**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 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:        |