

**Navrongo Health Research Centre**

**Institutional Review Board (NHRCIRB)**

Research & Development Division

Ghana Health Service

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15 April 2024

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*My Ref*………………………….......

*Your Ref*……………………………

**CONTINUING REVIEW SUBMISSION REQUIREMENTS**

As stated in the Standard Operating Procedure of Navrongo Health Research Centre IRB, a continuing review shall be conducted on all research protocols submitted to the Board. In the initial approval letter of the Board, it shall be stated when investigators are expected to submit progress reports to the Board. The progress report submission shall include copies of the following documents:

* A cover letter from the investigator and addressed to the Chairperson of the NHRCIRB
* Completed Continuing Review form (this form is available at the NHRCIRB secretariat)
* A summary of the protocol
* Copies of any changes/ amendments made to the protocol/consent forms since the last approval
* A status report on the progress of the research that includes any new information on the research that could alter the Board’s previous determinations with respect to risks to subjects or regarding any unanticipated problems involving risks on the study

Progress reports not received by the submission date risk a lapse in the Board’s approval.  This means that all research must stop after the project expiration date, however all safety follow-ups of participants shall continue

*Note: The Navrongo Health Research Centre Institutional Review Board meets every third 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**

**A. Principal Investigator**

|  |  |
| --- | --- |
| Name:  |  |
| Address: |  |
| E-mail address: |  |
| Phone number:  |  |

**B. Protocol Information**

|  |  |
| --- | --- |
| 1. Title of protocol:
 |  |
| 1. Protocol number:
 |  |
| 1. **Protocol version number & Date**
 |  |
| 1. Funding agency and grant number:
 |  |
| 1. Please indicate grant status: active/pending
 |  |
| 1. Location of research activity:
 |  |
| 1. \*Ethics approval dates from additional institutions if applicable:

*\*Please note that copies of current IRB approvals from additional institutions are required.* |  |

**C. Study Status**

|  |  |
| --- | --- |
| 1. Pending:

 If yes, please indicate the reason why the study has not yet begun: | Yes/No |
| 1. Active:

If yes, please indicate the month and year the study began: Please indicate remaining duration of the study: | Yes/No(mmm/yyyy) |
| 1. Closed:

If yes, please indicate date the study closed:*Please note that if the study is closed, a Request for File Closure must be submitted to the NHRC IRB.* | Yes/No |

**D. Participant Information:**

|  |  |
| --- | --- |
| 1. Is the study closed to enrollment?
 | Yes/No |
| 1. Total number of participants who consented for the study
 |  |
| 1. Number of participants enrolled since study begun
 |  |
| 1. Number of participants who have discontinued the study;
 | a. by investigator: \_\_\_\_\_\_\_\_\_b. voluntarily: \_\_\_\_\_\_\_\_\_c. due to SAE: \_\_\_\_\_\_\_\_\_d. lost to follow-up: \_\_\_\_\_\_\_\_\_e. other (specify): \_\_\_\_\_\_\_\_\_ |
| 1. Number of participants still to be enrolled
 |  |
| 1. Number of participants scheduled for follow-up
 |  |

**E. Data Sources**

|  |  |
| --- | --- |
| Check all categories that apply to your protocol: |  |
|  | Human subject intervention with use of informed consent form |
|  | Genetic analysis |
|  | Interviews, questionnaires, tests |
|  | Medical records or other human data |
|  | Other *please specify***:**  |

**F. Adverse Events or Unexpected Problems**

|  |  |
| --- | --- |
| 1. Has there been any ***adverse event(s)*** or unexpected problem(s) since the last approval?

If yes, please explain in detail and indicate when the NHRCIRB was notified of the event or problem. If the NHRCIRB was not notified, please explain why this was not done.  | Yes/No |
|  |
| 1. Does the study have a Data Safety Monitoring Board (DSMB)?

If yes, please indicate the date of the last DSMB review:*Please note that investigators are required to submit DSMB reports to the NHRCIRB at the time they are made available to the investigator.* | Yes/NoN/A |
|  |
|  |

**G. Protocol Amendments or Revisions**

|  |  |
| --- | --- |
| 1. Has there been any amendment(s) or revision(s) to the protocol?

If yes, please indicate the date of the approval from the NHRCIRB for the amendment or revision*.* | Yes/No |
|  |
| 1. Do you wish to submit an amendment at this time?

If yes, please describe the amendment request and rationale for the changes | Yes/No |
|  |
| 1. Are there new personnel working on this study?

If yes, please list new personnel   | Yes/No |

**H. Current Consent Form**

|  |
| --- |
| 1. Please attach a copy of your current consent form for renewal.
2. Is this the original consent form or a revised form? Original Revised

If revised, please provide date of NHRCIRB approval for the revision: |

**I. Protocol Progress Report**

|  |
| --- |
| **1.** Please submit a ***detailed*** progress report. The progress report must be substantive and complete, and include the goal(s) of the study, up-to-date findings, and plans for the next year/review  |

**J. Publications, Presentations and Recent Findings**

|  |
| --- |
| **a)** Has there been any presentation(s) or publication(s) resulting from this study since the last approval? Yes/noIf yes, please submit a copy of the abstract or the publication with this application. **b)** Has there been any recent finding(s) either from this study or a related study, that would have an effect on this study’s risk/benefit analysis? yes/noIf yes, please describe and cite references: |

|  |
| --- |
| **Additional Comments:** |

 **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature of Principal InvestigatorDate (dd/mmm/yyyy)

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

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