

# **Guidelines for the Writing of Dissertations for the Fellowship of the Ghana College of Physicians & Surgeons**

## **Introduction**

The Fellowship programs of the Ghana College of Physicians & Surgeons (GCPS) require senior residents to write a dissertation as part of the requirements for the award of the Fellowship of the GCPS. The dissertation should be a detailed research by the senior residents, which is assessed towards the final evaluation for the award of the Fellowship qualification.

Each senior resident will be assigned a supervisor by the Chairman of the Faculty or the Faculty Board to guide in the preparation, writing and submission of the dissertation. Alternatively, the Resident with the approval of the Faculty Board/Faculty Chairman may suggest a supervisor.

The Faculty Board must approve the topic of the dissertation and the proposal for the work. It is required that ethical approval for the conduct of the approved study will be obtained from the Research and Ethics Committee or Institutional Review Board of the Medical Schools/Universities, the Teaching Hospitals or the Ministry of Health of Ghana as appropriate. Financial support may be available from the Sponsoring Agency/College for the study.

## **Core Required Courses for Fellowship Programme and Dissertation Writing**

The following courses will be provided by the College and will be required for all residents intending to submit dissertations:

- Scientific communication
    - Proposal writing
    - Use of references
    - Presentation skills
  - Research Methods
  - Health Statistics
- 1.
  2. These courses will be run for Residents before or soon after admission for their Fellowship programmes.

## **Procedure for Submission of Dissertations to the College**

The following will be the laid down structure and procedures for the submission of dissertations at the College:

1. Conceptualization phase
2. This involves the selection of topic for dissertation. Based on the topic a supervisor will be chosen by the Faculty Board for the Resident.
3. Zero draft of dissertation proposal to be reviewed by supervisor
4. Final draft of the proposal to be presented to the Rector (GCPS) by the Faculty Chairman for its review.
5. Final proposal approved/disapprove by Reviewers.
6. Proposal submitted to Ethics Review Committee if approved.
7. Start of Study
  - Data Collection
  - Data Analysis
  - Report Writing
8. Notice of intent to submit Dissertation (Selection of Reviewers by the Faculty Board for approval of the Academic Board at this stage)
9. Submission of Dissertation to Faculty Chair
10. Submission of Dissertations to the Rector by the Faculty Chairman for onward submission to the suggested Reviewers/Examiners.
11. Return of Dissertation report to the Rector.
12. Defense of Dissertation
13. Reviewers/Examiners comments to the Faculty Chairman and copy the candidate.
14. Submission of the “Final Approved Version” of Passed Dissertation to College.

## **The Dissertation Proposal**

The outline of the final dissertation proposal document should include the following sections:

1. Title page
2. Abstract (up to 500 words; Include rationale/objectives of the study, materials and methods planned to be used, data management, analysis plan and expected outcomes of the study)
3. Table of Content
4. Introduction
5. Rationale for the study
6. Aims of the study including definition of research problem
7. Literature Review (not more than 1500 words)
8. Materials and Methods
9. Data management and analysis
10. Ethical and Legal Considerations
11. Logistics and Time Schedule
12. Budget/Resources
13. References (According to the Vancouver System)
14. Appendices

The Faculty Board will present the Dissertation Proposal/Dissertation Plan to the Dissertation Committee of the Academic Board for approval.

The Dissertation Committee of the Academic Board will review and approve the proposed study prior to submission of the proposal for ethical review by the Supervisor of the resident.

Actual execution of the study shall start only after obtaining ethical clearance. Please see Annex 1, Annex 2 and Annex 3 for the requirements of the ethical review Committees of the University of Ghana Medical School, the KNUST/SMS and the Ghana Health Service.

## **General Specifications for the Format of the Final Dissertation Report**

The general guidelines for the final dissertation report are given below:

The final dissertation shall be written in English. It should contribute to knowledge in the chosen field, show originality and should consist of the candidate's own account.

The dissertation should be a minimum of 120 pages.

The document must be written in the following format:

- The font should be New Times Roman
- The typeface should be 12-point font size, 1.5 spacing;
- The report must be professional, i.e. it must have Chapter titles and sub-titles and Table of Content, have indents for the beginning of each paragraph, page numbers (placed in the centre of the footer, , bold typeface, italics, and other editing facilities, where appropriate;
- Graphs or tables, made either by the resident or downloaded from the Internet may be used to illustrate the dissertation. Such Tables or Figures should be numbered consecutively based on Chapter numbers.
- Chapter sections and sub-sections should be numbered using alphanumerics in a hierarchical order
- The document must be checked for spelling errors

***Fabrication of data and Plagiarism are severe research misconduct and will result in the dissertation being disqualified and the candidate failing the whole examination in addition to any other institutional sanctions.***

## General Outline of the Dissertation

### 1. Cover and Title Pages

The **Title Page** should be as shown below:

**Ghana College of Physicians and Surgeons**

*Name of Faculty*

**Approved Title of the Study**

**Submitted to the Faculty of (Faculty's name), in partial fulfilment of the requirements for the conferment of a Fellow of the Ghana College of Physicians/Surgeons (FGCP)/(FGCS) as applicable**

**Author (full name)**

**Resident number (if applicable)**

**Month, Year**

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### 2. Introductory Pieces

- Declaration page

This page contains a statement to the effect that the research report is the resident's own work, and that it has not been used for other degrees or diplomas in the past.

- Certification page (supervisors' signatures)

- Acknowledgement page

- Abstract (with keywords)

An abstract of not more than 500 words organised under the following headings: introduction, methods, results, and conclusions.

- Table of Contents

- List of Tables

- List of Figures

- List of Abbreviations

**3. Abstract (up to 500 words)**

This should be a structured summary of the proposed research. It should have the following headings: introduction/rationale, methods used, results, interpretation and conclusions.

**4. Table of Content**

Include the different headings and sub-heading as in the dissertation.

**5. Introduction**

15. Content will be determined according to your proposal, but should include the following: why this subject is important, historical background, why study was initiated, definition of the problem/hypothesis/research question, justification for your study.

16.

**6. Objectives**

This section is usually in two parts – General objective or goal and Specific objectives. The general objective is a statement describing the kinds of knowledge or information that will be gained from the research while specific objectives will list the measurements to be made and any hypotheses to be tested. The rationale should be to explain how achievement of the specific objectives will further the general objective or goal.

17.

**7. Literature Review**

18. Review of relevant information about subject matter. This section provides a background to the study by reviewing the available evidence on the study. Both published and unpublished data sources may be important in informing the researchers of what is already known on the topic and what the relevant gaps in knowledge may be. The literature review should be detailed enough to identify potential confounding variables and to determine areas where new knowledge is needed. It might also include relevant results from previous studies.

**8. Materials and Methods**

19. This describes in some detail how the study was carried out. It will usually describe the study area, study population and sample to be studied, data sources etc. down to the procedures for the study. It must include:

- The Study design
- The study setting
- Study population and sampling

20. This section gives a brief description of the area where the study is proposed to take place. It should include the population to be studied (in terms of person, place and time) and methods for sampling the population and sample size. Any exclusion or inclusion criteria may be given.

- Data Collection and Measurements
  - How the data will be collected (e.g. by questionnaire interviews, review of discharge notes, abstracts of hospital in-patient records etc.) Any measurements to be made are to be described.
  - Measurement tools (e.g. clinical examination, questionnaire...)

- Measurement methods (detailed description of how measurements will be done)
  - Validity and reliability of measurement instrument (if applicable)
  - Quality control
  - Data Management and Analysis
21. This should include:
- Procedures for data management in the field to ensure that the data is of high quality and quality assurance and quality control measures for all aspects of the data
  - The methods for analysing the data. It includes all the major steps that will be used to reduce the raw data to the final result. Methods for comparing groups and presenting the results as well as statistical tests to be applied to the data to obtain point estimates and confidence intervals for other measures should be presented. The section should go beyond just stating which software will be used to analyse the data. The analysis section should detail the appropriate statistical methods to be used to analyse the data.
- 22.
9. Ethical and legal considerations
- Approval of study by the relevant Faculty Procedures
  - Ethical approval from the relevant Institutional Review Board (IRB)
  - Consent procedures (should give a brief description of the methods to be used to obtain consent for the study to allow estimation that the study follows acceptable ethical principles. The consent document must include sections on:
    - A general description of the study and why the individual is being invited to take part in the study
    - Voluntary participation (no one will be forced to take part in the study)
    - Privacy of information/confidentiality
    - Potential harms and benefits
    - Conflict of Interest if any
- 23.
10. Results
24. This section should state the results of the study without any attempt to explain or discuss them. A mixture of both narrative and images (Tables, Charts and Graphs) should be used to enhance the presentation.
- 25.
11. Discussion
26. This section should contain a discussion of the results of the study in the light of what is known in the literature and what others have found in similar studies. Negative findings should also be discussed. Policy and/or practice implications as well as contribution to existing knowledge should be part of this section. Limitations of the study should also be stated.
- 27.
- 28.
12. Conclusions and Recommendations
29. This section should state the main conclusions from the study and have any specific

recommendations in the light of the findings of the study

30.

**13. References**

In text citations should be in arabic superscript numerals *outside* periods and commas, *inside* colons and semicolons. When more than 2 references are cited at a given place in the manuscript, use hyphens to join the first and last numbers of a closed series; use commas without space to separate other parts of a multiple citation (AMA Manual of Style).

The list of references will follow the recommendations of the **International Committee of Medical Journal Editors (ICMJE) Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Sample References** ([http://www.nlm.nih.gov/bsd/uniform\\_requirements.html](http://www.nlm.nih.gov/bsd/uniform_requirements.html))

31.

**14. Appendices:**

32. This must include the:

- The Data Collection Instrument
- Letters of approval
- Consent forms including Assent Form in case of children
- IRB Approval

33.

34.

35.



## **Submission of the Dissertation**

Residents must submit three loosely bound copies of the dissertation to the Chair of the Faculty, at least three months before the final examination. An electronic version (CD) of the dissertation should also be submitted. The submitted dissertation must conform to the general specifications of the format for the final dissertation.

**The results arising from the dissertation should not have been published prior to the submission of the dissertation for examination.**

## **Examination of the Dissertation**

The dissertation shall be examined in two parts:

- Marking of the dissertation will be done by two (2) Assessors approved by the Academic Board of the College
- Oral defence of the dissertation will be conducted as part of the oral examination for the Fellowship by one of the external examiner and an internal assessor who shall not be the supervisor. The Oral defence will last for one (1) Hour. The supervisor of the dissertation may sit in the oral examination but will not be one of the examiners.

## **Submission of Final Passed Version of Dissertation**

The candidate will receive an examiner's report with all the corrections to be made to the dissertation after the oral defence of the dissertation. The final corrected version must be approved and passed by the Chairman of the Faculty.

The candidate will submit to the College three Bound Copies and three electronic (CDs) copies of the Final Approved and Passed Version of the Dissertation to the College within six (6) weeks of the oral examination. The colours of the bound dissertation shall be **Blue with gold lettering** for the Division of Physicians and **Burgundy with gold lettering** for the Division of Surgeons.

## Proposed Timeline for Management of Writing of Dissertation

1. Conceptualization phase: Concluded 31<sup>st</sup> March of Post-Membership year
2. Zero draft of proposal reviewed by supervisor: 31<sup>st</sup> August of Post-membership Year
3. Final draft of dissertation proposal presented to College Dissertation Committee by the Faculty Chairman: 30<sup>th</sup> November of Post-Membership Year
4. Final proposal approved by College: 31<sup>st</sup> March 28<sup>th</sup> February of 1<sup>st</sup> Fellowship Year
5. Submit proposal to Ethics Review Committee March – April of 1<sup>st</sup> Fellowship year
6. Start of Study data Collection: 1<sup>st</sup> May of 1<sup>st</sup> Fellowship Year
7. Notice of intent to submit Dissertation: 31<sup>st</sup> October of 2<sup>nd</sup> Fellowship Year
8. Selection of Reviewers by the Faculty Board for approval of the Academic Board:
36. 30<sup>th</sup> November of 2<sup>nd</sup> Fellowship Year
9. Submission of Dissertation to Faculty 1<sup>st</sup> December of 2<sup>nd</sup> Fellowship Year
10. Submission of Dissertations to Dissertation Committee for onward submission to the Reviewers: 15<sup>th</sup> December of 2<sup>nd</sup> Fellowship Year
11. Return of Dissertation through the Dissertation Committee to the candidate with Reviewers comments for action 31<sup>st</sup> January of 3<sup>rd</sup> Fellowship Year
12. Defence of Dissertation March Examinations of College
13. Submission of Examiner's report on Dissertation: One week after March College Examinations
14. Submission of Final Approved Version of Passed Dissertation to the College:
37. 31<sup>st</sup> May of 3<sup>rd</sup> Fellowship Year
- 38.
- 39.
40. GCPS/Dissertation Guidelines version July 2012.01

41. ANNEX 1

**ETHICAL AND PROTOCOL REVIEW COMMITTEE**  
**UNIVERSITY OF GHANA MEDICAL SCHOOL**  
**COLLEGE OF HEALTH SCIENCES**  
**GUIDELINES FOR SUBMISSION OF PROPOSALS**

The Ethical and Protocol Review Committee is responsible for approving any research performed by Students and Faculty of the University of Ghana Medical School.

- The Committee meets on the **last Thursday of every month** of the year except in July when the University is on recess. Submission to the Committee should be made at least **two weeks before** the meeting at which the submissions would be reviewed.
- All submissions for academic protocols made should have a **covering letter from the Head of Department** and should be certified by the supervisor in the case of students.
- **All Researchers involved should sign the proposal** prior to its presentation to the Head of Department.
- Proposal should have a **Font of size 12** and **Spacing 1.5**.
- **A proposal coming from outside the Medical School attracts a processing fee.**

The Protocol submitted to the Committee should be in the following sections:

**TITLE PAGE**

- This page should have the title of the Protocol and the names, addresses and departments and affiliations of Investigators.

**STRUCTURED ABSTRACT** *(It should be between half and one page and must not have references)*

- Background
- General Aim
- Methodology
- Expected Outcome (expected results or what you hope to achieve from study)

**BACKGROUND** *(Limit of 1-3 pages)*

Introduction

Problem statement:

- Statement of problem which requires research.
- Problem definition from the available data/literature/statistics
- Incidence and prevalence of the problem
- Distribution of the problem –geographical, population group, etc
- Possible explanations for the problem

Justification/Relevance

- Why the problem requires research-
- Potential impact/contribution of the research to health or policy.

Hypothesis (if applicable)

- The expected association/relationship between one or more independent variables and the dependent variable which the study will establish.

### **AIM(S)**

- What is expected to be achieved? Proposal must typically have one or two broad aim(s).

### **SPECIFIC OBJECTIVES**

- Proposal may have several immediate or specific objectives. This describes the **specific action** or experiment(s) that will be undertaken to achieve the broad aim(s).

### **LITERATURE REVIEW**

- Limit of 5pages for literature review

### **METHODOLOGY** (*Limit 8 pages for Methodology*)

Study design:

- Human studies- could be retrospective (case-control), prospective (cohort, clinical trial, case-control) or cross-sectional.

Study sites

- Describe site briefly including facilities available

### **Subjects/study population**

Inclusion/exclusion criteria

- List inclusion and exclusion criteria separately.

Sample size determination

- Use appropriate Power Calculations for type of study

Procedures to be used

- Data collection methods and instruments.
- Should be reproducible by other investigators
- Needs to be precise.

Data handling

May include

- Coding
- Quality control (pre-testing, supervision, training) measures.
- Data security and confidentiality

Statistical analysis

- Descriptive statistics (frequency, central tendencies, associations)
- Inferential statistics (test of means, correlation coefficient, etc)

### **DISSEMINATION OF RESULTS**

- To Project sponsors and policy makers (where applicable)
- At workshops, seminars and conferences
- In different types of publications

### **REFERENCES**

- Use either Harvard or Vancouver Style. Must choose one and must be consistent

### **ETHICAL ISSUES**

- For Human Subjects
  - Consider Recruitment and sampling procedures, Potential risks and benefits, confidentiality.
  - For vulnerable subjects (children, pregnant women, institutionalized subjects), state how subjects' protection will be ensured.
  - Provide **Consent Form** with simple and clear language.
- For Vertebrate Animals
  - Justification for use of animals
  - Housing and veterinary care
  - Processes to minimize discomfort
  - Euthanasia

### **TIMELINES/WORK SCHEDULE**

- This is usually in the form of a Gantt chart (to show different activities versus time frames for expected completion).

### **PERSONNEL OF THE STUDY TEAM INCLUDING PERCENTAGE EFFORT**

- Role of each member (*Not applicable for students*)

### **BUDGET & LOGISTICS**

- To be detailed even if no external funding is required.
- For funds managed by UGMS Administration, charges will apply.

### **APPENDIX**

- Questionnaire (if any)
- Any other attachments

Revised June 2012



## COMMITTEE ON HUMAN RESEARCH, PUBLICATIONS AND ETHICS

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY,

### APPLICATION FOR ETHICAL REVIEW OF RESEARCH PROTOCOL

Submission forms may be obtained from the CHRPE Office, Room 8 Block J, School of Medical Sciences, Kwame Nkrumah University of Science and Technology, Kumasi or [chrpe.knust.kath@gmail.com](mailto:chrpe.knust.kath@gmail.com). Completed forms must be returned, collated and stapled/clipped, to the CHRPE Office, SMS, KNUST.

The following documents should be enclosed to make a submission complete:

	NUMBER OF COPIES		
	General Research	Student Research	Please <input checked="" type="checkbox"/>
<b>A For all research:</b>			
◇ Personalised Covering letter from the Investigator	1	1	
◇ Completed CHRPE Application Form	10	5	
◇ Copies of the research protocol	10	5	
◇ Participant Information Leaflet and Consent Form	10	5	
◇ Summary of protocol (Maximum of 3 pages)	10	N/A	
◇ Data capturing sheet(s)/questionnaires/interview guide	10	5	
◇ Proof of notification or written approval or permission from research site/facility (where study is to be conducted)	10	5	
◇ Soft Copies of all submitted documents (on CD)	1	1	
<b>B. Where applicable:</b>			
◇ For sponsored research, proof of payment of CHRPE Fees	1	1	
◇ For all Clinical and Field trials, abridged Curriculum Vitae of Principal Investigator showing research experience	1	1	
◇ Written approval or permission on official letterhead from Supervisor (Research for Academic Purposes)	N/A	1	
◇ Other (Please specify) e.g. copy of diary cards	10	5	

**Please note that ethics review is conditional upon submission of all the required documents in A above and B, where applicable**

## **1.0 GENERAL INFORMATION**

### **1.1 Title of Study**

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### **1.2 Principal Investigator's Status**

SMS Staff ☐ KATH Staff ☐ Student ☐ Other ☐ Please specify ☐

### **1.3 Purpose of Research**

Non Degree Purposes ☐ Diploma ☐ 1<sup>st</sup> Degree ☐ 2<sup>nd</sup> Degree ☐ PhD ☐

### **1.4 Nationality of Principal Investigator**

Ghanaian ☐ Non- Ghanaian (Resident) ☐ Non-Ghanaian (Non-Resident) ☐

### **1.5 Principal Investigator**

Name	
Degree(s)	
Title: Prof/Dr/Mr/Miss/Ms	
Institution & Department	
Telephone:	Postal Address:
Email:	

### **1.6 Co-Investigator (I)**

Name and Signature	
Degree(s)	
Title: Prof/Dr/Mr/Miss/Ms	
Institution & Department	

Telephone:  233-244-785-208  Email:	Postal Address:
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### 1.7 Co-Investigator (II)

Name and Signature	
Degree(s)	
Title: Prof/Dr/Mr/Miss/Ms	
Institution & Department	
Telephone:  Email:	Postal Address:

List all other co-investigators below (names, degrees, departments and institutions).

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### 1.8 If this is a student project:

1.8.1 For which degree/diploma is the study being conducted? *(Please state specific degree and Institution)*

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### 1.8.2 Who will be the supervisor? *(Check where Applicable)*

☐ Principal Investigator      ☐ Other *(fill in details below)*

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Name and Signature of Supervisor (If different from PI)	
Department	



Telephone:	Postal Address:
Email:	

**1.9 Where will the Research be carried out (site)?** (Provide name of Hospital/Institution and specific Department or Town/District/Village etc.)

--

\*Please submit proof of notification or written approval/permission on official letterhead from proposed research site/facility

**1.10 Have you had Good Clinical Practice (GCP) or Good Laboratory Practice (GLP) training in the past three years?**

Yes ☐

No ☐

N/A ☐

Please state the name of the place and year of training.

\_\_\_\_\_

—

**1.11 If this is a new drug trial, do you have Food and Drugs Board Approval?** Yes ☐ No ☐ N/A ☐

**1.12 Can your work be classified as research?** (Read the following statements and check where applicable):  
The activity I wish to undertake is a systematic investigation<sup>1</sup>, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge<sup>2</sup>.

Yes (my work is research) ☐

No (my work is not research) ☐

<sup>1</sup> Typically a predetermined method for studying a specific topic, answering a specific question(s), testing a specific hypothesis(es), or developing theory. Examples: observational studies, interview or survey studies, group comparison studies, program evaluation, test development, interventional research.

<sup>2</sup> Typically requires that results (or conclusions) of the activity are intended to be extended beyond a single individual or an internal program. Examples: activities where there is an intent to publish the results in a peer-reviewed journal or to present at a regional or national meeting, as well as, theses or dissertation projects conducted to meet the requirements of a graduate degree.

**1.13 Does your work involve human participants?** Yes ☐ (Check below, where applicable): No ☐  
but my work involves identifiable human tissue/records No ☐ (please consult us, your proposal may not require ethics review)

☐ My work will involve a living individual about whom an investigator conducting research obtains data through interaction<sup>3</sup> with the individual

☐ My work will involve a living individual about whom an investigator conducting research obtains data through interaction<sup>4</sup> with the individual.

☐ My work will involve a living individual about whom an investigator conducting research obtains identifiable<sup>5</sup> private information<sup>6</sup>.

☐ My work will involve using records already gathered on people.

☐ My work has earlier been approved by CHRPE (please submit letter of approval or quote CHRPE Reference Number)

☐ My work will involve using human samples. If so, where will the samples be kept?

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**Note:** Ethical issues surrounding the storage of blood and/or tissue samples internationally stipulate that if blood specimens are to be stored for future analysis and it is planned that such analysis will be done outside the facility/country where research is to be conducted, then the blood must be stored in the facility with release of sub-samples only conditional on approval of such a project by authorities of the facility as well as CHRPE.

## 1.14 Work Plan

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<sup>3</sup> Both physical procedures (e.g. venipuncture) and manipulations of living individuals or the living individuals' environments.

<sup>4</sup> Communication or interpersonal contact between the investigator (or research team) and the living individual. Examples: interviews, questionnaires, surveys, observations, manipulations of subject behaviour, diet, or environment, physical measurements, specimen collection (e.g. blood tissue), administration of experimental drugs or devices.

<sup>5</sup> If 1) the identity of the individual from whom the information was obtained is ascertained or may be readily ascertained by the investigator; or 2) the identity of the individual from whom the information was obtained is associated or may be readily associated with the information.

<sup>6</sup> Private Information: information about behaviour that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place or information that has been provided for specific purposes that the individual can reasonably expect will not be made public (e.g. medical record, employee or student records).

Project Start date:		(dd/mm/yr )
Project End date:		(dd/mm/yr )
Recruitment Start Date:		(dd/mm/yr )
Recruitment End Date:		(dd/mm/yr )

**1.15 How do you intend to fund the study?**

Donor/Grant ☐ (please name sponsor)

KNUST/KATH ☐ (please specify fund)

Ghana Government ☐ (please name agency)

Other ☐ (please name agency)

Self (please explain how you can guarantee this, if for clinical or interventional research)

**2.0 INFORMATION ABOUT YOUR PROPOSED RESEARCH**

**2.1 Study Background** (including relevant African and/or Ghanaian Literature, with references)

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**2.2 Study Aim and Objectives**

--

**2.3 Study Hypothesis or Conceptual framework**

--

**2.4 Study Design**

## 2.5 Procedures to be undertaken

Please mark ☒ all research procedure(s) that will be employed:

Record review ☐

Interview schedule or guide (must be attached) ☐

Questionnaire (must be attached) ☐

Physical Examination ☐

Drug or other substance administration ☐

X-rays ☐

Biopsy ☐

Isotope administration ☐

Blood sampling: venous ☐ ; arterial ☐

Please summarise all procedures/processes to be involved in the study (*maximum of 1 page*):

## 2.6 Inclusion and Exclusion criteria for the Study Population (*Please list and explain where necessary*)

## 2.7 Please describe how you will contact and maintain same with participants

## 2.8 Please describe how you will undertake the consent process and its documentation

## 2.9 Will participants be completely anonymous? Yes ☐ No ☐

If no, explain how participants' identities will be protected

--

**2.10 How long, and in what way will records be retained?**

--

**2.11 Who will have access to the Study Data?**

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**2.12 Risks to participants** *(including possible loss of confidentiality, discomfort to participants, delays in service delivery etc)*

--

*Risk should, as much as possible, be minimal i.e. the probability and magnitude of harm or discomfort anticipated in the research should not be greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological exam or test.*

**2.13 Methods of minimising risks of participation in the study**

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**2.14 Potential direct benefits to participants** *(benefits that **only** research participants hope to gain as a result of participating in this study)*

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**2.15 Potential benefits to study population, science and/or society** *(relevance of proposed study to society)*

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**2.16 Sample size** *(please justify statistically, the selected number in your proposal)*

Number of participants to be enrolled per year	
Total number of study participants	

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**Principal Investigator's Signature**

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 (dd/mm/yr)

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**Name of Investigator**

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**Student's Signature *(if applicable)***

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 (dd/mm/yr)

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**Supervisor's Signature *(if applicable)***

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 (dd/mm/yr)

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**Name of Supervisor**

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42.

43.

#### 44. ANNEX 3.

##### GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

RESEARCH AND DEVELOPMENT DIVISION

P.O BOX MB 190

ADABRAKA POLYCLINIC

OPPOSITE ACCRA PSYCHIATRIC HOSPITAL

CATHEDRAL SQUARE

CASTLE ROAD

hru-ghs.org

**Tel: (233) (021) 681109 Fax: (233) (021) 226739**



#### PROTOCOL SUBMISSION REQUIREMENTS

Thirteen sets (bounded) of new protocol must be submitted to the Ghana Health Service ETHICAL REVIEW COMMITTEE for consideration, at least two months before the starting date of the proposed study. Each set must include copies of the following:

1. Principal Investigator's Application for submission
2. Cover letter from head of the Principal Investigator's Institution (Institutional Support letter)
3. A letter affirming that the protocol has gone through a scientific review and has been approved. (if applicable)
4. Full Protocol
5. Consent forms )
6. Field guide i.e. questionnaire, enrolment forms, tool
7. Curriculum vitae of investigators ( CV must not be more than 1 year old)
8. Completed ERC checklist (copy attached)
9. Insurance Cover for participants if the proposed project is a Clinical/Vaccine Trial Study
10. Transfer Agreement for shipment of Specimen/ Biological materials
11. Letters from Participating/Collaborative Institutions involved in the study
12. Budget for the study
13. Administrative information on Sponsors
14. Institutional Review Boards Approval letter
15. Any other additional/relevant informational or document that may facilitate the review process.
16. Food and Drugs approval letter (if study is clinical trial)
  
16. A CD copy of the full protocol and all relevant supporting documents
17. Please ensure that the protocols are signed by all collaborative institutions involved (if the study is multi-centre trial)

**Note: Please note that late submissions (i.e. Two weeks before the Committee's specified meeting days) would not be accepted)**

#### **Meeting Days**

*The Ghana Health Service Committee Ethics Review Committee meets on the forth Wednesday of every other month (every two months).*

#### **Submit Applications to:**

Postal Address

The Chairman or Administrator

Ghana Health Service Ethics Review Committee

Research and Development Division

P.O.Box MB 190

Accra- Ghana

Delivery Address

The Chairman or Administrator

Ghana Health Service Ethics Review Committee

Health Research Unit

Adabraka Polyclinic

Opposite Accra Psychiatric Hospital

Cathedral Square – Castle Road

45.