**FORM A – PROTOCOL SUBMISSION FORM**

**INSTRUCTIONS:** *Please consult the* ***IRB Submission Guidelines*** *and apply the instructions for each requirement. DO NOT LEAVE ANY INPUT BLANK. If any requirement is not applicable, state NA. Use* ***Times New Roman*** *Font size 12 with 1.5 Line Spacing.*

**SECTION A: BACKGROUND INFORMATION**

|  |  |
| --- | --- |
| **Title of Protocol/Proposal:** |  |

**Name of Principal Investigator:**

|  |  |
| --- | --- |
| Institution and Department: |  |
| Postal Address: |  |
| Telephone: |  |
| Fax Number: |  |
| E-mail Address: |  |

**Co-PI-1 Details:**

|  |  |
| --- | --- |
| Name |  |
| Institution and Department: |  |
| Postal Address: |  |
| Telephone: |  |
| E-mail Address: |  |

**Co-PI-2 Details:**

|  |  |
| --- | --- |
| Name |  |
| Institution and Department: |  |
| Postal Address: |  |
| Telephone |  |
| E-mail Address: |  |

**Has protocol been submitted for previous IRB Review?**

|  |  |
| --- | --- |
| No |  |
| Yes |  |

**If submitted previously, provide details below:**

|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **Name of other IRBs protocol has been submitted to (if applicable)** | **Status of proposal/ protocol:**  **Awaiting final decision**  **Approved, Not approved, N/A** | **If protocol not approved, reasons why** |
| **1** |  |  |  |
| **2** |  |  |  |

**Collaborating Institutions: *collaborating with PIs on the research***

|  |  |
| --- | --- |
| Institution: |  |
| Postal Address: |  |
| Telephone: |  |
| Fax Number: |  |
| E-mail Address: |  |

**Source(s) of Funding:** (Name and Address)**:**

|  |  |
| --- | --- |
| Self-funded |  |
| Other individual |  |
| Sponsor organization/ Funding organization |  |

**Funder information (if source of funding is other individual, or funding organization):**

|  |  |
| --- | --- |
| Funder |  |
| Telephone: |  |
| E-mail Address: |  |

**Other entities, eg** clinical laboratory(ies), medical and/or technical department(s) and/or other institutions involved in the research, providing technical services.

|  |  |
| --- | --- |
| Institution1 |  |
| Telephone: |  |
| E-mail Address: |  |

|  |  |
| --- | --- |
| Institution2 |  |
| Telephone: |  |
| E-mail Address: |  |

**Type of Research:**

|  |  |
| --- | --- |
| **Experimental [Primary data, randomized as treatment and control]:**  Clinical Trial/ RCT: *A new drug, device or vaccine trial,* patients, locations may be randomized, with(out) blinding |  |

|  |  |
| --- | --- |
| Quasi-Experimental (may have treatment, control arms but not randomized) |  |

**Observational [Primary data, not randomized]:**

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| --- | --- |
| Biomedical/Epidemiological/ Nutritional |  |
| Laboratory/ Genetic:  Human biological materials (e.g., tissues, cells, fluids, blood, genetic material etc.) |  |
| Social Science or Policy: *Social/ Behavioural / Economic/ Policy* |  |
|  |  |
| Monitoring and Evaluation/Implementation Research |  |
| Testing, evaluating, validating tool, device or method as observational study |  |

**Secondary data analysis:**

|  |  |
| --- | --- |
| Analysis of patient or other hospital data, case reports, meta-analysis (incl medical, laboratory, genetic, etc.) |  |
|  |
|  |  |
| **Mixed studies:** |  |
| Aspects of the research involve quantitative; whilst other aspects involve qualitative data collection. |  |

|  |
| --- |
| Others (please specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Research Sites** [List **ALL** sites/locations where data is to be collected in this research study]

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Proposed start of project (DD/MM/YYYY)** |  |  |  |  |  |  |  |  |
| **Proposed end of project (DD/MM/YYYY)** |  |  |  |  |  |  |  |  |

**SECTION B – PROPOSAL OUTLINE**

**Abstract (Not more than 500 words):**

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| --- |
|  |

**INTRODUCTION AND LITERATURE REVIEW**

Background (Not more than 1 page)

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|  |

Statement of the Problem (Not more than 1 page)

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| --- |
|  |

Literature Review (Not more than 5 pages)

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| --- |
|  |

Rationale (Not more than 1 page)

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**AIMS OR OBJECTIVES OF STUDY**

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| --- |
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**METHODOLOGY**

Study Design

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| --- |
|  |

Study Area/ Setting

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| --- |
|  |

Study Population

|  |
| --- |
|  |

**Sample Size, Sampling Approaches, Inclusion and Exclusion Criteria**

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| --- | --- | --- | --- | --- |
| Sample Size   |  | | --- | |  |   Sampling technique   |  | | --- | |  |   Study Inclusion criteria   |  | | --- | |  |   Study Exclusion criteria   |  | | --- | |  | |

