

**Navrongo Health Research Centre**

**Institutional Review Board (NHRCIRB)**

Research & Development Division

Ghana Health Service

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17 September 2024

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*My Ref*…………………………......

*Your Ref*……………………………

**SERIOUS ADVERSE EVENTS SUBMISSION REQUIREMENTS**

**A Serious Adverse Event (SAE): An event that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect [21 CFR 312.32(a)**

**All SAEs must be reported to the NHRCIRB within 48 hours of the investigator becoming aware of the event.**

**Please complete this form in addition to a Serious Adverse Event form that conforms to the CIOMS format.**

**The completed forms should be submitted to (via email):**

**The Administrator**

**Navrongo Health Research Centre Institutional Review Board**

**P.O. Box 114**

**Navrongo-Ghana**

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| **PLEASE COMPLETE THIS FORM ELECTRONICALLY BEFORE PRINTING IT OUT** |

|  |  |
| --- | --- |
| 1. Project Title
 |  |
| 1. IRB Approval Number
 |  |
| 1. Name of Principal Investigator
 |  |
| 1. Subject ID
 |  |
| 1. Gender (tick)
 |  Male Female |
| 1. Date of report
 |  |
| 1. Status of Report
 |  Initial Follow-up |
| 1. Event related to the study?
 |  Definitely Related Possibly Probably Not related Unknown |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of reporting officer Date (dd/mmm/yyyy) |

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

|  |
| --- |
| Reviewed By:  |
| Date reviewed: |
| Comments: |
| Board’s comment sent out:  |