

# **COVID-19 Clinical Trial Issuances in the Philippines**

**Date of update: 21Jan2022**

# Summary of COVID-19 Issuances



PHILIPPINE CLINICAL RESEARCH PROFESSIONALS, INC

Regulatory Body	Subject	Requirement
<b>DOH</b>	2020-0326: Directive for the Conduct of all Clinical Trials for COVID-19 Date: 01Sep2020	Principal Investigators to notify DOH using a Clinical Trial Notification on <b>weekly</b> basis addressed to the Health Research Division ( <a href="mailto:covid19evid@gmail.com">covid19evid@gmail.com</a> )
<b>FDA</b>	2020-029: Guidance on Application for the Conduct of COVID-19 Clinical Trials Date: 14Oct2020	Consolidated guidelines for Sponsors, CROs and Investigators on COVID-19 related clinical trial applications. *requires <b>monthly</b> progress report to FDA * SJREB and VEP approval prior to FDA review
<b>PHREB</b>	002554: PHREB Resolution on the Timelines of Approval for COVID-19 Clinical Trial Proposal Date: 15Oct2020	Authorization of Level 3 REC to amend their SOP to participate a joint review with SJREB for COVID-19 trials, Incorporate an option to accept SJREB decision
<b>DILG</b>	2021-011: Guidelines for LGU and DILG Field Support for the COVID-19 Vaccine Trials Date: 26Jan2021	Zoning Guidelines and LGU Support on WHO Solidarity Trials and Independent Trials
<b>IATF</b>	Resolution No. 136: Untitled	Application for conduct of new clinical trials in general healthy adult populations may be considered for third dose of a vaccine with EUA and Second Generation COVID-19 vaccines under EUA

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<b>SJREB</b>	Site attendance to SJREB meetings where COVID-19 Vaccine Trials are discussed Date: 09Jun2021	Site REC to attend scheduled meeting of SJREB
<b>SJREB</b>	Declaration of Conflict of Interest Date: 21Jul2021	Principal Investigators to provide completed COI to SJREB
<b>SJREB</b>	Guidance on the Implementation of COVID-19 Vaccine Trials (CVTs) in Community Settings Simultaneous with the COVID-19 Vaccine EUA Date: 08Nov2021	LGU consent or permission is secured prior to the commencement of the trial. It is recommended that an approval at the level of the municipal/city health office be secured Progress report to submitted to REC and SJREB every <b>6 months</b>

The background of the slide is a light blue color with a subtle grid pattern. Overlaid on this are various geometric shapes, primarily hexagons, in different shades of blue and white. Some hexagons are solid, while others are outlined. There are also some faint, larger hexagonal shapes in the background, creating a layered, technical aesthetic.

**Thank you**