GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE RECOMMENDED FORMAT FOR A RESEARCH PROTOCOL

The information below is a guide for the Principal Investigator regarding the content of the protocol to be submitted to ERC

General information

- Protocol title, protocol identification number (if any), and date.
- Name and address of the sponsor/funder.
- Name and title of the investigator(s) who is (are) responsible for conducting the research, and the address (including email address) and telephone number(s) of the research site(s), including their responsibilities.
- Name(s) and address(es)(email address) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the research.

Protocol summary

The protocol summary should be no more than 300 words and at the most, a page long (font size 12, 1.5 spacing). Summarize all the central elements of the protocol, for example the background, rationale/objectives, methods, and expected outcomes. It should stand on its own, and not refer the reader to points in the project description.

Background and Rationale

The Rationale specifies the reasons for conducting the research in the light of current knowledge. It should include a well-documented statement of the need/problem that is the basis of the research, the cause of this problem and its possible solutions. It should answer the question of why and what: why the research needs to be done and what will be its relevance. The magnitude, frequency, affected geographical areas, ethnic and gender considerations etc. of the problem should be followed by a brief description of the most relevant studies published on the subject.

Literature Review with References

The protocol should provide relevant reviewed literature related to the subject area of the study in the last 10 years at least.

Study goals and objectives

Goals are broad statements or general objective of what the study hopes to accomplish. Specific objectives are statements of the research question(s). Furthermore, the specific objectives must be related or come out of the goals/general objectives. They must also be SMART (i.e., specific, measurable, achievable, relevant and time-oriented). After statement of the primary objective, secondary objectives may be mentioned.

Methodology

The methodology section is the most important part of the protocol. The scientific integrity of the study and the credibility of the study data depend substantially on the study design and methodology. The methodology section of the protocol should include information on the type of study, vividly describe the study area, the study variables, the study population or the sampling

frame, who can or cannot take part (the inclusion/exclusion criteria), the sample size determination, the sampling procedure/approach, the data collection techniques/tools, the data processing approach, the data/statistical analysis of the objectives, the quality control and assurance, the study limitations, and the ethical consideration of the study. It should include detailed information on the interventions to be undertaken, procedures to be used, measurements to be taken, observations to be made, laboratory investigations to be done etc. If multiple sites are engaged in a specified protocol, methodology should be standardized and clearly defined.

In the describing the study area, the protocol should provide a concise but brief description of the study area, including reasons for their selection and evidence of approval by the relevant authorities in the study area.

Interventions should be described in detail, including a description of the drug/device/vaccine that is being tested. Interventions could also be in the realm of social sciences for example providing training or information to groups of individuals.

Procedures could be biomedical (collection of blood or sputum samples to develop a diagnostic test), or in the realm of social sciences (doing a questionnaire survey, carrying out a focus group discussion as part of formative research, observation of the participant's environment, etc.).

Standardized and/or documented procedures/techniques should be described and bibliographic references, if not provided earlier should be provided. Instruments which are to be used to collect information (questionnaires, qualitative guides, observation recording form/checklist, case report forms etc.) must also be provided.

In the case of a randomized controlled trial additional information on the process of randomization and blinding, description of stopping rules for individuals, for part of the study or entire study, the procedures and conditions for breaking the codes etc. should also be described. A graphic outline of the study design and procedures using a flow diagram must be provided. This should include the timing of assessments.

Safety Considerations

The safety of research participants is foremost. Safety aspects of the research should always be kept in mind and information provided in the protocol on how the safety of research participants will be ensured. This can include procedures for recording and reporting adverse events and their follow-up, for example. It is useful to remember that even administering a research questionnaire can have adverse effects on individuals.

Follow-Up

The research protocol must give a clear indication of what follow up will be provided to the research participants and for how long. This may include a follow up, especially for adverse events, even after data collection for the research study is completed.

Quality Assurance

The protocol should describe the quality control and quality assurance system for the conduct of the study, including GCP, follow up by clinical monitors, DSMB, data management etc.

Expected Outcomes of the Study
The protocol should indicate how the study will contribute to advancement of knowledge, how the results will be utilized, not only in publications but also how they will likely affect health care, health systems, or health policies.

Dissemination of Results and Publication Policy
The protocol should specify not only dissemination of results in the scientific media, but also to the community and/ or the participants, and consider dissemination to the policy makers where relevant. Publication policy should be clearly discussed- for example who will take the lead in publication and who will be acknowledged in publications, etc.

Problems Anticipated
This section should discuss the difficulties that the investigators anticipate in successfully completing their projects within the time frame stipulated and the funding requested. It should also offer possible solutions to deal with these difficulties.

Project Management
This section should describe the role and responsibility of each member of the team

Data Management and Statistical Analysis
The protocol should provide information on how the data will be managed, including data handling and coding for computer analysis, monitoring and verification. The statistical methods proposed to be used for the analysis of data should be clearly outlined, including reasons for the sample size selected, power of the study, level of significance to be used, procedures for accounting for any missing or spurious data etc. For projects involving qualitative approaches, specify in sufficient detail how the data will be analyzed and reported.

Ethical Considerations
The protocol should have a detailed description of ethical considerations relating to the study. This should not be limited to providing information on how or from whom the ethics approval will be taken and permission to study site, but this section should document the issues that are likely to raise ethical concerns such as voluntary participation and withdrawal, potential risks and how they will be addressed, benefits, privacy/confidentiality, and compensation. It should also describe how the investigator(s) plan to obtain informed consent from the research participants (the informed consent process), duration of the interview, data management/usage, data storage and duration, data ownership, and declaration of conflict of interest. It should be noted that there is no research that does not have any risk and so the statement often used by researchers that "this study or research does not have any risk" is not appropriate.

Budget
The budget section should contain an itemized breakdown of the funds (with a cedi equivalent if the budget is denoted in a foreign currency) for the study, along with a justification for each item.

Duration of the Project and Work plan
The protocol should specify the time that each phase of the project is likely to take, along with a detailed month by month timeline for each activity to be undertaken. The section must also outline detailed activities to be carried out in the study with specific dates. **It should include duration for ethical review processes for approval**.

List of study references
The main protocol should end with a list of references.

Participants' Information Sheet and Consent Forms
The approved version of the protocol must have copies of participants' information sheet and consent form, both in English and the local language in which they are going to be administered. If the research involves more than one group of individuals, for example healthcare users and healthcare providers, a separate specifically tailored participants' information sheet and consent form must be included for each group. This ensures that each group of participants will get the information they need to make an informed decision. For the same reason, each new intervention also requires a separate participants' information sheet and consent form.
NB: The final participants' information sheet and consent form approved by the ERC will be stamped, signed and dated for use in the study.

Other support for the Project
This section should provide information about the funding received or anticipated for this project from other funding organizations, letters of support from collaborators, study area approvals etc.

Other research activities of the investigators
The Principal investigator should list all current research projects that he/she is involved in, the source of funding of those projects, the duration of those projects and the percentage of time spent on each.

Financing and Insurance
Financing and insurance if not addressed in a separate agreement and where relevant should be described (**Where applicable**)

Curriculum Vitae of investigators
The abridged CV of the Principal investigator and each co-investigator(s) should be provided. In general each CV should not be more than 3 pages, unless a complete CV is specifically requested for.