**RESEARCH OPERATIONS OFFICE**

**INSTITUTE OF HEALTH RESEARCH**

**UNIVERSITY OF HEALTH AND ALLIED SCIENCES**

**RESEARCH ETHICS COMMITTEE (REC)**

**PROTOCOL AMENDMENT FORM**

**Requirements:**

1. All sections of this protocol amendment submission form must be completed before protocol can be considered for review.
2. A cover letter from the PI requesting for protocol amendment must be attached
3. The protocol with proposed *changes (in your protocol, consent form and/or other revised study documents)* **highlighted**. Revised documents should be version controlled
4. All the documents above should be put together as one pdf file and emailed to [rec@uhas.edu.gh](mailto:rec@uhas.edu.gh).
5. Once submitted, changes must be approved by the UHAS-REC before your study changes can be implemented.
6. The REC will determine whether the amendment is ❑ minor or ❑ major (which may require submission of a new protocol).

**Section 1 – Background Information**

|  |  |  |
| --- | --- | --- |
| Title of Study |  | |
| Protocol Number: | | Date of Approval: |
| Principal Investigator |  | |
| PI’s Address |  | |
| Email: | | Phone: |
| REC Clearance Expiration Date: | |  |

**Section 2 – Details of Amendment Requested**

|  |  |
| --- | --- |
| 1. Type of Amendment   *(check all that apply)* | Protocol amendment  Modifications to consent form  Modification to data collection instruments  Other (specify) |
| 1. Describe the proposed amendments and explain how they differ from the originally approved protocol. | |
| 1. Explain why you propose to make the amendments. | |
| 1. Describe any anticipated effects (risks, benefits, etc.) of the proposed change on subjects or potential subjects. | |

**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