



NATIONAL HEALTH RESEARCH AND TRAINING INSTITUTE
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CLOSEOUT REPORT FORM (CLINICAL TRIALS)

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CLOSEOUT REPORT FORM (CLINICAL TRIALS)

Page **2** of **7**



Complete this form following completion of study activities at a study site. All research activities related to this protocol must have been completed, including participant enrolment, participant follow-up, and work with identifiable information related to the study participants, including medical or research records and data analysis utilizing identifiable data collected from study participants.

1. SITE INFORMATION

Protocol Title:	
Protocol Identification number:	
Protocol version number & date:	
ZAMRA Clinical trial Certificate number: Date of approval:	
NBA permit number: Date of approval:	
NHRA reference number: Date of approval:	
HREC reference number: Date of approval:	
Sponsor details:	<i>Name:</i>
	<i>Physical Address:</i>
	<i>E-mail address:</i>
	<i>Telephone number:</i>
Principal Investigator:	<i>Name:</i>
	<i>Physical Address:</i>
	<i>E-mail address:</i>

**CLOSEOUT REPORT FORM (CLINICAL TRIALS)**

	<i>Telephone number:</i>
Name and address of clinical site(s):	
Date of last participant's visit:	
Reason for closure (Termination or end of study)	
Trial start and completion dates:	<i>Start:</i>
	<i>Completion:</i>
Clinical Site Personnel Involved with the Study: (attach delegation log)	

II. CLINICAL SITE CLOSE-OUT CHECKLIST

Please provide comment(s) for each of the items listed below. Additional sheets may be attached if necessary.

OBJECTIVE	COMMENTS
1. All regulatory and other essential records are up-to-date and on file. Refer to Guidelines for the Conduct of Clinical Trials)	<i>Provide a list of documents on file at the site</i>
2. Notification of all relevant oversight bodies of the closure of the study	☐ HRECs ☐ NHRA ☐ ZAMRA ☐ NBA
3. Signed, informed consent is on file for each study participant	<i>Provide a list of participants (use codes/ study IDs)</i>



4. Documentation of all protocol violations/ deviations and/ or appropriate “note-to- file” in the relevant essential document file	<i>Provide list</i>
5. Appropriate follow-up and reporting of all SAEs to relevant oversight bodies (checklist) ☐ HRECs ☐ NHRA ☐ ZAMRA ☐ NBA	<i>Provide the number of SAEs reported. Summary of outcome for SAEs listed is relevant</i>
6. Completion of all Case Report forms for each participant	☐ No ☐ Yes
7. Entry/ submission of all relevant data into the database/ to the sponsor/ coordination centre. If not complete, indicate the timeline for accomplishing this and document in the comments section	
8. Status of all outstanding data edits, queries and timeline for their resolution:	☐ Incomplete ☐ Complete <i>If not complete, explain the plan for completion</i>
9. Tentative date for submission of full Clinical Study Report	
10. Requirements for retention of study records as per institutional guidelines. Indicate how each requirement will be fulfilled	☐ NHRA Explain how: ☐ ZAMRA Explain how: ☐ NBA



	Explain how: ☐ HRECs Explain how
11. Investigational product (IP) accountability	<i>Indicate quantity in units</i> Quantity of IPs received: Quantity of IPs utilized in the study: Quantity of IPs disposed of (attach copy of disposal certificate (s) or other supporting documents: Quantity of IPs onsite/ returned to sponsor:
12. Status/ shipment/ analyses of all participant specimens according to protocol requirements (including plans for future shipments or period of time they will be stored on- site)	
13. If a blinded study IP was used, confirm that the tear-off labels were not opened. For any that were opened, documentation should be obtained, noting the reason for unblinding	

III. STATUS OF PAST OBSERVATIONS/ RECOMMENDATIONS MADE DURING MONITORING/ GCP INSPECTIONS: (Have corrective measures been implemented for all observations and recommendations?), Provide summary of measures implemented for each point)

IV. OUTSTANDING ISSUES OR ACTIVITIES TO BE IMPLEMENTED: (Include problems identified, if any, and recommendations/ action items for corrections)

Prepared by:..... Date:



Document No.: REC/GUD/002

CLOSEOUT REPORT FORM (CLINICAL TRIALS)

Page **7** of **7**

Signature: