PROTOCOL VIOLATION/DEVIATION REPORTING FORM

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PROTOCOL VIOLATION/DEVIATION REPORTING FORM

This form should be completed for all research and submitted to HRECs and NHRA. The form shall be submitted to ZAMRA (and NBA, where applicable) for Clinical trials involving investigational medicines and allied substances (or genetically modified organisms). All protocol violations and deviations shall be reported *within 10 working days of site awareness.*

This form must be completed and submitted as follows:

— Major Deviations/Violations (affecting participant safety, rights, data integrity, or representing serious/continuing noncompliance): Submit to ZAMRA, NHRA, NBA, relevant REC, and Sponsor within 72 hours of site awareness, or as stipulated by each institution's guidelines (whichever is shorter).

— Deviations implemented to eliminate immediate hazards to participants: May be implemented without prior IRB/REC approval but must be reported within 24 hours of occurrence (ICH E6(R3), Section 2.5.4).

— Minor Deviations/Violations: Submit with the next biannual progress report, or per institutional requirements. This form must be completed and submitted to NBA, NHRA, RECs or ZAMRA as stipulated in the guidelines of each institution.

ZAMRA Clinical trial Certificate number: Date of approval:			
NHRTI reference number: Date of approval:			
REC reference number: Date of approval:			
NBA permit number: Date of approval:			
PACTR / ClinicalTrials.gov / Other Registry Number:			
Principal Investigator:	Name: Address: E-mail:		Phone: Mobile:
Study Title:			
Location of Deviation/Violation:	Date of Occurrence:	Participant ID.:	Date of Site Awareness:
Classification: ☐ Protocol Deviation (Any unplanned departure from the IRB/REC-approved protocol.) ☐ Protocol Violation (A deviation that affects participant safety, rights, or well-being; compromises data integrity; or represents serious or continuing noncompliance with GCP or regulatory requirements).			
Type of Deviation/ Violation	☐ Eligibility Criteria ☐ Consent ☐ Study Procedures or Assessments ☐ Intervention-Related ☐ Drug-Related ☐ Device-Related ☐ Staff (Delegation, Training) ☐ Participant non compliance ☐ Deviation to eliminate immediate hazard to participant (ICH E6(R3), Section 2.5.4) — implemented without prior approval *If this deviation was implemented to eliminate an immediate*		

	hazard:		
	— Describe the immediate hazard: _____ *— Date and time deviation was implemented: //_____Time: _____* *— Was the IRB/REC notified after the fact? ☐ Yes (date: ___) ☐ No* *— Was the Sponsor notified? ☐ Yes (date: ___) ☐ No* *— Was ZAMRA notified? ☐ Yes (date: ___) ☐ No* ☐ Other, specify: _____		
Please describe the Deviation / Violation			
Major Deviation / Violation	Did deviation/violation harm or pose a risk of harm to the participant's rights, safety or well-being?	☐Yes ☐No	*Any **Yes** indicates a Major Deviation/Violation* *Any **Yes** requires prompt reporting to the ZAMRA, NHRTI, NBA & RECs.*
	Did deviation/violation significantly damage the overall reliability of the study data?	☐Yes ☐No	
	Does deviation/violation represent noncompliance with requirements for *ZAMRA, NHRTI, NBA & RECs,* that may be serious or continuing?	☐Yes ☐No	
Minor Deviation / Violation	Does the deviation/violation NOT have a major impact on the participant's rights, safety, or well-being?	☐Yes ☐No	*Any **Yes** indicates a Minor Deviation/Violation to be reported to ZAMRA, NHRTI, NBA & RECs.*
	Does the deviation/violation NOT have a major impact on the reliability of the overall study data?	☐Yes ☐No	
Describe the impact of the deviation/violation on risk/benefit ratio			

Describe the impact of error on data integrity	

Describe the impact of error on willingness to continue in the study		
Explain the reasons for deviation/ violation		
Describe any steps taken to address this deviation/violation		
Describe what corrective actions you have taken to prevent recurrence		
Were the following notified?	NHRTI ☐ No ☐ Yes Date of Notification: ZAMRA ☐ No ☐ Yes Date of Notification: NBA ☐ No ☐ Yes Date of Notification: RECs ☐ No ☐ Yes Date of Notification:	SPONSOR ☐No ☐ Yes Date of Notification:
Additional comments		
Report prepared by:		Phone: Email:

_____	.....
Signature	Date