#

Office Use Only

Protocol Number:

# FORM A – INITIAL PROTOCOL SUBMISSION FORM

(For use by Students only)

**INSTRUCTIONS:**

1. Please complete all sections before it will be considered for ethics review.
2. Send a single pdf file of all documents to nirb@noguchi.ug.edu.gh to facilitate the review process. The soft copy should be signed and dated.
3. The proposal and the consent form should be paged separately.
4. Use very clear font size such as Times New Roman 11pt / 12pt, Arial 11 pt., Calibri 12pt.
5. Download the NMIMR-IRB Researchers Checklist for further instructions.

|  |
| --- |
| **SECTION A – BACKGROUND INFORMATION** |

|  |  |
| --- | --- |
| **Title of Study:** |  |
| **Name of Student** |
| 1. Full Name

*(Surname First)* |  |
| 1. Institution
 |  |
| 1. Faculty/Department/School
 |  |
| 1. Address
 |  |
| 1. Student Number
 |  |
| 1. Phone Number
 |  |
| 1. Email Address

(Please provide one email address) |  |
|  |  |
| **Supervisors** |  |
| 1. Name of Supervisor

*(Surname First, Title, Qualifications)* |  |
| 1. Institution/Faculty/Department/School
 |  |
| 1. Address
 |  |
| 1. Phone Number
 |  |
| 1. Email Address

(Please provide one email address) |  |
|  |
| 1. Name of Supervisor

*(Surname First, Title, Qualifications)* |  |
| 1. Institution/Faculty/Department/School
 |  |
| 1. Address
 |  |
| 1. Phone Number
 |  |
| 1. Email Address

(Please provide one email address) |  |
| *NB: Add on if you have more than two supervisors.* **Proposed Study Information** |
| 1. Type of Research/Study
 | [ ] Biomedical [ ] Social/Behavioural [ ]  Others (Please specify) |
| 1. Student Status
 | [ ]  Undergraduate [ ]  Masters [ ]  PhD |
| 1. Duration of Research/Study
 | Number of years:Study Start Date: End Date: |
| 1. Source(s) of Funding

*(Name, Address and Email)* |  |
| 1. Departmental Thesis Approval Letter and Introductory Letter from Head of Department

*(Attach Letter of Approval)* |  |
| 1. Prior IRB Review

 *(Name any other IRB this proposal has been submitted to and attach approval letter if applicable. In case of rejection, state reasons)* |  |
| 1. Collaborating Institutions

*(Attach Letter of Approval)*  |  |

|  |
| --- |
| **SECTION B – RESEARCH PROPOSAL OUTLINE** |

**ABSTRACT/EXECUTIVE SUMMARY**

(Not more than 250 words)

**BACKGROUND OR RATIONALE OF STUDY**

(This should include the aims and objectives, literature review; not more than 1500)

**METHODS**

(This should include the study site, population, study design, sampling, data collection, data analysis, inclusion and exclusion criteria)

**ETHICAL CONSIDERATIONS**

(Provide a description of the likely ethical issues and how it would be resolved. i.e. consent procedures, confidentiality, privacy, risks and benefits, etc.)

**EXPECTED OUTCOME/RESULTS**

**KEY REFERENCES**

**WORK PLAN**

**BUDGET AND BUDGET JUSTIFICATION**

**CONSENT FORM**

(Download the NMIMR-IRB Consent form Template for guidance)

**ASSENT FORM AND PARENTAL CONSENT FORM**

(Only applicable where children of ages 12 to 17 would be recruited as research participants)

**DATA COLLECTION INSTRUMENTS**

(i.e. Interview Guide, Questionnaire, etc.)

|  |
| --- |
| **SECTION C – SIGNATURES** |

I. As the **Student Investigator** on this project, my signature confirms that:

1. I will ensure that all procedures performed under the study will be conducted in accordance with all relevant policies and regulations that govern research involving human participants.
2. I understand that if there is any change from the project as originally approved I must submit an amendment to the NMIMR- IRB for review and approval prior to its implementation. Where I fail to do so, the amended aspect of the study is invalid.
3. I understand that I will report all serious adverse events associated with the study within seven days verbally and fourteen days in writing.
4. I understand that I will submit progress reports each year for review and renewal. Where I fail to do so, the NMIMR-IRB is mandated to terminate the study upon expiry.
5. I agree that I will submit a final report to the NMIMR-IRB at the end of the study.

|  |
| --- |
|  Name of Student :Signature of Student :Date: :  |

II. As the **Student Supervisor** on this project, my signature confirms that I have read the students work which has been reviewed and approved by the departmental review committee/ scientific and technical committee:

|  |
| --- |
|  Name of Supervisor:Signature of Supervisor: Date: |