Republic of the Philippines
Department of Health
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INSTITUTIONAL REVIEW BOARD

PROGRESS REPORT (FORM 3.3)

IRB Protocol No.		Initial Approval Date	
Protocol Title			
Coordinating Investigator		Sponsor	

Any amendment since the last review? Describe briefly.	☐Yes	☐ No
Any change in participant population, recruitment or selection criteria since the last review? Explain the changes.	☐Yes	☐ No
Any change in the Informed Consent process or documentation since the last review? Please explain.	☐Yes	☐ No
Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? Summarize.	☐Yes	☐ No
Any unexpected complication or side effect noted since the last review? Summarize.	☐Yes	☐ No

Were there protocol deviation/violation reports? Summarize. What corrective actions were taken?	☐Yes	☐ No
Any new investigator that has been added to or removed from the research team since the last review? Please identify them and submit the CVs of new investigators.	☐Yes	☐ No

Summary of recruitment:	
☐	Accrual ceiling set by IRB
☐	New participants accrued since last review
☐	Total participants accrued since protocol began
☐	No. of participants who are lost to follow-up
☐	No of participants withdrawn from the study
☐	No. of participants who experienced SAEs/SUSARs

Are there any new collaborating sites that have been added or deleted since the last review? Please identify the sites and note the addition or deletion.	☐Yes	☐ No

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For IRB use:

Name of Reviewer:	Signature:	Date:

Assessment by the Primary Reviewer:

Questions:	Yes	No	Comments:
Do the risks to the study participants remain reasonable in relation to anticipated benefits?			
Are there new findings in the IB or literature (e.g., important toxicity or adverse event information) that need to be included in the informed consent?			
Is there need to revise the ICF?			
Is there need to re-consent subjects enrolled in the study?			
Are there concerns about conduct of the research team (e.g., suspension of medical license, frequent protocol violation, patient or third party complaints, etc.) or institutional commitment that may affect patient safety?			

Check the protocol file to ensure consistency of the progress report with actual reports (SAE, Protocol Deviation/Violation, etc.) submitted by the Principal Investigator.

Recommendations
- ☐ Approve
- ☐ Request further action. Specify.
- ☐ Request further information. Specify.

Type of review:
- ☐ Expedited review
- ☐ Full board review

Date of meeting:

Others comments:

Primary Reviewers:	**Signature:**	**Date:**