**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:

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Supervisor’s Name Supervisor’s Signature Date