

**Navrongo Health Research Centre**

**Institutional Review Board (NHRCIRB)**

Research & Development Division

Ghana Health Service

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*My Ref*………………………….......

*Your Ref*……………………………

**NEW PROTOCOL SUBMISSION REQUIREMENTS**

A new protocol must be submitted to the NHRCIRB at least two months before the proposed commencement date of the research and must include copies of the following:

1. Protocol Application form (this form is available at the NHRCIRB office)
2. Cover letter from the Head of the institution an investigator is applying from. If the applicant is a student, the cover letter must come from the head of department/faculty or lead-supervisor.
3. Summary of protocol
4. Full Protocol (insert version number with an effective date)
5. Consent forms (PIs could submit a previously approved consent form). Final English versions of more than minimal risk studies should be translated into the dominant local language(s) of the study area and back translated into English and submitted for review).
6. Field guide i.e. questionnaire, enrolment forms, Case Report Forms (Insert Version number with an effective date)
7. Current Curriculum Vitae of all investigator(s). **CV must not be more than six months since last updated.**

**NB: CVs must be a maximum of 3 pages, signed and dated.**

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

**All new protocol applications should be submitted electronically.**

**The e-copy of the application should be submitted via the NHRCIRB email account to:**

**The Administrator**

**Navrongo Health Research Centre Institutional Review Board**

**P.O. Box 114**

**Navrongo-Ghana**

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

**(BOLD ANSWERS WHERE OPTIONS ARE REQUIRED)**

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| **NEW PROTOCOL SUBMISSION FORM** | |
| 1. Project Title |  |
| 1. **Protocol version No. and Date (Final version according to investigator and date of revision)** |  |
| 1. Proposed Date of commencement of data collection |  |
| 1. Name of Principal Investigator (PI) |  |
| 1. Address of PI   (include email and telephone number) |  |
| 1. (a) Co-Investigator(s)   (b) Student Investigator  (If student Investigator, indicate status and level of involvement in Research) | Status  Undergraduate Masters level Doctoral Level  Level of involvement  Thesis Dissertation Assisting faculty Other |
| 1. Collaborating institution (if applicable) |  |
| 1. Proposed Project Duration   (from data collection to final submission) | From: \_ \_ / \_ \_ \_ / \_ \_ \_ \_ to \_ \_ /\_ \_ \_ / \_ \_ \_ \_  (dd/mmm/yyyy) (dd/mmm/yyyy) |
| 1. Are other IRBs involved in the review of this protocol? | Yes/No  If yes, name of IRB\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Status. Under review Approved Disapproved |
| 1. Funding Status of protocol? | Not Funded Funded |
| 1. Source of funding (name of funder(s)) |  |
| 1. Proposed Population   (Circle all that apply) | 1. Males 2. Females 3. Adolescents (12-17 yrs. of age) 4. Children (under 12 yrs. of age) 5. Pregnant women 6. Elderly 7. Prisoners 8. Other (specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. Proposed sample size    1. Number of Children:    2. Male   c. Female |  |
| 1. Research Site (s) |  |
| 1. Should serious events or emergencies occur during the conduct of the research what will you do? What facilities are available to deal with such incidents? |  |
| 1. Type of Study (Circle all that apply) | 1. Survey 2. Case control/Case study 3. Secondary data analysis 4. Clinical trial 5. Community based trial 6. Epidemiological 7. Oral history/biographical 8. Mental health 9. Longitudinal study 10. Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. Mark all research procedure(s) that will be employed | * 1. Record interview (interview schedule or guide must be attached)   2. Questionnaire (must be attached)   3. Physical Examination   4. Drug or other substance administration   5. X-rays   6. Biopsy   7. Isotope administration   8. Blood sampling: 1. Venous 2. Arteria   3. Others (Specify) \_\_\_\_\_\_\_\_\_\_\_ |
| 1. Consent Process (Circle all that apply) | 1. Written English 2. Oral English 3. Oral Local Dialect 4. Written Local Dialect 5. Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. Will you require the use of a translator or will you use documents translated into a language other than English?   If yes to using a translator, please describe how the translator will be utilized.  NB: If using translated documents, please provide a copy of the documentation in English and a copy in the translation. | * 1. No   2. Yes |
| 1. If the participants in your study are unable to consent for themselves, explain how you intend to obtain informed consent. How will adequate information be provided to those who will give consent on their behalf? |  |
| 1. If reimbursement or any other incentives will be provided to participants, please explain the nature of the reimbursement or incentives and provide a rationale for it. |  |
| 1. Does your research involve an entire community?   NB: If yes, please explain what measures you have taken to consult and engage with the community regarding your research work. | * 1. No   2. Yes |
| 1. In what form will you publish this research? | * 1. Thesis   2. Journal article / book / chapter   3. Report to organization   4. On-line web based   5. Oral presentation   6. Others: please specify…………………….. |
| 1. In what form will information about results of the research be communicated to participants, parents and guardians and/or community? | 1. Copy of journal article / book / chapter 2. Report to organization 3. On-line web based 4. Oral presentation 5. Results will not be communicated to participants and / or public 6. Other, please specify………….. |
| 1. Level of risk involved in this research.   Note: Minimal risk is defined as “a risk where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater in and of themselves than those ordinarily encountered in daily life. | 1. Greater than minimal risk 2. Minimal risk 3. No risk |
| Name of person completing the form: -------------------------------------------------------------------  Role on the study: ------------------------------------------------------------------------------------  Signature: --------------------------------------------------------  Date: \_ \_ /\_ \_ \_ / \_ \_ \_ \_ (dd/mmm/yyyy) | |

For all student projects:

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Student Investigator Date (dd/mmm/yyyy) \*Mentor’s Signature Date (dd/mmm/yyyy)

\**Please note that letter from mentor is also required.*

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

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