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SAMAREC STUDY CLOSURE FORM, July 2026, V2

This form is intended to accompany the final summary of study results and should be submitted once the study has been completed and final results are available for reporting to SAMAREC. It should be submitted by the Principal Investigator upon completion/closure of the project and submission of the final report, or upon cancellation of the project. This should be accompanied by a Progress Report, the monitor's report, Data Safety and Monitoring Board (DSMB) report (where applicable), and summary of the study results and an outline of the dissemination of these results.

Please note: Once a Project Closure Form has been completed, no further data may be collected from any of the subjects in the study. Even if new enrolment of subjects has ended, projects must remain open if the follow-up of subjects will continue.

Date: _____ Name of PI: _____ Protocol ID: _____

Protocol Title: _____

Total Duration of the Study (mm-yy to mm-yy): _____

Date of last Research Ethics Committee (REC) continuing review (if applicable): _____

Date of Closure of project: _____

Reason for closure:

- ☐ Project never initiated (no human subjects were recruited)
- ☐ Project cancelled. Please specify reason:
- ☐ Project completed, **as approved by REC**.

If not, please explain why: _____

_____

Do you verify that informed consent was obtained for all subjects and that all signed consent forms are on file?
Yes ☐ No ☐

Was the consent process changed from that reported to the REC? Yes ☐ No ☐

If Yes, please explain: _____

_____

Please explain any adverse events/reactions occur with this project that need to be reported to REC:

Please fill out the following checklist for the period from the last review (this is also the "Period under review") of this protocol.

1. Total expected number of participants to be recruited during the entire study period. (Total number of participants who were expected to be recruited during the entire study period).			
2. Total number of participants actually recruited during the entire study period.			
3. Number of participants recruited since last review.			
4. Number of participants who withdrew, were not available or were excluded after initial enrolment during the entire study period.			
5. Who provided oversight to this project?			
6. How many monitoring visits have taken place since the last approval(last annual renewal or last approved document)?			
	Yes	No	N/A
7. Is a Progress Report for the period under review attached?	☐	☐	☐
8. Is a comprehensive report from the Monitor (where applicable), for the Period Under Review, attached?	☐	☐	☐
9. Were all the issues raised during the monitoring visits addressed to the satisfaction of the sponsors?	☐	☐	☐
10. Was a DSMB convened?	☐	☐	☐
11. Are the findings and recommendations from the DSMB meeting attached?	☐	☐	☐
12. Were the DSMB recommendations incorporated into the research protocol used in the Period Under Review?	☐	☐	☐
Give details here:			
13. Have there been any changes in the research protocol since the last approval period (last annual renewal or last approved document)?	☐	☐	☐
If Yes, give details here:			
14. Had this change been communicated to REC and been approved?	☐	☐	☐

If Yes, give details here:			
15. Have the consent documents been revised?	☐	☐	☐
If Yes, give details here:			
16. Were the revised consent documents approved by REC?	☐	☐	☐
17. Did the participants suffer from some unforeseen problems or outcomes in the period under review? This could include physical, psychological or emotional harm. Were there any problems encountered during the consenting process. Were there any unanticipated adverse events?	☐	☐	☐
If Yes, give details here:			
18. Was the REC previously informed of these unforeseen problems or outcomes?	☐	☐	☐
19. Did any new findings, knowledge, or adverse effects come to light that should have been communicated to research participants?	☐	☐	☐
If yes, give details here:			
20. Were these changes communicated to the research participants?	☐	☐	☐
If Yes, then explain how these have been communicated:			
21. Were there any revisions to the project made since last approval (last annual renewal or last approved document) that were not previously approved by REC?	☐	☐	☐

22. If you have ticked Yes, then summarize the changes, with reasons provided for making those changes.

**Adapted from the [World Health Organization Research Ethic Committee (WHO REC) Project Closure Form for Principal Investigator]*