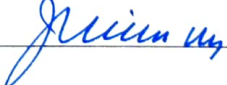




Philippine Children's Medical Center
Institutional Research – Ethics Committee (IR-EC)
SOP 20.0 Management of Queries and Complaints

Effective Date:
JUN 25 2021

PCMC IR-EC SOP 20.0: Management of Queries and Complaints

Supersedes:	PCMC IRB-EC SOP 01.0, V. 3.0
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Effective Date:	
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20.0 MANAGEMENT OF QUERIES AND COMPLAINTS

20.1 Policy Statement

The IR-EC shall consider for action all queries and complaints from participants and family members, community members in community-based research and from stakeholders of a research pertaining to protocols that have been approved.

20.2 Purpose of the Activity

To ensure safety of study participants, maintain public support, promote transparency and accountability in research as well as trust in research and the researchers.

20.3 Scope

This SOP includes the procedures for the management of queries and complaints that begins from the receipt of the complaint or inquiry and ends with filing of pertinent documents.

20.4 Process Flow/Steps for Management of Queries and Complaints

NO.	ACTIVITY	PERSON/S RESPONSIBLE
1	Receipt of the complaint or inquiry	IR-EC Secretariat
2	Review of the complaint/inquiry	IR-EC Chair
3	Discussion in convened meeting or reporting the decision/action taken to full board	IR-EC Members, Chair
4	Communicating IR-EC's response	IR-EC Secretariat, Chair
5	Filing pertinent documents	IR-EC Staff

20.5 Detailed Instructions

20.5.1 Receipt of the complaint or inquiry

20.5.1.1 The PCMC IR-EC secretariat shall receive the inquiry or requests from research participants / patients or the community through various forms of communication (email, telephone call, letter, etc.).

20.5.1.2 The PCMC IR-EC secretariat shall request the person with the inquiry or request to record the request and information in the Request/Query Record form (PCMC IR-EC Form 20.1) and keep a copy in the files. The Secretariat may assist to put the complaint in writing especially if the complainant or inquiring party is a research participant.



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20.5.1.3 It shall be the responsibility of the Principal Investigator to determine whether a protocol violation/deviation is major or minor, and ensure proper recording to IR-EC. If the PI is unsure whether the variance is a violation or deviation s/he should seek advice from the sponsor to ensure appropriate action is taken.

20.5.1.4 The IR-EC Secretariat shall record the submitted document in the Log of Incoming Documents.

20.5.2 Review of the complaint/inquiry

20.5.2.1 The IR-EC Chair shall review the complaint.

20.5.2.2 The PI may be contacted to provide clarification or further information.

20.5.2.3 The Chair shall take action or refer the request / query to Full Board, if necessary.

20.5.2.4 If action to the request or query can be done without Full Board decision, the Chair shall reply to the request or query and record the information and any action taken in the Request / Query Record Form (Form 20.1). The Chair shall sign and date the form and forward to the Secretariat for filing.

20.5.3 Discussion in convened meeting or reporting the decision/action taken to full board

20.5.3.1 The Chair shall present a serious complaint to full board for discussion. He presents the information gathered and his recommendations.

20.5.3.2 The IR-EC members shall discuss to take appropriate actions.

20.5.4 Communicating IR-EC's response

20.5.4.1 The IR-EC Secretariat shall prepare response to inquiry complaint within 7 days from the time of review

20.5.5 Filing pertinent documents

20.5.5.1 The IR-EC Secretariat shall file the accomplished Form 4.8 together with the letter of inquiry / complaint and excerpts of the meeting minutes when this was deliberated or reported in the protocol file folder.

20.5.5.2 IR-EC Secretariat shall update the protocol file index.

20.6 Forms

Form 20.1 V.3.0 Request/Query Record

20.7 Glossary