**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](mailto: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 Number of participants withdrawn: | | | |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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |