	Research Institute for Tropical Medicine Institutional Review Board	Form No.	3.3.
	APPLICATION FOR CONTINUING REVIEW	Version No.	5
		Approval Date	31 July 2023
		Effective Date	1 August 2023

INSTRUCTIONS TO INVESTIGATORS: Please submit the accomplished form together with the related documents via email to irb@ritm.gov.ph. Also, please submit 1 hard copy of the documents arranged according to the sequence listed in item 10, fastened in an A4 size folder to the IRB Secretariat at Room 205 of the Residence Hall. Kindly **FILL OUT THE NECESSARY INFORMATION AT THE FOOTER.**

1. RESEARCH IDENTIFICATION

- 1.1. IRB Number Click or tap here to enter text.

- 1.2. Title of Protocol

- 1.3. Name and Signature of Principal Investigator

- 1.4. Sponsor

- Click or tap to enter a date.
- 1.5. Date of Expiry of Approval

- (mm/dd/yyyy)

2 CURRENT STATUS OF THE RESEARCH

2.1. Did the study commence?

Yes **(Continue with the rest of the form)**

Date of Commencement: Click or tap to enter a date.

No, reason: _____

Date when research is expected to commence Click or tap to enter a date.
(mm-yyyy)


(If the study did not commence, please proceed to Section 5)

2.2. What is its current status? (Check all that applies)

Recruitment of subjects ongoing or data collection ongoing

Enrolment complete


Follow-up ongoing

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Data collection complete, data analysis only

3. PROGRESS SUMMARY STATISTICS

3.1.	FOR NON-CLINICAL TRIALS	Sample size	% Completed	Data Collection Completed?
	Data Collection Procedures			
3.1.1.	Chart review			<input type="checkbox"/> No <input type="checkbox"/> Yes
3.1.2.	Individual interviews , survey interviews			<input type="checkbox"/> No <input type="checkbox"/> Yes
3.1.3.	Focus Group Discussions			<input type="checkbox"/> No <input type="checkbox"/> Yes
3.1.4.	Physical examination and assessment			<input type="checkbox"/> No <input type="checkbox"/> Yes
3.1.5.	Other procedures, specify :			<input type="checkbox"/> No <input type="checkbox"/> Yes
3.1.6.	Other procedures, specify :			
GO TO ITEM 4				
3.2.	FOR CLINICAL TRIALS			
3.2.1.	Enrolment			
	Sample size approved by the IRB			
	Number enrolled since the last approval			
	Enrolment complete?			<input type="checkbox"/> No <input type="checkbox"/> Yes
	For unmet or exceeded enrolled subjects, please provide explanation			
3.2.2.	Administration of Intervention			
	Total number of enrolled participants who received complete intervention (Complete intervention means received the complete number of doses of the study product)			

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	% of enrolled participants who received complete intervention	
	Administration of intervention to enrolled participants complete?	<input type="checkbox"/> No <input type="checkbox"/> Yes
3.2.3.	Follow-up of Participants	
	Total number of participants who received the complete intervention and followed-up	
	% of total participants who received the complete intervention and completed follow-up	
	Follow-up of all participants who received complete intervention complete?	<input type="checkbox"/> No <input type="checkbox"/> Yes
3.2.4.	Withdrawals	
	Total number of participants who withdrew/were withdrawn from the study	
	% of enrolled participants who withdrew/were withdrawn from the study	
	Attach the list of participants who withdrew/were withdrawn and reasons for withdrawal	
3.2.5.	Serious Adverse Events (SAEs)	
	Total number of SAEs reported since the last approval	
	% of SAEs related to the intervention	
	% of SAEs that resulted to permanent disability	
	% of SAEs that resulted to death	
	Total number of SAEs related to the intervention resolved at reporting period	
3.2.6.	Suspected Unexpected Serious Adverse Events (SUSAR)	
	Total number of SUSARs reported in ALL study sites	
	Total number of SUSARs reported in investigator's study site/s	
3.2.7.	Site Inspection/Audit	
	Has the site been inspected or audited by P-FDA or US FDA or other regulatory agencies?	<input type="checkbox"/> No <input type="checkbox"/> Yes
3.2.8.	IDMC Meetings	
	Submit the decision of the IDMC in the meetings conducted since the last approval	
4	Protocol Violations/Deviations	
4.1.	Total number of protocol violations/deviations since the last approval	

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4.2.	Submit a list of the protocol violations/deviations and the nature of these violations/deviations	
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5 HISTORY OF AMENDMENTS TO THE RESEARCH

5.1. Has there been any amendment to the protocol since the last approval? Yes No NAP

If Yes, provide the date of Approval of Amendment.

