In case of reply the number
And the date of this
Letter should be quoted

My Ref. No.....
Your Ref. No.....

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FORM D – Serious Adverse Event (Sae) Report Form

Instructions:

1. Please complete all sections and submit 1 hardcopy to the KBTH-IRB Office
2. Send a soft copy to rdo@kbth.gov.gh to facilitate the review process.
3. Use very clear font size such as Times New Roman 12pt, Arial 11 pt, Calibri 12pt.

Section A – Background Information			
Study title			
REC/IRB		Protocol no.	
Study start date		Anticipated end date	
Maximum number of subjects/samples/records planned (local)			

Section B – Study Site(S) Involved

☐ Overseas site(s) (Submit report(s) from sponsor and omit section 3-5)

☐ Local site(s) Name of study site:

Section C – Subject Outcome At Time Of Report

☐ Complete recovery ☐ Recovery with sequelae ☐ Events not yet resolved

☐ Unknown ☐ Death; cause:

Section D – Serious Adverse Event

Subject reference: Code Initials Age Sex

i. Relevant medical history & current treatments:

ii. Nature of SAE:

(Describe temporal relationship with intervention & other concomitant therapies)

SAE start date ____ SAE stop date ____ /not resolved*

Type of SAE ☐ initial ☐ follow up

Frequency ☐ One episode ☐ Intermittent ☐ Continuous

Seriousness

☐ Death
☐ Life threatening
☐ Significant disability/incapacity
☐ Required hospitalisation
☐ Persistent disability/incapacity
☐ Prolonged hospitalisation
☐ Congenital anomaly/birth defect
☐ None of the above
☐ Other medically important condition

Section E – Suspected Relationship To Study

☐ Definite ☐ Probable ☐ Possible ☐ Not related ☐ Not assessable

Section F – Remedial Actions

On the affected subject:

☐ None
☐ Adjusted dosage
☐ Interrupted temporarily
☐ Discontinued/ terminated study

For all subjects/ study design:

Section G – Signature

Report by

Name	Signature	Date