**RESEARCH OPERATIONS OFFICE**

**INSTITUTE OF HEALTH RESEARCH**

**UNIVERSITY OF HEALTH AND ALLIED SCIENCES**

**RESEARCH ETHICS COMMITTEE (REC)**

**FINAL REPORT/STUDY CLOSURE FORM**

INSTRUCTIONS

1. Please complete all sections of this form.
2. For submission, accompany this form with a maximum of three page report.
3. 14 hard copies of this form together with other required documents should be submitted and a soft copy sent to rec@uhas.edu.gh.

***NB: The detailed report should contain an introduction, materials and methods, preliminary results, discussion, further studies, etc.***

**Section 1 - Background Information**

|  |  |
| --- | --- |
| Title of Study |  |
| Principal Investigator |  |
| Co-Investigators |  |
| Certified Protocol Number |  |
| E-mail address |  |
| Contact Numbers |  |

**Section 2 - Status of Protocol**

|  |  |
| --- | --- |
| 1. Location of Study
 |  |
| 1. Duration of Study
 |  |
| 1. Has study commenced?
2. If yes, state when.
3. If no, state why.
 |  Yes No  |
|  |
| 1. If you want to request for extension, state the duration
 |  |

**Section 3 - Information of Participants**

|  |  |
| --- | --- |
| 1. Total number of participants expected for study
 |  |
| 1. Total number of participants enrolled to date
 |  |
| 1. Number of participants withdrawn:
 |
| 1. Voluntarily
2. By Investigator
3. Due to SAE
4. Other reasons (specify)
 | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. In case of animal/vector study,
2. What is the expected total number to be sampled?
3. How many have been sampled to date?
 | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Section 4 - Assessment of Study**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **YES** | **NO** | **N/A** |
| 1. Has any participant/parent/guardian/community member/staff lodged any complaint about the study?
 |  |  |  |
| 1. Were there changes in the anticipated risks or benefits during the study?
 |  |  |  |
| 1. Was your study audited or monitored by the REC-UHAS or any other agency? If yes, please attach a copy of the findings and any corrective actions that have been implemented as a result of this audit or monitoring.
 |  |  |  |
| 1. Did this study have any Data Safety and Monitoring Board? If yes attach the most recent report from them.
 |  |  |  |
| 1. Are there any publication regarding this study? If yes, please attach an abstract, quoting the reference publication.
 |  |  |  |

**Section 5 – Reason for Study Closure**

|  |
| --- |
|  **YES/NO** |
| 1. Completion of Data analysis \_\_\_\_\_\_\_\_\_\_
2. Interim analysis determined study is not safe or useful. \_\_\_\_\_\_\_\_\_\_
3. No funding \_\_\_\_\_\_\_\_\_\_
4. Time Constraints \_\_\_\_\_\_\_\_\_\_
5. No personnel to carry out study \_\_\_\_\_\_\_\_\_\_
 |

**Section 6 - Signature**

As the **Principal Investigator / Co-investigator** on this project, my signature confirms that:

1. The study was conducted in accordance with all relevant policies and regulations that govern research involving human participants.
2. I agree that the study should be closed.

|  |
| --- |
| Name of Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |