NEW PROTOCOL SUBMISSION REQUIREMENTS

A new protocol must be submitted to PASS at least two months before the proposed commencement date of the research or two (2) weeks to the next scheduled Scientific Review Committee (SRC) meeting (usually first Monday of every month) and must include copies of the following:

1. Cover letter from PI listing the documents being submitted for review (Addition for student protocols; cover letter from Head of Department, Supervisor or Institution).
2. Executive summary and full Protocol (Please submit 4 hard copies and electronic copy of your protocol and related documents for scientific clearance).
3. Information sheet and Consent/Assent forms
4. Data collection tools; Field guides, questionnaire, screening/enrolment forms
5. Curriculum vitae of Investigators (Please attach most current CV)
6. Study Budget
7. Any other information and documents relevant to the review process (check items required by the SRC, page 3)

Diagram: Structure of Protocol submission processes and review at KHRC

PASS: Physical review for completeness and applicable requirements for submission to ethics committees

SRC: Protocols submitted through KHRC will first be reviewed by the Scientific Review Committee before ethical evaluation

GHS ERC: Clinical trials, multi country/site research, research conducted at GHS facilities

KHRC IEC: Human subject’s research conducted at Central part of Ghana (B.A), student’s research, Individual research projects, Institutional research, etc

FDA: Clinical trials of medicinal products (drugs, devices, etc)

GHS ERC – Ghana Health Service Ethical Review Committee
KHRC IEC – Kintampo Health Research Centre Institutional Ethics Committee
FDA – Food and Drugs Authority, Ghana
Please take note of the following:

- Investigators who are not affiliated to KHRC could submit electronic copy of the protocol and pay for cost of paper and printing/photocopying.
- The submitted study proposal will first be reviewed by the Scientific Review Committee (SRC) and if approved, forwarded to the ethics committee(s) for ethical evaluation.
- Study protocols are submitted simultaneously to the various ethics committees and FDA if applicable, after the SRC approval.
- The Kintampo Health Research Centre Institutional ethics committee (KHRCIEC) meets on the third Tuesday of every month. Please submit your study documents two weeks to the next scheduled meeting.
- The Ghana Health Service Ethical Review Committee meets on the last Wednesday of every month. Please submit your study documents two weeks to the next scheduled meeting.
- All study protocols submitted for ethical review shall attract review fees. Fees would be determined by the type of study protocol (clinical, Biomedical, Social sciences, student, etc) submitted for review.
- Please contact the PASS Administrator for guidance before submitting your final study documents for review

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Items required by the SRC in order to review a proposal

1. Title of the proposed research project.

2. Justification of the need for the research project.

3. Statements on the specific hypothesis (or hypotheses) to be addressed and on the aims and specific objectives of the research.

4. Description of the location where the research is to be conducted. If all or part of the research is to be performed outside of Kintampo District then justification is required for this. This includes laboratory analyses which need to be performed outside KHRC.

5. Names and qualifications of each member of KHRC staff who will be a principal investigator or co-investigator on the project. Names, qualifications and addresses of all external collaborators who will be principal or co-investigators should also be included.

6. Name(s) and address(es) of the proposed sponsor(s) for the research project should be indicated in the protocol.

7. The description of the type of research (cohort study, case-control study, clinical trial etc) should also be indicated. Further information on study design should be included as appropriate for the type of research. For example for a clinical trial the minimum information would include: trial design (cluster or individual randomization, parallel groups or cross-over), blinding techniques (none, double or single), methods and procedures for randomization should all be specified in the protocol.

8. The protocol should provide details of the study population including inclusion and exclusion criteria, processes to recruit study subjects, method and timing of allocation of study subjects into different investigational groups.

9. Sample size calculations should show the number of subjects who will be recruited for the study to achieve adequate power. The calculations must take into account realistic rates of refusal to participate and loss to follow-up. The assumptions on which the sample size calculations are based must be stated clearly. The feasibility of recruiting the required sample size within an appropriate time-frame should be discussed.
10. Description and justification of the interventions should be indicated. These should include the route of administration, dosage, frequency of administration, and treatment duration.

11. Description of any implications of the intervention for other medication or treatments which the study subjects may be receiving.

12. Description of all field, clinical and laboratory tests to be performed on the study subjects. This should consider the relevance of the procedures to the research objectives of the study.

13. Description of any inconvenience which study subjects will be subjected to during field, clinical and laboratory tests. This includes a full description of the methods and frequency of all measurements to be performed. Any potential risks to study subjects should be justified in detail.

14. Criteria for discontinuation of individual subjects from the trial.

15. Criteria for terminating the entire research project or any part of the study prior to the dates originally proposed.

16. Methods for investigating and recording adverse events and the provisions for dealing with any such events.

17. Provisions for compensation for any complications of adverse events arising from the trial interventions or trial procedures.

18. Procedures for holding subject identification codes, treatment records and case report forms. Records should be kept in a way which ensures that patient confidentiality is maintained.

19. Details of how the trial randomization code will be held. The procedures should ensure that the blinding is not broken inappropriately but that individual treatment allocations can be revealed if required for safety reasons. Under what circumstances the randomization code can be broken and by whom should be clearly stated.

20. Description of measures to ensure the safe handling, storage and eventual destruction of investigational materials.

21. Description of the methods to be used to analyse the results.
22. Time schedule for the planning, implementation and completion of the research project.

23. Description of information which will be given to the trial communities when seeking community agreement for a clinical trial to take place. This will include how and when the communities will be informed about the trial.

24. Description of information which will be given to the trial participants when seeking individual consent. This will include who will obtain consent and when and how they will do it. Reassurances must be provided that individuals will not be given undue inducements to participate in a trial.

25. Description of how staff will be recruited to work on a research project and how, when and by whom they will be trained.

26. Description of ethical considerations relating to the trial should be provided. This will include the details of the ethics committees from which approval is being sought.

27. Description of any medical care which will be provided during and after the trial. Any implications of such provision for the local health services should be fully discussed.

28. A reference list of literature referred to in the proposal must be produced. Three relevant key papers should be provided to assist the reviewers in considering the importance of the proposed research project.

Each research proposal should address all of the above points. If the investigators feel that any of the above points does not apply to their project they should state this in the research proposal or in a covering letter to the SRC. If one or more items are ignored without justification, it is likely to delay SRC approval.