**Data collection process [all studies apart from secondary data analysis]**

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| --- |
|  |

**Data Sources [Secondary Data Analysis only]**

|  |  |  |
| --- | --- | --- |
| Specify/ explain the nature and owner(s) of the dataset/ archival records   |  | | --- | |  |   Explain your level of access to the dataset/ archival data   |  | | --- | |  | |

**Data Management [Primary Data]**

|  |
| --- |
|  |

**Data Sources and Management [Secondary Data]**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Data Sources   |  | | --- | |  |   State whether variables to be collected contain personal data. If so, list the variables   |  | | --- | |  |   If personal data is to be used, a justification as to why this is the case   |  | | --- | |  |   Indicate whether dataset, archival data is already anonymized, whether you plan to anonymize it or whether you will use individual level data and link data to individuals.:   |  | | --- | |  |   **Data Management for secondary data:**  Data cleaning/ processing, software for data management, analysis etc   |  | | --- | |  | |

**Data Analysis: *Must be filled for either Quantitative or Qualitative, or both sections for mixed studies***

**Quantitative Studies**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Study Variables:** [Explain how variables are measured, categorized, whether indexes and scales are to be used. *Add on as many variables as required*]   |  |  |  | | --- | --- | --- | | **Category** | **Variable(s)** | **Measurement scale:**  Continuous (includes interval and ratio scales)  Indexes (eg Mental Health Index etc),  Scales (such as Likert Scale etc),  Counts, Ordinal or Nominal scale | | Dependent | *Main DV here* |  | | *Second DV (if any)* |  | | Independent |  |  | |  |  | |  |  | | Control, if any |  |  | |  |  | |  |  | |   **Analysis Plan and Software(s):** Describe analyses to be done and link with research questions/ objectives   |  | | --- | |  | |

**Qualitative Studies**

|  |  |  |
| --- | --- | --- |
| **Variables, themes, concepts, phenomena etc** of interest/ to be observed/ analyzed in the study   |  | | --- | |  |   **Analytic approach and Software(s):** *Describe your application of approaches (e.g. Phenomenology, Ethnographies, Thematic Analysis etc) to explore themes within the context of each research question*   |  | | --- | |  | |

**Expected Outcomes/Results**

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**References**

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| --- |
| **At least 20 references** |

**SECTION C: WORK PLAN AND BUDGET**

**Work Plan/ Timetable/ Timelines**

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**Budget and Budget Justification**

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**SECTION D: ETHICAL CONSIDERATIONS**

**For Primary Data: Experimental or Observational**

Participant Information Sheet and Consent Form

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Participant Information Sheet, Parental Consent and Assent Forms (15-17 years)

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|  |

Participant Information Sheet and Parental Consent Forms (Children below 15)

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**SECTION E-A: DOCUMENT ATTACHMENTS**

***CVs should not exceed 4 pages***

PI-CV

|  |
| --- |
|  |

Co-PI-1 CV

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| --- |
|  |

Co-PI-2 CV

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| --- |
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Previous IRB approval letter(s) (if applicable)

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Letter of Support from Collaborating Institution

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Data Collection Instruments (i.e., Interview Guide, Questionnaire, etc)

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Full Protocol or student proposal **(Add as separate attachment to email.** The name of the attachment should have the name of the main PI together with the word “PROPOSAL”)

**SECTION E-B: OTHER MANDATORY DOCUMENTS FOR CLINICAL TRIALS**[[1]](#footnote-1)

***Please attach all documents that apply as separate documents to the submission email. Each attachment should be named with the name of the main PI and the name of the document)***

* Summary of previous study i.e., Phase 1 & Phase II studies
* Investigator Agreement (PI’s responsibility), Page duly signed, with name and date.
* Current Certificate of Training in Good Clinical Practice (GCP) for PI(s) and researchers
* Data Safety Monitoring Board (DSMB) membership and Charter of Work/Current Curriculum Vitae of members.
* Insurance cover for study participants
* Food and Drugs Authority approval letter for use of the Investigational Product/ Devices and clinical trial approval Current CVs of PI & Co-Investigators
* Clinical trial registration with Pan African Clinical Trial Registry (PACTR)
* For multi-country studies, Ghana specific addendum/proposal is required.
* Investigator’s Brochure (including safety information)
* Adverse Drug Reaction/Adverse Event Reporting form
* Material Transfer Agreement

**SECTION F – SIGNATURES**

As the **Principal Investigator / Co-Investigator** on this project, my signature confirms that:

1. I 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. I understand that if there is any change from the project as originally approved I must submit an amendment to the UGMC-IRB for review and approval prior to its implementation. Where I fail to do so, the amended aspect of the study is invalid.
3. I understand that I will report all serious adverse events associated with the study within seven days verbally and fourteen days in writing.
4. I understand that I will submit progress reports each year for review and renewal. Where I fail to do so, the IRB is mandated to terminate the study upon expiry.
5. I agree that I will submit a final report to the UGMC-IRB at the end of the study.

|  |
| --- |
| Name & Signature of Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. Ghana Health Service Requirements for Submission of Research Protocols [↑](#footnote-ref-1)