GUIDELINES FOR THE WRITING OF DISSERTATIONS FOR FELLOWSHIP

GHANA COLLEGE OF PHYSICIANS AND SURGEONS

Updated: January, 2023

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1.0 INTRODUCTION

The Fellowship programmes 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 detailed research by the senior resident, which is assessed towards the final evaluation for the award of the Fellowship qualification.

Each senior resident will be assigned a Supervisor by the Head of Department to guide in the preparation, writing and submission of the dissertation.

The department 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.

2.0 CORE REQUIRED COURSES FOR FELLOWSHIP PROGRAMME AND DISSERTATION WRITING

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

- Scientific communication
    - Proposal writing
    - Use of references
    - Presentation skills
- Advanced Research Methods
- Systematic Review and Meta Analysis

3.0 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.

- Conceptualization phase: This involves the selection of topic for dissertation. This will be done under the guidance of the supervisors who have been assigned to the resident.
- Zero draft of dissertation proposal to be reviewed by Supervisor
- Final draft of the proposal to be presented to the Rector (GCPS) by the Head of Department for its review.
- Final proposal approved/disapproved by Reviewers.

- Proposal submitted to Ethics Review Committee if approved.
- Start of Study
- Data Collection
- Data Analysis
- Report Writing
- Notice of intent to submit Dissertation (Selection of Reviewers by the Faculty Board for approval of the Academic Board at this stage)
- Submission of Dissertation to Head of Department
- Submission of Dissertations to the Rector by the Head of Department for onward submission to the suggested Reviewers/Examiners
- Return of Dissertation report to the Rector
- Defense of Dissertation
- Reviewers/Examiners comments to the Candidate and copy the Faculty Chair
- Submission of the "Final Approved Version" of Passed Dissertation to College

4.0 THE DISSERTATION PROPOSAL

PROCESS GUIDE FOR SUBMISSION OF DISSERTATION PROPOSALS

PROCESS
Conceptualization phase: Resident meets HOD/ Training Coordinator and indicates readiness to commence Dissertation
HOD/Training Coordinator appoints Supervisor(s)
Supervisor(s) guides the Resident to select a topic
Resident writes the Proposal under the guidance of the Supervisor(s)
Proposal is presented to and reviewed by the Department
Final Proposal is submitted by the HOD

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 Contents
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

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.

5.0 GENERAL SPECIFICATIONS FOR THE FORMAT OF THE FINAL DISSERTATION REPORT

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

1. The final dissertation shall be written in English;
2. It should contribute to knowledge in the chosen field, show originality and should consist of the candidate's own account.
3. The dissertation should have between 15,000 and 20,000 words excluding the cover page, table of contents, abstract, tables, figures, appendices and references
4. The word count of the dissertation should be indicated on the title page
5. The final dissertation should be submitted with a Turnitin similarity report. The level of similarity should not be more than 25%

The document must be written in the following format:

a. The font should be New Times Roman.
b. The typeface should be 12-point font size, 1.5 spacing.
c. 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.
d. Graphs or tables may be used to illustrate the dissertation. Such Tables or Figures should be numbered consecutively based on Chapter numbers.
e. Chapter sections and sub-sections should be numbered using alphanumeric in a hierarchical order.
f. 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.

6.0 GENERAL OUTLINE OF THE DISSERTATION

6.1 Cover and Title Pages

The cover page should be as shown below

Ghana College of Physicians and Surgeons

Name of Faculty

Approved Title of the Study

Author Name & Titles

Month, Year

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

Word Count

Month, Year

6.2 Introductory Pieces

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

b. Certification page (supervisors' signatures)
c. Acknowledgement page
d. Abstract (with keywords)
   An abstract of not more than 500 words organised under the following headings: introduction, methods, results, and conclusions.

e. Table of Contents
f. List of Tables
g. List of Figures
h. List of Abbreviations

6.3 Abstract (up to 500 words)

This should be a structured summary of the proposed research. It should have the following headings:

a. Introduction
b. Methods
c. Results
d. Interpretation and conclusions.

6.4 Table of Contents

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

6.5 Introduction

Content will be determined according to the 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.

6.6 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.

6.7 Literature Review

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 about 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.

6.8 Materials and Methods

a. This describes in 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:
b. The study design
c. The study setting
d. Study population and sampling
e. 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.
f. Data Collection and Measurements
g. 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.
h. Measurement tools (e.g. clinical examination, questionnaire…)
i. Measurement methods (detailed description of how measurements will be done)
j. Validity and reliability of measurement instrument (if applicable)
k. Quality control
l. Management and Analysis. 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.

6.9 Ethical and legal considerations

a. Approval of study by the relevant Faculty Procedures
b. Ethical approval from the relevant Institutional Review Board (IRB)
c. 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:
d. A general description of the study and why the individual is being invited to take part in the study
e. Voluntary participation (no one will be forced to take part in the study)
f. Privacy of information/confidentiality
g. Potential harms and benefits
h. Conflict of Interest if any

6.10 Results

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.

6.11 Discussion

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.

6.12 Conclusions and Recommendations

This section should state the main conclusions from the study and have any specific recommendations in the light of the findings of the study

6.13 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 Vancouver style of referencing must be used.

6.14 Appendices

This must include the:

a. Data Collection Instrument
b. Letters of approval
c. Consent forms including Assent Form in case of children
d. IRB Approval

7.0 SUBMISSION OF THE DISSERTATION

Residents must submit three loosely bound copies of the dissertation to the Head of Department, at least three months before the final examination. An electronic version 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.

8.0 EXAMINATION OF THE DISSERTATION

The dissertation shall be examined in two parts:

a. Marking of the dissertation will be done by two (2) examiners approved by the Academic Board of the College
b. Oral defence of the dissertation will be conducted as part of the oral examination for the Fellowship by both external and internal examiners.

c. The oral defence will last for one hour and thirty minutes. The candidate will do a presentation of their project for thirty minutes and then have an hour interaction with the examiners. The supervisor of the dissertation may sit in the oral examination but will not be one of the examiners.

9.0 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 Chairperson of the Faculty.

The candidate will submit to the College three Bound Copies and three electronic 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.

10.0 PROPOSED TIMELINE FOR WRITING OF FELLOWSHIP DISSERTATION

No.	Activity	Proposed Timelines	Year
1	Assignment of supervisors by HOD	First two weeks of admission into Fellowship programme	
2	Conceptualization phase	First two months of admission into Fellowship programme	
3	Zero draft of proposal submitted to supervisors.	By end of fourth month of First year of Fellowship programme	Year 1
4	Supervisors' comments to candidates	By end of fifth month of first year of Fellowship programme	
5	Submission of revised proposal to supervisors.	By end of sixth month of first year of Fellowship programme	
6	Submission of final approved proposal to HOD.	By second week of seventh month of first year of Fellowship programme	
7	Submission of dissertation proposal to Rector by HOD.	By end of seventh month of first year of Fellowship programme.	
8	Final proposal approved by College	Within 3 months after submission to Rector's office	
9	Submit proposal to Ethics Review Committee.	By end of first year of Fellowship programme	
10	Data collection and writing of dissertation	First eight months of second year of Fellowship programme	Year 2
11	Submission of dissertation draft to supervisors	By 1st September for March exams By 1st April for September exams	
12	Supervisors' comments to candidates	By 1st October for March exams By 1st May for September exams	
13	Submission of final draft to supervisors	By 1st December for March exams By 1st June for September exams	
14	Submission of dissertation to HOD	By 15th December for March exams By 15th June for September exams	
15	Submission of Dissertation to Rector by HOD.	By first Friday in January for March exams By 30th June for September exams	
16	Defence of Dissertation	March and September Examinations of College	
17	Submission of Final Approved Version of Passed Dissertation to the College	Two months after dissertation defence	
18	Graduation of senior residents	1st or 2nd week in December	

11.0 ANNEXES

11.1 ANNEX 1: ETHICAL AND PROTOCOL REVIEW COMMITTEE UNIVERSITY OF GHANA MEDICAL SCHOOL

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.

a. 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.

b. 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**.**

c. **All Researchers involved should sign the proposal** prior to its presentation to the Head of Department**.**

d. Proposal should have a **Font of size 12** and **Spacing 1.5**.

e. **A proposal coming from outside the Medical School attracts a processing fee**.

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

1. **TITLE PAGE**

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

2. **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)

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

a. Introduction
b. 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

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

d. Hypothesis (if applicable)
   The expected association/relationship between one or more independent variables and the dependent variable which the study will establish.

4. AIM(S)

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

5. 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).

6. LITERATURE REVIEW

Limit of 5pages for literature review

7. METHODOLOGY *(Limit 8 pages for Methodology*)

a. Study design**:**
   i. Human studies- could be retrospective (case-control), prospective (cohort, clinical trial, case-control) or cross-sectional.

b. Study sites
   i. Describe site briefly including facilities available

c. Subjects/study population
   i. Inclusion/exclusion criteria

- List inclusion and exclusion criteria separately.

d. Sample size determination
   i. Use appropriate Power Calculations for type of study

e. Procedures to be used
   i. Data collection methods and instruments.
   ii. Should be reproducible by other investigators
   iii. Needs to be precise.

f. Data handling

May include
   i. Coding
   ii. Quality control (pre-testing, supervision, training) measures.
   iii. Data security and confidentiality

g. Statistical analysis
   i. Descriptive statistics (frequency, central tendencies, associations)
   ii. Inferential statistics (test of means, correlation coefficient, etc)

8. DISSEMINATION OF RESULTS

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

9. REFERENCES

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

10. ETHICAL ISSUES

a. For Human Subjects
   i. Consider Recruitment and sampling procedures, Potential risks and benefits, confidentiality.
   ii. For vulnerable subjects (children, pregnant women, institutionalized subjects), state how subjects' protection will be ensured.
   iii. Provide **Consent Form** with simple and clear language.

b. For Vertebrate Animals
   i. Justification for use of animals
   ii. Housing and veterinary care

iii. Processes to minimize discomfort
iv. Euthanasia

11. TIMELINES/WORK SCHEDULE

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

12. PERSONNEL OF THE STUDY TEAM INCLUDING PERCENTAGE EFFORT

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

13. BUDGET & LOGISTICS

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

14. APPENDIX

a. Questionnaire (if any)
b. Any other attachments

11.2 ANNEX 2 – COMMITTEE ON HUMAN RESEARCH, PUBLICATIONS AND ETHICS

COMMITTEE ON HUMAN RESEARCH, PUBLICATIONS AND ETHICS

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY,

SCHOOL OF MEDICAL SCIENCES &

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. 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 ☑**
A For all research:			
☐ 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. Where applicable:			
☐ **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

1.2 Principal Investigator's Status

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

1.3 Purpose of Research

Non Degree Purposes ☐ Diploma ☐ 1st Degree ☐ 2nd 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:

1.7 Co-Investigator (II)

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

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

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)*

_____

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

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

Name and Signature of Supervisor (If different from PI)	
Department	
Telephone: Email:	Postal Address:

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[1], including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge[2].

Yes (my work is research) ☐ No (my work is not research)☐

[1] *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.*

[2] *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 interraction[3] with the individual

☐ My work will involve a living individual about whom an investigator conducting research obtains data through interaction[4] with the individual.

☐ My work will involve a living individual about whom an investigator conducting research obtains identifiable[5] private information[6].

☐ 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?
_____

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.

[3] *Both physical procedures (e.g. venipuncture) and manipulations of living individuals or the living individuals' environments.*

[4] *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.*

[5] *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.*

[6] *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).*

1.14 Work Plan

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)*

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?

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

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

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

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	

_____

Principal Investigator's Signature (dd/mm/yy)

_____ **Name of Investigator**

_____

Student's Signature *(if applicable)* (dd/mm/yy)

_____

Supervisor's Signature *(if applicable)* (dd/mm/yy)

_____

Name of Supervisor

11.3 ANNEX 3 – GHANA HEALTH SERVICE REVIEW COMMITTEE

GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

RESEARCH AND DEVELOPMENT DIVISION

P.O BOX MB 190

ADABRAKA POLYCLINIC

OPPOSITE ACCRA PHYCHIATRIC 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 I 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)
17. A CD copy of the full protocol and all relevant supporting documents
18. 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

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