



CLINICAL TRIAL AMENDMENT FORM

MCA-F-501/08

MEDICINES CONTROL AGENCY

54 Kairaba Avenue, K.S.M.D. Pipeline, The Gambia. Telephone: (+220) 4380632, P.O. Box 3162, website: www.mca.gm

Date of Amendment		Current Protocol version/Date		Protocol Number	
Sponsor			Principal Investigator		
Title of Trial or Acronym					
MCA CT Number		PACTR No			
Amendment no.		Amended Protocol Version/Date			

Other revisions required

- Information Sheet Yes No Not applicable
- Consent form Yes No Not applicable
- Statistical Analysis Plan Yes No Not applicable
- Other Yes No Not applicable *If yes specify.*
-

Amendment Rationale:

.....

Proposed Changes

SECTION (PAGE) <i>Current section and page being changed</i>	CURRENT <i>Text currently in use in protocol</i>	PROPOSED CHANGE <i>Text amended</i>	SUMMARY OF CHANGE <i>Change summarised</i>	JUSTIFICATION <i>State specific reason for the change or refer to rationale</i>

Amendment incorporates administrative changes and typo errors along with the substantial changes

Name:

Role:

Signature:

Date: