Republic of the Philippines
Department of Health

SINGLE JOINT RESEARCH ETHICS BOARD

08 November 2021

TO : Principal Investigators, Sponsors, and Sites Implementing COVID-19 Vaccine Trials

RE : Guidance on the Implementation of COVID-19 Vaccine Trials (CVTs) in Community Settings Simultaneous with the COVID-19 Vaccine EUA Rollout

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In view of the guidance on the use of placebo for COVID-19 vaccine trials issued by the Philippine Health Research Ethics Board (PHREB) and the LGU and community challenges that emerged, the Single Joint Research Ethics Board (SJREB) shall be implementing the action points listed below as discussed during the consultative meeting held last 19 October 2021 with concerned stakeholders (i.e., DOST, PCHRD, VEP, CROs). All research ethics committees who subscribe to SJREB are requested to strictly comply with these items:

1. Research Ethics Committees (RECs) that will provide oversight to COVID-19 vaccine clinical trials are required to attend all SJREB meetings that include discussion of COVID-19 vaccine trials in the agenda;
2. All site RECs should include the following in their review of COVID-19 vaccine clinical trials:
    a. Protocol provisions about safety of participants in the intervention and placebo arms;
    b. Comprehensive information in the informed consent form about safeguards related to placebo use;
    c. Provisions for reconsenting among enrolled participants to inform them of the option to withdraw and be unblinded should vaccines that are part of the national roll-out are already accessible to the site in consonance with the recent guidelines of PHREB on the use of placebo;
    d. Detailed declaration of COI by PIs (especially those involved in multiple/competing vaccine trials) using the attached SJREB form;
    e. Recruitment outside Metro Manila is highly encouraged especially on sites with lower percentage of vaccination by the national government; and,
    f. Site management measures in place (list of approved sites, LGU permission, recruitment plan, safety measures, etc.).
3. All participating site RECs shall wait for SJREB approval and subsequently submit approval letters to SJREB of all COVID-19 vaccine clinical trials being implemented at their respective sites, or sites under their oversight. The document should indicate specific provisions/conditions that the site imposed prior to granting approval of the study;
4. RECs shall ensure that 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; and,
5. RECs shall require principal investigators of COVID-19 vaccine clinical trials to submit a progress report **every 6 months** from the date of approval. The coordinating principal investigator shall submit a consolidated progress report to SJREB **every 6 months**.

Meanwhile, the principal investigators and sponsors, apart from submitting the required documents to the site RECs as listed above, are expected to facilitate the conduct of GCP training (by DOH and DOST-PCHRD) for community workers/staff who will be doing the actual recruitment for the trial.

Should you have any questions regarding the information outlined in this recommendation letter, you may contact the SJREB Secretariat staff through email at sjreb.doh@gmail.com.

We look forward to receiving your confirmation of your support.

Very truly yours,

JACINTO V. BLAS MANTARING III, MD, MSc
SJREB Chair

Conforme:

Name

Designation/ Organization

Signature