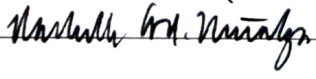
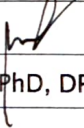
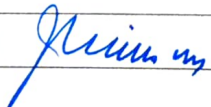




Philippine Children's Medical Center
Institutional Research – Ethics Committee (IR-EC)
**SOP 11.0 Management of Protocols Undergoing
Parallel DOH-SJREB Review**

Effective Date:
JUN 25 2021

PCMC IR-EC SOP 11.0: Management of Protocols Undergoing Parallel DOH-SJREB Review

Supersedes:	PCMC IRB-EC SOP 01.0, V. 3.0
Authored by:	SOP Team / PCMC IR-EC Members
Effective Date:	
Prepared by:	Rachelle Angeli R. Niñalga, MD 
Endorsed by:	Mary Ann C. Bunyi, MD 
Approved by:	Julius A. Lecciones, MD, PhD, DPA, CESO III 
Approval Date:	

PCMC IR-EC address: Quezon Ave. corner Agham Road, Quezon City, Philippines
Contact number: (02) 8588-9900 Loc. 356 ; Fax Number: (02) 8924-0840
E-mail address: irec@pcmc.gov.ph



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11.0 MANAGEMENT OF PROTOCOLS UNDERGOING PARALLEL DOH-SJREB REVIEW

11.1 Policy Statement

The IR-EC shall conduct full review for protocols that entail more than minimal risk and have vulnerability issues.

The initial communication on the initial review shall be released within 28 working days after receipt of the complete protocol package.

11.2 Purpose of the Activity

To ensure effective contribution to multi-site review.

11.3 Scope

This SOP includes the procedures for the management of protocols undergoing DOH-SJREB review that begins from the receipt of initial protocol package and verification of documents and ends with notification of PI.

11.4 Process Flow/Steps for Management of Protocols Undergoing DOH-SJREB Review

NO.	ACTIVITY	PERSON/S RESPONSIBLE
1	Receipt of Initial Protocol Package and Verification of Documents	IR-EC Secretariat
2	Assignment of Primary Reviewer	Chair/Secretary
3	Accomplishment of SJREB Assessment Forms	Primary Reviewer
4	Attendance and Participation in SJREB Full Board Meeting	Primary Reviewer/Designated Member
5	Notification PI of Decision	IR-EC Secretariat

11.5 Detailed Instructions

11.5.1 Receipt of Initial Protocol Package and Verification of Documents

11.5.1.1 There shall be parallel submission of protocol documents to SJREB and IR-EC. IR-EC shall conduct a preliminary review of the protocol documents in preparation for the SJREB Full Board Meeting.

11.5.1.2 The SJREB Secretariat shall send the study protocol package to IR-EC at least 7 days before scheduled SJREB Full Board Meeting.



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11.5.1.3 For resubmitted documents, the IR-EC decision for re-evaluation (major revision) of documents (protocol, ICF, etc.) requires full review of revisions.

11.5.1.4 The IR-EC SOP for initial review shall be followed.

11.5.2 Assignment of Primary Reviewers

11.5.2.1 The IR-EC shall conduct preliminary review of the protocol documents and a representative from the IR-EC shall be assigned to participate in the discussion during the SJREB Full Board Meeting to reflect the views of the IR-EC.

11.5.2.2 The Chair shall designate Members (one medical member and one non-medical member) as Primary Reviewers for the parallel initial review process of the IR-EC taking into consideration the appropriate expertise needed to assess the study protocol. The Primary Reviewers shall accomplish the appropriate IR-EC Assessment Forms (Forms 10.1 and 10.2) in reviewing the study protocol.

11.5.2.3 An Independent Consultant who is the appropriate expert needed may be assigned to evaluate the study protocol. The Independent Consultant shall also accomplish the appropriate PCMC IR-EC Assessment Forms.

11.5.3 Accomplishment of SJREB Assessment Forms

11.5.3.1 The assigned IR-EC Primary Reviewers shall accomplish the SJREB Assessment Forms as parallel review.

11.5.3.2 The IR-EC Secretariat shall send an electronic copy of the accomplished SJREB Assessment Forms prior to the scheduled SJREB Full Board Meeting.

11.5.4 Attendance and Participation in SJREB Full Board Meeting

11.5.4.1 The designated IR-EC Primary Reviewers shall attend the scheduled SJREB Full Board Meeting on behalf of the IR-EC with the accomplished SJREB Assessment Forms.

11.5.4.2 The designated IR-EC Primary Reviewers shall participate in the SJREB initial review of the study protocol and shall report on the SJREB comments and recommendations during the next IR-EC full board meeting.

11.5.5 Notify PI of SJREB Decision

11.5.5.1 The IR-EC shall accept the SJREB decision except when there are strong ethical issues that still need to be addressed.



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- 11.5.5.2** The IR-EC shall be responsible to inform the PI of the outcome of the SJREB review.
- 11.5.5.3** The IR-EC Secretariat shall send Notice of Decision (Form No. 27.1) and or Notice of Research Protocol Approval (Form No. 10.3) duly signed by the IR-EC Chair together with the Notice of REC Decision from SJREB to the PI.
- 11.5.5.4** The IR-EC shall retain its review functions related to protocol amendments, SAE reports, protocol deviation and violation reports and final reports, all of which involve events at specific sites.

11.6 Forms

Form 10.1 V.2.0 Protocol Assessment Form
Form 10.2 V.2.0 Informed Consent Assessment Form
Form 10.3 V.3.0 Notice of Research Protocol Approval
Form 27.1 V.3.0 Decision Letter of IR-EC
SJREB Assessment Form

11.7 Glossary

SJREB - The Single Joint Review Ethics Board SJREB is organized by the Department of Health (DOH) Health Policy Development and Planning Bureau (HPDPB) with the following objectives: (1) To streamline the review process of health-related protocols to be conducted in multiple sites in the Philippines. (2) To harmonize the results of ethics review among various site RECs through joint review. (3) To strengthen the ethics review capacity of PHREB Level 3 RECs to review different types of protocols that are conducted at their sites (4) To shorten the turn-around time of ethics review of multi-site protocols.