

Philippine Children's Medical Center Institutional Research – Ethics Committee (IR-EC)

Effective Date: JUN 25 2021

STANDARD OPERATING PROCEDURES

TABLE OF CONTENTS

SOP	TITLE
SOP 1.0	Writing SOP
SOP 2.0	Revising or Updating SOP
SOP 3.0	Structure and Composition of the IR-EC Membership
SOP 4.0	Appointment of the IR-EC Members
SOP 5.0	Appointment of Independent Consultants
SOP 6.0	Training of IR-EC Members, Independent Consultants and Staff
SOP 7.0	Facilitating Compensation of IR-EC Members and Independent Consultants
SOP 8.0	Management of Initial Submissions including Exemption from Review
SOP 9.0	Management of Expedited Review
SOP 10.0	Management of Full Review
SOP 11.0	Management of Protocols Undergoing Parallel DOH-SJREB Review
SOP 12.0	Management of Resubmission
SOP 13.0	Management of Appeals
SOP 14.0	Management of Protocols on Medical Device
SOP 15.0	Review of SAE
SOP 16.0	Review of Protocol Amendments
SOP 17.0	Review of Progress Reports
SOP 18.0	Review of Protocol Violation/ Protocol Deviation
SOP 19.0	Management of an Application for Continuing Review
SOP 20.0	Management of Queries and Complaints
SOP 21.0	Site Visits
SOP 22.0	Review of Early Protocol Termination
SOP 23.0	Review of Final Reports
SOP 24.0	Preparing for a Meeting
SOP 25.0	Preparing for the Minutes of the Meeting
SOP 26.0	Conduct of Meetings
SOP 27.0	Communicating IR-EC Decision to Principal Investigator
SOP 28.0	Management of Active Study Files, Documents and Records
SOP 29.0	Management of Incoming and Outgoing Communication
SOP 30.0	Archiving of Inactive Files
SOP 31.0	Management of Access to Confidential Files
Annex 1	List of Acronyms and Glossary of Terms
Annex 2	List of IR-EC Forms

PCMC IR-EC 2020 V.4.0 Page 1