

Philippine Health Research
Ethics Board

PHILIPPINE HEALTH RESEARCH ETHICS BOARD

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

PCHRD

Records Section

Rec'd by: Manuela
Time: 12:47 p.m.
Date: 11/25/20
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PHREB Resolution No.20-005
Series of 2020
November 19, 2020

RESOLUTION

“PHREB Resolution on the Compensation of Participants in COVID-19 Vaccine Clinical Trials and Involvement of Principal Investigators in Multiple COVID-19 Vaccine Clinical Trials”

Submitted Ad referendum on 19 November 2020

Cognizant of the urgent need to conduct COVID-19 Clinical Trials in the Philippines;

Mindful of the importance of conducting such trials in a way that conforms to international standards of ethics and research integrity;

Recognizing the need to address issues which have been brought to the attention of the Philippine Health Research Ethics Board, namely:

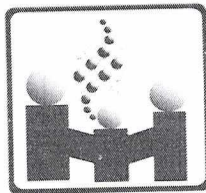
- (1) That there may be a risk of undue inducement in the process of participant recruitment for the COVID-19 vaccine clinical trials conducted by different pharmaceutical companies; and
- (2) That there may be cases wherein primary investigators or clinical trialists are hired by competing pharmaceutical companies to conduct clinical trials for their respective COVID-19 vaccines simultaneously;

Considering that the ethical principle of Justice, as explained by the PNHRs National Ethical Guidelines for Health and Health-Related Research 2017, provides that “*Research participants shall be reimbursed for lost earnings, travel costs, and other expenses incurred when taking part in a study. Where there is no prospect of direct benefit, participants may be given a reasonable and appropriate incentive for the inconvenience. The payments shall not be so large as to induce prospective participants to consent to participate in the research against their better judgment (undue inducement).*”;

Recognizing that simultaneous involvement of principal investigators and collaborators in multiple similar and/or competing studies poses a risk to the integrity of the results of the studies due to the potential conflict of interest and duties (e.g. arising from the need to abide by non-disclosure/confidentiality agreements, the duty to share knowledge on how to improve the study design, the potential difficulty of managing multiple clinical trials on top of clinical practice and/or frontline duties, and the potential impact of conflicting loyalties on the PI’s involvement in participant recruitment);

The Philippine Health Research Ethics Board (PHREB) hereby provides the following guidance for the RECs:

- a) To set the maximum acceptable amount for both monetary and non-monetary incentive or total compensation at PhP2,500 for each patient visit;
- b) To decide when to consider giving higher compensation for research participants based on reasonable justification stated in the protocol;
- c) To require a declaration from the principal investigator(s) or collaborators of their involvement in any other similar or competing clinical trial; and
- d) To encourage COVID-19 vaccine clinical trialists to inhibit participation in multiple clinical trials.



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

ADOPTED by the Philippine Health Research Ethics Board by Ad Referendum, this 19th day of November 2020 with the following members voting for approval:

PHILIPPINE HEALTH RESEARCH ETHICS BOARD

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Member

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Member

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