#

Office Use Only

Protocol Number:

# FORM A – INITIAL PROTOCOL SUBMISSION FORM

(For use by NMIMR Researchers 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.
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.

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| **SECTION A – BACKGROUND INFORMATION** |

**Title of Proposal:**

**Name of Principal Investigator:** (Institution and Department, Postal Address, Telephone, Fax Number, E-mail

Address)

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

**NMIMR STC Number:**

**NMIMR STC Approval Date:** (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/Behavioral [ ]

 Others (please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Duration of project**:

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| **SECTION B – PROPOSAL OUTLINE** |

**Abstract/Executive Summary** (Not more than 250 words)

**Introduction/Rationale** (Not more than 5 pages)

**Literature Review** (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 benefits, 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.)

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| **SECTION C – SIGNATURES** |

I. 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.

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|  Name & Signature of Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |

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|  Name & Signature of Co-Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |