**RESEARCH OPERATIONS OFFICE**

**INSTITUTE OF HEALTH RESEARCH**

**UNIVERSITY OF HEALTH AND ALLIED SCIENCES**

**RESEARCH ETHICS COMMITTEE (REC)**

**NEW PROTOCOL SUBMISSION FORM**

**Requirements:**

1. A new protocol must be submitted to the REC **at least three months before** the proposed commencement date of the research to ensure you have clearance before the proposed start date.
2. **All sections of this form must be completed** and the outline of protocol in Section 3 of this document must be strictly followed before protocol can be considered for review.
3. A soft copy of your application dossier (cover letter, completed protocol submission checklist, completed New Protocol Submission Form, the study protocol and other attachments) **saved as one pdf file** **should be emailed to** ***rec@uhas.edu.gh*** **for approval before printing**.
4. **8 bound copies** of the application dossier (cover letter, completed protocol submission checklist, completed New Protocol Submission Form, the study protocol and other attachments) should be submitted at the Institute of Health Research by the submission deadline for the month. **Printing should be one-sided.**

**Section 1 – BACKGROUND INFORMATION**

|  |  |
| --- | --- |
| **1.1** **Title of Study:** |  |
| **1.2 Principal Investigator (PI)** |
| 1. Full Name

*(Surname First, Title, Qualifications)* |  |
| 1. Postal Address:
 |  |
| 1. Institutional Affiliation:
 |  |
| 1. Phone Number:
 |  |
| 1. Email Address:
 |  |
| **1.3 Co-Investigator(s)** |  |
| **First Co-Investigator** |  |
| 1. **Name of 1st Co-Investigator :**

*(Surname First, Title, Qualifications)* |  |
| 1. Postal Address:
 |  |
| 1. Institutional Affiliation:
 |  |
| 1. Phone Number:
 |  |
| 1. Email Address:
 |  |
|  **Second Co-Investigator (if applicable)** |
| 1. **Name of 2nd Co-Investigator**

 *(Surname First, Title, Qualifications)* |  |
| 1. Postal Address:
 |  |
| 1. Institutional Affiliation:
 |  |
| 1. Phone Number:
 |  |
| 1. Email Address:
 |  |
| **Third Co-Investigator (if applicable)** |
| 1. **Name of 3rd Co-Investigator**

 *(Surname First, Title, Qualifications)* |  |
| 1. Postal Address:
 |  |
| 1. Institutional Affiliation:
 |  |
| 1. Phone Number:
 |  |
| 1. Email Address:
 |  |
| **1.4 Proposed Study/Research Information** |
| 1. Type of Proposal
 | [ ] Student Research [ ] Grant Application [ ]  Faculty Research |
| 1. Student Status *(for student applicants only)*
 | [ ]  Undergraduate [ ]  Masters [ ]  PhD [ ] Fellowship |
| 1. Type of Research/Study:
 | [ ]  Clinical Trial [ ]  Biomedical [ ]  Epidemiological Study [ ]  Social Science [ ]  Implementation Research [ ]  Others (specify)  |
| 1. Location of Research/Study:

*(Region, District, Towns)* | *Region: District(s):* *Towns:* |
| 1. Duration of Research/Study:
 | Study Start Date: End Date: |
| 1. Source(s) of Funding:

*(Name, Postal Address and Email)* |  |

**Section 2 - SIGNATURE**

*As the* ***Principal Investigator / Co-investigator / Researcher/ Student Investigator*** *on this project, your signature on the proposal confirms that:*

1. *You will ensure that all procedures performed under the study will be conducted in accordance with all relevant policies and regulations that govern research involving human participants.*
2. *You understand that if there is any change from the project as originally approved you must submit an amendment to the REC for review and approval prior to its implementation. Where you fail to do so, the amended aspect of the study is invalid.*
3. *You understand that you will report all serious adverse events associated with the study within seven days verbally and fourteen days in writing.*
4. *You understand that you will submit progress reports each year for review and renewal. Where you fail to do so, the REC is mandated to terminate the study upon expiry.*
5. *You agree that you will submit a final report to the REC at the end of the study.*

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

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

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

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

**For Student’s Supervisor(s)**

I the undersigned supervisor have read through the proposal thoroughly (Scientific Review of the proposal) and reviewed the research instrument(s).

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

Supervisors Name Supervisor’s Signature Date

**Section 3 – Outline of Protocol**

***Protocols must be written using Times New Roman font type and font size 12 with line spacing of 1.5. Printing should be one-sided.***

1. **COVER PAGE**
2. **LIST OF ACRONYMS AND ABBREVIATIONS**
3. **STRUCTURED SUMMARY *(1 page maximum and must not have references)***
* Background
* General Aim
* Methodology
* Expected Outcome (expected results or what you hope to achieve from study)
1. **BACKGROUND *(1-3 pages maximum)***
* Introduction
* Problem statement:
* Justification/Relevance
* Hypothesis (if applicable)
* Aim (s)
* Specific Objectives
1. **LITERATURE REVIEW** ***(5 pages maximum)***
2. **METHODOLOGY *(8 pages maximum*)**
* Study Design
* Study Site
* Subject/Study Population
* Inclusion/Exclusion Criteria
* Sample Size Determination
* Procedures to be used (Data Collection methods and instruments)
* Data handling (May include coding, quality control, data security and confidentiality)
* Statistical Analysis
1. **DISSEMINATION OF RESULTS**
	* To Project sponsors and policy makers (where applicable)
	* At workshops, seminars and conferences
	* In different types of publications
2. **ETHICAL ISSUES**
3. *For Human Subjects*
4. Consider Recruitment and sampling procedures, Potential risks and benefits, confidentiality.
5. For vulnerable subjects (children, pregnant women, institutionalized subjects), state how subjects’ protection will be ensured.
6. Provide **Consent Form** with simple and clear language.
7. *For Vertebrate Animals*
8. Justification for use of animals
9. Housing and veterinary care
10. Processes to minimize discomfort
11. Euthanasia
12. **REFERENCES**
* Referencing style used must be consistent
1. **TIMELINES/WORK SCHEDULE/WORK PLAN**
* This is usually in the form of a Gantt chart (to show different activities versus time frames for expected completion).
1. **PERSONNEL OF THE STUDY TEAM INCLUDING PERCENTAGE EFFORT**
* Role of each member (Not applicable for students)
1. **BUDGET & BUDGET JUSTIFICATION**
* To be detailed even if no external funding is required.
1. **APPENDIX**
* **Consent Form** (UHAS-REC Consent form template available)
* **Assent Form and Parental Consent Form** (Only applicable where children of ages 12 to 17 would be recruited as research participants, UHAS-REC template available)
* **Data Collection Instruments** (e.g. Questionnaire, interview guide etc. if applicable)
* **Letters of Support** (if applicable)
* **Principal Investigators’ CV and CVs of all Co-Investigators** (not applicable to UHAS students, for non-UHAS students, supervisor’s CV is required)
* **Prior Scientific Review:** (Attach Letter of Approval)
* **Prior Ethical and Protocol Review:** (Name any other Ethical and Protocol review board/committee this proposal has been submitted to and attach approval letter if applicable. In case of rejection, state reasons)
* **Collaborating Institutions: (Attach Letter of Approval)**
* Any other attachments