GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE
SERIOUS ADVERSE EVENTS SUBMISSION FORM

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SERIOUS ADVERSE EVENTS SUBMISSION REQUIREMENTS

An adverse event is any event, related to the research study, which in the opinion of the investigator might affect the rights, wellbeing or safety of the research participant. Serious adverse events include, death, a life threatening experience, hospitalization (21 CFR 312.32)

All adverse events, which fit the following criteria, must be reported to the ERC within **3** (**72 hours**) working days from the time the investigator becomes aware of the event.
□□Event is **SERIOUS** (i.e., death, a life-threatening adverse experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect [21 CFR 312.32(a)]), **AND**
□□Event is **UNANTICIPATED** (An unanticipated event is any adverse experience where the nature, severity or frequency is not identified in the investigator brochure or described in the protocol. Events which are already cited in the investigator brochure or protocol are not unanticipated and do not have to be reported to ERC), **AND**
□□Event is **RELATED** to the study design, procedures, or drug/device (possibly, probably or definitely related, or unknown). If the adverse event is clearly not related to the study drug, device, procedures, or washout process, it would not represent a risk to other subjects in the research and, therefore, does not have to be reported to GHS-ERC.

This form should be submitted to:
The ERC Administrator
Research & Development Division

Ghana Health Service

P. O. Box MB 190

Accra.

Date Received

ADVERSE EVENT SUBMISSION FORM

1. Project Title
2. ERC Approval Number
3. Principal Investigator
4. Subject ID
5. Subject sex (tick) □Male □Female
6. Date of report (dd/mm/yy)
7. Status of Report □Initial □Follow-up
8. Serious Adverse Events Description/Treatment/Outcome

□First dose (dd/mm/yy)
() Serious Adverse Events Onset (dd/mm/yy)
9. Seriousness of event (Circle all that apply)
□Death □Life threatening □Hospitalization □Disability □Other (specify)_____
10. Event related to the study?
□Definitely Related □ □Possibly □Probably □Not related □Unknown
11. Action taken
□Resolved (How?)
□Ongoing (specify)
12. Is a DSMB advising the PI/study team?
□Yes (if yes attach the DSMB report) □ No
13. Do you recommend any changes to the protocol?

□Yes (if yes attach a protocol)	□No
Signature of reporting officer	Date

Please do not fill below this line (For ERC use only)

Reviewed By:
Date reviewed:
Comments:
ERC's comment sent out:

[1] **Updated Version 3 dated October 23, 2018 - Property of GHS-ERC Secretariat only**