

**Navrongo Health Research Centre**

**Institutional Review Board (NHRCIRB)**

Research & Development Division

Ghana Health Service

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*My Ref*………………………….......

*Your Ref*……………………………

**PROTOCOL AMENDMENT SUBMISSION REQUIREMENTS**

**Requests for protocol amendment or modifications to consent forms should include the following:**

1. A cover letter from the investigator and addressed to the Chairperson of the NHRCIRB
2. A summary of the initial protocol
3. Completed protocol amendment form (forms are available at the NHRCIRB Secretariat)
4. Summary of the request (investigators must justify why the change is necessary)
5. Copies of the revised documents should be tracked to indicate the amendments
6. Clean copies of the revised documents should also be enclosed as part of the submission
7. All revised consent forms should be submitted with their translations into the dominant local languages of the study area and back translated into English
8. Revised documents should be version controlled

***Note: The Navrongo Health Research Centre Institutional Review Board meets every second Saturday of every other month.***

**Submit the Application to (via email):**

**The Administrator**

**Navrongo Health Research Centre Institutional Review Board**

**P.O. Box 114**

**Navrongo-Ghana**

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

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| **PROTOCOL AMENDMENT FORM** | |
| 1. Project Title |  |
| 1. NHRCIRB Approval No. |  |
| 1. Protocol version no. & date |  |
| 1. Principal Investigator (PI) |  |
| 1. Address of PI |  |
| 1. Type of Amendment (circle all that apply) | 1. Protocol amendment 2. Modifications to consent form 3. Other (specify): ……………………… |
| 1. Summary of request |  |

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Person completing this form  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Contact Address  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Email  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Phone  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date (dd/mmm/yyyy) |

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

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| Reviewed By: |
| Date reviewed: |
| Comments: |
| Action: |