

**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