5.2. Has there been any amendment to the informed consent documents since the last approval? Yes No NAP

If Yes, provide the date of Approval of Amendment.

5.3. Has any new investigators been added or deleted since the last approval? Yes No NAP

If Yes, provide the date of Approval of Amendment

5.4. Has any new study site been added since the last approval? Yes No NAP


If Yes, provide the date of Approval of Amendment

6 NEW AND OTHER INFORMATION

6.1. Has any new information appeared in recent literature, OR has evolved from your research or from other research sites, or comments to the research topic you are doing which may affect the participant's willingness to continue to participate in your research? Yes No NAP

IF YES, PLEASE PROVIDE THE IRB WITH A COPY OF THIS INFORMATION OR JOURNAL PUBLICATION.

6.2. Has there been any complaints about the conduct of the research you are doing from among the participants? Yes No NAP

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If Yes, include in the narrative report.

- 6.3. Has there been any complaints about the conduct of the research in the community where you are doing it ?
- Yes No NAP

If Yes, include in the narrative report.

- 6.4. Has there been any complaints from your research collaborators ?
- Yes No NAP

If Yes, include in the narrative report.

- 6.5. Are there any concerns in the implementation of your research activity, e.g. funding, supplies, etc.
- Yes No NAP

IF Yes, include in the narrative report.

7. Investigators' Availability to Continue to Conduct the Study

7.1. How many researches are you currently doing ?

7.2. How many of these are in their recruitment and enrolment phase ?

8 CONFLICT OF INTEREST

- 8.1. Are there changes in your conflict of interest declaration or those of other members of the research staff?
- Yes No

If Yes, how do you propose to manage it?


9. OTHER REQUESTS

9.1. Are you requesting for approval of amendments together with this application?

IF YES, FILL OUT RITM-IRB FORM 3.1. AND SUBMIT THE APPLICATION AND DOCUMENTS REQUIRED IN A SEPARATE FOLDER.

10. DOCUMENTARY REQUIREMENTS

The following **MUST** be included with this application:

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- Narrative Progress Report, to include (1) other information about the progress of your research activity which may not be included in this form, (2) summary of preliminary findings if applicable, (3) a summary of findings from recent literature or relevant information, especially about risks associated with the use of the product and (4) plans for the next year.

For protocols which was not renewed prior to expiration of the approval, indicate the following in a separate document: (1) reason/s for non-renewal prior to expiration (2) study activities that continued despite IRB expired approval


- Line listing on reasons for withdrawals by participants, if applicable
- Copy of information or journal article on new information which contains new information which may be related to the study, if applicable
- Documentation of any complaints received about the conduct of the study, if applicable
- Summary report of all SAEs experienced by the participants since the start of the study, if applicable
- Summary report of all protocol deviations/ violations since the last approval, if applicable
- Letter of recommendations from the data safety monitoring board or independent data monitoring committee, if applicable.

10.1. Other Documents Which MUST be Submitted

- If enrolment in the study is still continuing**, submit last approved version of the information sheets used to obtain consent, parental consent, assent in both English and in the dialect, for stamping of current approval.
- Submit all other documents which will still be used, for approval.
- Updated Disclosure of Conflict of Interest (COI) form of all research staff.
- IF CLINICAL TRIAL:** the PRC license and most recent GCP certificate of Principal investigator, Co-investigators and Sub-investigators.

11. Action Requested by Investigator

- Renewal of approval for continuation of the study, e.g. recruitment, enrolment

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- Renewal of approval for purposes of participant follow-up
- Renewal of approval for data analyses and report writing

DO NOT FILL OUT THE SECTION BELOW THE LINE

- 12. Date of Receipt of Application** Click or tap to enter a date.
 (e.g. month is Jan, Feb, etc.) (mm/dd/yyyy)
-
- 13. Time Received :**
-
- 14. Received by :**
-

15. Type of Review the Application Will Undergo

Type of Review :		Check those which apply
<input type="checkbox"/>	For expedited review (protocol was initially reviewed in an expedited manner)	
<input type="checkbox"/>	For full review (protocol was initially reviewed thru full review manner)	

16. Reviewers of Application

	Type of Review	Reviewers		
		IRB Chair	Medical/Scientist	Lay Reviewer
	Expedited Review			
	Full Review			

Signature over Printed Name of IRB Chair Date of Signing