Office Use Only
Protocol Number:

FORM A – INITIAL PROTOCOL SUBMISSION FORM

(For use by Non - NMIMR Researchers only)

INSTRUCTIONS:

1. Please complete all sections before it will be considered for ethics review. Submit 9 hardcopies of the proposal and all supporting documents (i.e. consent form, data collection instruments, letters, CV, etc.) to the NMIMR-IRB Office. In addition, send a soft copy of all documents to nirb@noguchi.ug.edu.gh to facilitate the review process.
2. The proposal and the consent form should be paged separately.
3. Use very clear font size such as Times New Roman 11pt / 12pt, Arial 11 pt, Calibri 12pt.
4. Download the NMIMR-IRB Researchers Checklist for further instructions.

SECTION A –

Title of Proposal:

Principal Investigator: (Name, Qualification (Specialty), Institution and Department, Postal Address, Telephone, Fax Number, E-mail Address)

Co-PIs: (Name, Qualification (Specialty), Department, Postal Address, Telephone, Fax number, E-mail Address)

Prior Scientific Review: (Attach Letter of Approval)

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)

Collaborating Institutions: (Attach Letter of Approval)

Source/s of Funding: (Name and Address)

Type of Research: Biomedical ☐

Social/Behavioural ☐

Others (please specify _____

Duration of project:

SECTION B – PROPOSAL OUTLINE

Abstract/Executive Summary (Not more than 250 words)

Introduction/Rationale (Not more than 5 pages)

Aims or Objectives of study

Methodology (Include Inclusion and Exclusion Criteria)

Ethical Considerations: (i.e. consent procedures, confidentiality, privacy, risks and benefit, etc.)

Expected Outcome/Results

References

Work Plan

Budget and Budget Justification

Consent Form (Download NMIMR-IRB Consent form template)

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 – SIGNATURE

As the **Principal Investigator / Co-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 & Signature of Principal Investigator / Co-investigator:_____

Date:_____