

**KINTAMPO HEALTH RESEARCH CENTRE (KHRC)
 PROTOCOL ADMINISTRATION FOR STANDARD SUBMISSION (PASS)
 Protocol Submission Requirements**

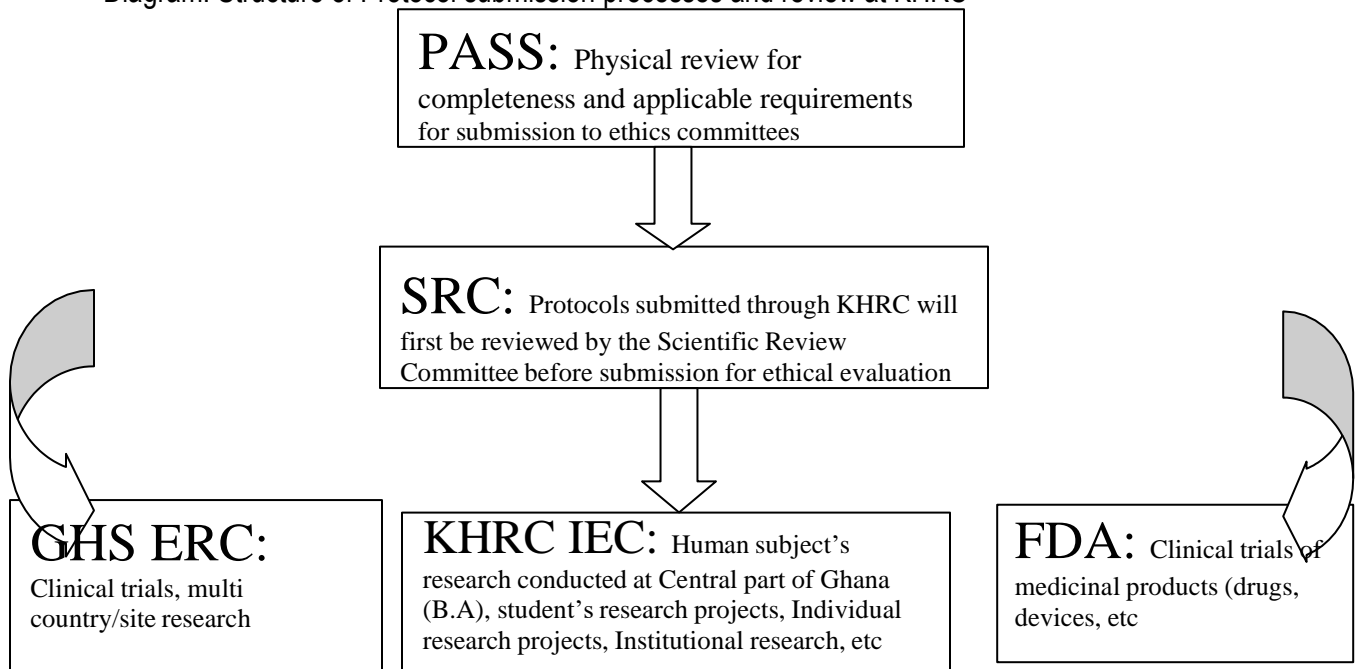
P.O BOX 200
 KINTAMPO, BRONG AHAFO REGION
 GHANA
 Tel: (+233) 556847860, EXT: 117

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 (clearly identified and dated), together with supporting documents and annexes.
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 recent CV)
6. Study Budget
7. Any other information and documents that could be of interest to the review process

Diagram: Structure of Protocol submission processes and review at KHRC



GHSERC – Ghana Health Service Ethical Review Committee
KHRCIEC – Kintampo Health Research Centre Institutional Ethics Committee
FDA – Food and Drugs Authority, Ghana

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Please take note of the following;

- *Investigators who are not affiliated with KHRC will be required to pay for the cost of paper and print/photocopies of the submitted documents (2 copies).*
- *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 before 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 before 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 if you have any questions*
- ***All study applications must be submitted electrically to the PASS & IEC Administrators***

Contact persons:

Fred Kanyoke
PASS & IEC Administrator
Kintampo Health Research Centre
P.O.Box 200
Kintampo, Ghana
Email: fred.kanyoke@kintampo-hrc.org
Ethics@kintampo-hrc.org
Tel: +233 556847860
+233 246954713

Ms. Ophelia Opoku
Assistant Administrator (PASS & IEC)
KHRC, Box 200
Kintampo, Ghana
Email: ophelia.opoku@kintampo-hrc.org
Tel: 0549629341

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**Kintampo Health Research Centre (KHRC) Scientific Review Committee (SRC)
Preferable Structure of Study Protocol - Guide**

Your study protocol should be guided by the following format;

- ✓ Title: This should be on a title page and must include the study title, name of Investigators (PI & Co-PIs/Supervisor(s)), Sponsor (if applicable), protocol version and date. For students, must include school and level of study.
- ✓ Table of content
- ✓ List of abbreviations
- ✓ Executive summary/Abstract (as far as possible in non-technical language): Should be limited to a page or two.
- ✓ Introduction: includes but is not limited to
 1. Background
 2. Problem statement
 3. Justification
 4. Study aims and/objectives
- ✓ Literature Review (if applicable)
- ✓ Methods: This should include but not be limited to
 1. Study design
 2. Study population and sampling
 3. Data processing methods and analysis plan
 4. Ethical considerations
- ✓ Results dissemination
- ✓ Timelines (this could be presented in a Gbant chart)
- ✓ Budget
- ✓ Referencing style: References complete, correct and consistent use of a referencing style
- ✓ Information sheet and consent/assent forms
- ✓ Data Collection Tools: Field guides, questionnaires, screening/enrolment forms, etc.
- ✓ CVs of investigators
- ✓ Additional information and documentation may be required for clinical trial protocols
- ✓ The protocol should be properly numbered.