



PHILIPPINE HEALTH RESEARCH ETHICS BOARD

Philippine National Health Research System
c/o Philippine Council for Health Research and Development
Department of Science and Technology

PHREB Resolution No.20-003
Series of 2020
October 15, 2020

PCHRD	
Records Section	
Rec'd by:	<u>Noraine</u>
Time:	<u>8:00 am</u>
Date:	<u>10/20/2020</u>
Ref. No:	<u>002554</u>

RESOLUTION

“PHREB Resolution on the Timelines of Approval for COVID-19 Clinical Trial Proposal”

submitted ad referendum on 15 October 2020

Mindful of the urgent nature of scientific studies like clinical trials, and the urgent need to conduct COVID-19 Clinical Trials in the Philippines; and

Considering the need to streamline and facilitate the Ethics review of COVID 19 vaccine proposals;

The Philippine Health Research Ethics Board (PHREB), in consultation with the Committee on Standards and Accreditation (CSA), is hereby authorizing the PHREB Level 3 accredited Research Ethics Committees (RECs) to amend their Standard Operating Procedures (SOPs) to:

1. Incorporate provisions to enable their participation in Single Joint Review Ethics Board (SJREB) deliberations to act on pertinent COVID-19 Trial proposals; and
2. Incorporate the option to accept the SJREB's decision as their own institutional REC's decision or to opt out of participation in the ethics review deliberations and in the corresponding trial.

Consistent with the above and the existing SJREB SOPs, the PHREB provides the following advice:

- a) for DOH hospital RECs and non-DOH RECs to submit a letter of intent to SJREB to participate in the joint review;
- b) for site RECs to do an expedited review of each pertinent protocol prior to joining the corresponding SJREB meeting to address site specific and local issues;
- c) for all RECs participating in the SJREB joint review to agree to be assigned as primary reviewers;
- d) that site-specific RECs are required to attend (physically or electronically) the SJREB meetings when the specific protocol is being discussed;
- e) site RECs shall be responsible for the subsequent monitoring and review of site specific: protocol deviations, SAEs, SUSARs, progress reports, and final report: and
- f) that RECs should submit SOP amendments to PHREB-CSA within 30 days.

The Philippine Health Research Ethics Board hereby approves and promulgates this resolution.

ADOPTED by the Philippine Health Research Ethics Board by Referendum, this 15th day of October 2020 with the following members voting for approval:



Philippine Health Research
Ethics Board

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