**RESEARCH OPERATIONS OFFICE**

**INSTITUTE OF HEALTH RESEARCH**

**UNIVERSITY OF HEALTH AND ALLIED SCIENCES**

**RESEARCH ETHICS COMMITTEE (REC)**

**CONTINUING REVIEW SUBMISSION 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 **16** hardcopies and send a soft copy of all documents to [rec@uhas.edu.gh](mailto:rec@uhas.edu.gh) to facilitate the review process.
4. Use very clear font size such as Times New Roman 12pt.

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| **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:

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| **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:
   1. by investigator:
   2. voluntarily:
   3. due to SAE:
   4. Other Reasons (Specify):
5. In case of animal/vector studies
   1. list number sampled to date:
   2. list number yet to be sampled in the upcoming year:

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| **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)

1. 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.

1. Have the risks or benefits changed as a result of any new information?
2. Does this study have a Data Safety and Monitoring Board?

If yes, provide the most recent report from that board.

1. Have there been any amendments approved since the last review?
2. Have there been changes in participant population, recruitment, study

procedures or consent procedures that were **not** submitted for approval

by the REC?

1. 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**

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| **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 UHAS REC 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 UHAS REC is mandated to terminate the study upon expiry.
5. I agree that I will submit a final report to the UHAS REC at the end of the study.

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