FORM B – CONTINUING REVIEW FORM

INSTRUCTIONS:

1. Please complete all sections and attach a report (details outlined below section C of this form).
2. Under Section C, check boxes with X and attach a memo explaining any "yes" answers.
3. Submit 14 hardcopies and send a soft copy of all documents nirb@noguchi.ug.edu.gh to facilitate the review process.
4. Use very clear font size such as Times New Roman 12pt, Arial 11 pt, Calibri 12pt.

SECTION A – BACKGROUND INFORMATION

Title of study:

Principal Investigator:

Co-Investigators:

Certified Protocol Number (CPN):

Initial Date of Approval:

Recent Date of Approval:

Duration of Project:

a) How long has project run?
b) Time remaining

If requesting for an extension state duration required:

SECTION B – ENROLLMENT

1. Total number of participants enrolled *to date*: _____
2. Number of participants enrolled *since last renewal*: _____
3. Estimated number to be enrolled in upcoming year: _____
4. Number of participants discontinued:
    a. by investigator: _____
    b. voluntarily: _____
    c. due to SAE: _____
    d. Other Reasons (Specify): _____
5. In case of animal/vector studies

a. list number sampled to date _____
b. list number yet to be sampled in the upcoming year _____

SECTION C – STUDY ASSESSMENT

	NO	YES	N/A
1. Have there been any complaints received from anyone about the study? [Participants, Parents/Guardians, Community Members, Staff, etc)	☐	☐	☐
2. Have there been any unanticipated problems or serious adverse events involving risk to participations since the last renewal? If yes, include all copies of serious adverse event reports with this submission.	☐	☐	☐
3. Have the risks or benefits changed as a result of any new information?	☐	☐	☐
4. Does this study have a Data Safety and Monitoring Board? If yes, provide the most recent report from that board.	☐	☐	☐
5. Have there been any amendments approved since the last review?	☐	☐	☐
6. Have there been changes in participant population, recruitment, study procedures or consent procedures that were **not** submitted for approval by the IRB?	☐	☐	☐
7. Are you requesting any changes (i.e. protocol amendment) in participant population recruitment, study procedures or consent procedures as part of this renewal?	☐	☐	☐

NB: A maximum of 3 page report should be attached. The report should address the following:

1) **A brief introduction to the study including objectives**
2) **Progress towards achieving research objectives**
3) **Barriers to meeting set objectives and strategies to overcome them**
4) **Likelihood of meeting original timeline**
5) **Interim analysis of data and adverse events**
6) **Opinion as to whether the risk/benefit ratio for the study remains reasonable**
7) **For Community studies, how any findings have been shared with the local community**

SECTION D – 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:_____ Date: