GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE
REQUIREMENTS FOR SUBMISSION OF RESEARCH PROTOCOLS

1.0 Submission of Application for Ethics Review and Approval

- All applications for ethics review of research should be submitted to the ERC secretariat.
- The Application letter must be signed by the PI.
- Where PI and researchers are all foreigners, a Ghanaian researcher must be included in the team, and should include support letters and CV(s).
- Support letters of all collaborators and collaborating institutions should be included.

2.0 Deadline for Submission of Application

- Prospective researchers must submit their protocols and other relevant documents two weeks prior to the next ERC meeting. The deadline for submission for each month is posted on the GHS website

3.0 Student's Application

Applications shall be submitted under the responsibility of a supervisor involved in the oversight of the student's work or in the student's name, co-signed by the supervisor.

4.0 Protocol Submission

An application for ethics review of a proposed health related research shall be submitted by a Principal Investigator (PI) qualified to undertake the study. The PI is directly responsible for the ethical and scientific conduct of the research.

5.0 Protocol Presentation format:

The Standard Font size should be 12, 1.5 spacing, and pages printed on one side only.

The applicant should submit all documents required for ethical review of the proposed research. These may include but is not limited to:

i. Principal Investigator's Application for submission
ii. Co-Investigator(s)' Support letter(s)
iii. Cover letter from head of the PI's Institutions i.e. (Institutional Support letter for the study (where applicable)
iv. Confirmation letter from collaborator(s) or participating/collaborating institution involved in the study
v. Permission letter to the study site (s)
vi. Material Transfer Agreement (MTA) for shipment of specimen/biological materials (where applicable)

vii. Administrative Information on the sponsors of the study
viii. Signed agreement between the sponsor and the PI (where applicable)
ix. Signatory page of key persons of the collaborating institutions involved in the study i.e. Sponsor Signatory Approval Page duly signed, with date (where applicable)
x. A statement that the researcher(s) agree to comply with ethical principles set out in relevant guidelines
xi. Completed GHS-ERC administrative information form (copy can be accessed from GHS-website)
xii. Completed GHS-ERC checklist (copy can be accessed from GHS-website)
xiii. Full Protocol (refer to recommended format for research protocol) including:

a). Table of content,
b). List of abbreviation,
c). Summary of research
d). Main protocol (Background/introduction, literature review, methodology, etc)

- Detailed budget
- Work plan
- List of study references
- Information sheet and written Informed Consent form and (with dates and version number) and translations into the local language (where necessary)
- Written Parental Consent form for children < **15years** (if study involves Minors)
- Written Parental Consent for & Assent form for children < 18 years (**15-17years)** (if study involves Adolescent).
- All data collection forms to be used in the research including but not limited to case report forms, diary cards, questionnaires, interview schedules, etc. clearly indicated and dated.
- Referral forms for treatment (where applicable)
- All forms, documents, advertisements to be used in the recruitment of potential participants (where applicable)
- Any other information deemed necessary to facilitate the review process.
- CV(s) of Principal Investigator and Co-Investigator(s), Collaborator(s) (Abridged, not more than 3 pages, relating to current work)

Note: The protocol should be paged sequentially, and contents arranged as above

5.1 Additional requirements for Clinical Trials:

- Summary of previous study i.e. Phase 1 & Phase II studies (where applicable)
- 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

- Investigational Product Brochure for the study
- Data Safety Monitoring Board (DSMB) membership and Charter of Work/Current Curriculum Vitae of members.
- Insurance cover for study participants
- Scientific review approval
- Food and Drugs Authority approval letter for use of the Investigational Product/ Devices and clinical trial approval Current CVs of PI & Co-Investigators (Abridged – Three pages relating to current work)
- Clinical trial registration with Pan African Clinical Trial Registry (PACTR)
- For multi-country studies, Ghana specific addendum/proposal is required.

5.2 Additional Requirements by Undergraduates, and Postgraduate Students:

- Covering letter and CV of supervisor
- Covering letter from school/college confirming student status
- Students not taking their academic programme in Ghana are required to identify a local supervisor and submit his/her covering letter and CV
- Ethics Approval letter from the student's foreign university

6.0 Number of Copies of Protocol for New Submission:

- **Institutional/Individual/PhD & Fellowship Students**:
  Applicant shall submit **4 hard copies (strictly comb bound)** of the full research protocol with the items indicated above **after the electronic version has been accepted by the secretariat.**

- **Master/Undergraduate Student Protocols:**
  Applicant shall submit the full research protocol with the items indicated electronically only.

Note: The full protocol together with all supporting documents must first be submitted to the ERC Secretariat via email (ethics.research@ghs.gov.gh) for administrative checks before final submission for ERC review. This should be done at least a week before the deadline of submission for that particular month.