**RESEARCH OPERATIONS OFFICE**

**INSTITUTE OF HEALTH RESEARCH**

**UNIVERSITY OF HEALTH AND ALLIED SCIENCES**

**RESEARCH ETHICS COMMITTEE (REC)**

**STUDY CLOSURE FORM**

**Instructions:**

1. **This form should be completed when all aspects of the research proposal have been concluded.**
2. All sections of this study closure form must be completed
3. A two (2) page detailed report should be attached to this form which should have an introduction, methods, preliminary results, discussion, conclusion, etc.
4. A soft copy of this completed form and the two page detailed report and other documentations should be emailed as one pdf file to *rec@uhas.edu.gh*

**Section 1 – Background Information**

|  |  |
| --- | --- |
| Title of Study |  |
| Protocol Number: | Date of Approval: |
| Principal Investigator |  |
| Email: | Phone: |
| Study Closure Date: |  |
|  |

**Section 2 – Reason for Study Closure**

1. The recruitment and enrolment of study subjects have been completed [ ]  Yes [ ]  No
2. The data, specimen and records of all study subjects have been obtained [ ]  Yes [ ]  No
3. All research- related interventions, including long-term follow-up, have ceased [ ]  Yes [ ]  No
4. Use or access of private identifiable information is no longer necessary [ ]  Yes [ ]  No
5. Interim analysis determined study is not safe or efficacious [ ]  Yes [ ]  No
6. No funding, time constraints or personnel to do the study [ ]  Yes [ ]  No
7. The sponsor has formally confirmed site closure. (*not applicable to self-funded projects*) [ ]  Yes [ ]  No
8. Other (Please explain)

**Section 3 – Research Status**

1. Total number of participants enrolled \_\_\_\_\_\_\_\_\_\_\_\_\_
2. Total number of participants that withdrew from study;
3. Voluntarily \_\_\_\_\_\_\_\_\_\_\_\_\_
4. By investigator \_\_\_\_\_\_\_\_\_\_\_\_\_
5. Due to Serious Adverse Events \_\_\_\_\_\_\_\_\_\_\_\_\_
6. Other reasons (Please specify) \_\_\_\_\_\_\_\_\_\_\_\_\_
7. Total number of participants data/information was collected from: \_\_\_\_\_\_\_\_\_\_\_\_\_
8. Total number of participants that completed the study \_\_\_\_\_\_\_\_\_\_\_\_\_
9. Has anyone submitted complaints about the study? [ ]  Yes [ ]  No
10. Have there been any relevant information revealed, since the last REC review that may have altered the level of risk or benefits to participants? [ ]  Yes [ ]  No
11. Since the last REC review, has there been any unanticipated problems or adverse effects that have not been reported to the REC? [ ]  Yes [ ]  No
12. Has your study been audited or monitored by UHAS-REC or any other agency? (If yes please attach a copy of findings and corrective actions taken) [ ]  Yes [ ]  No
13. Was there a Data Safety and Monitoring Board for this study? [ ]  Yes [ ]  No
*(If yes please attach a copy of the most recent report from the board)*
14. Are there any publications regarding this study? [ ]  Yes [ ]  No

*(if yes, please attach an abstract, quoting the reference publication)*

**Section 4 – SIGNATURE**

*As the* ***Principal Investigator / Co-investigator / Researcher*** *on this project, your signature confirms you understand that the closure of this study means:*

1. *The study was conducted in accordance with all relevant policies and regulations that govern research.*
2. *No further data collection, follow-up with participants, coding of data, data analysis and manuscript preparation that requires personal indefinable information may be conducted.*
3. *You agree to retain all research materials for at least 3 years after closure of the study and acknowledge that these documents may be subject to review by the REC, when necessary.*
4. *You certify that to the best of your knowledge, the information provided on this form is true and accurate.*

**Section 3 - SIGNATURE**

Name of person completing the form: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Role on the study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

For all student projects:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Supervisor’s Name Supervisor’s Signature Date