

# R&D REGISTRATION AND IRB APPLICATION GUIDELINES

## R&D REGISTRATION GUIDELINES

1. Complete R&D registration application online at <https://sites.google.com/site/infectiousprings2013/>?
2. Print out confirmatory submission email.
3. Upload the electronic copy of the protocol/proposal at [kathrdu@gmail.com](mailto:kathrdu@gmail.com).
4. Send your confirmatory submission email print-out to the KATH Cash office of main accounts and collect payment voucher in return.
5. Pay the non-refundable KATH-IRB fees appropriate for the funding category at any of the Fidelity Banks at the hospital.
6. Submit one bound signed printed/hardcopy of the proposal, print-out of the confirmatory email and the official receipt of the KATH-IRB fees to R&D for processing. Proposal/Protocol (*sample format attached as a guide only*), should have been signed and dated by the PI or Co-PI.
7. R&D reviews the protocol/proposal and sends a copy of it to the HODs/Unit for comments/approval (*Applicants should no longer contact HODs/HOUs directly for their departmental approval*).
8. Based on comments from HODs/HOUs and R&D internal review, a Certificate of Registration (COA) will be issued for applicant to seek KATH-IRB approval (*See KATH-IRB application guidelines below*).
9. Collect your COA from R&D and proceed to make your submission to KATH-IRB

## KATH-IRB APPLICATION SUBMISSION GUIDELINES

10. Complete KATH-IRB Application form, obtainable from <http://www.kathhsp.org/units/research-and-development/>, and send it with all the required documents to the KATH-IRB Office located at the R&D.
11. Submit soft copies of all KATH-IRB required documents to [kathirb@kathhsp.org](mailto:kathirb@kathhsp.org) and copy [kathirb25@gmail.com](mailto:kathirb25@gmail.com)
12. Once KATH-IRB approval is granted, applicants are notified by either a phone call, email or text message to pick up their approved letters from the KATH-IRB office.
13. Next, the principal investigator notifies KATH-IRB the official start date of the study; and when the study closes.
14. The principal investigators of all approved research projects are required to submit quarterly report to the R&D Unit.
15. All protocol amendment(s) for approved research studies conducted at the hospital should receive KATH-IRB approval prior to implementation.

## **SAMPLE RESEARCH PROTOCOL/PROPOSAL GUIDELINES**

The Protocol/proposal should at least contain the following details:

- **Title page** (This page should have the title of the Protocol and the names, addresses, e-mail, departments and affiliations of Investigators).
- **Structured abstract (Maximum of 300)**
  - i. Background
  - ii. General Aim
  - iii. Methodology
  - iv. Expected Outcome
- **Background**
  - Problem Statement
  - Hypothesis (if applicable)
  - Aim(s)
  - Specific objectives
  - Literature review
- **Methodology**
  - Study design:
  - Study sites (Please indicate if it's a multicenter study and indicate the other centre)
  - Subjects/study population
- **Inclusion/exclusion criteria**
  - Provide inclusion and exclusion criteria appropriately
- **Sample size**
  - Procedures to be used
  - Data collection methods and instruments
- **Data handling**
  - 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, policy makers and study participants (where applicable)
  - At workshops, seminars and conferences
  - In different types of publications
- **Ethical issues**
  - Recruitment and sampling procedures, Potential risks and benefits,
  - Confidentiality
  - For vulnerable subjects (children, pregnant women, institutionalized Subjects), state how subjects' protection will be ensured.
  - Consent Form with simple and clear language.
- **Timelines/work schedule**
  - This may be in the form of a Gantt chart.
- **Personnel of the study team**
  - Please state all personnel involved in your study including the role of each member of the team
- **Budget & logistics**
  - To be detailed even if there is no external funding
  - This should include funding agency, total funds available to the project and the institution administering funds.
  - If it's a multicentre study, please give details of site specific budget with reference to KATH.
- **References**
- **Appendix**
  - Copy(ies) of all regulatory approvals already acquired elsewhere (eg GHS-ERC ,CHRPE, FDA etc ).
  - Questionnaire (if any)
  - Any other attachments
  - CV for the PI (maximum 2 pages)

## KATH-IRB APPLICATION FEES

Funding Category	Full Committee Review	Amendments Review
Studies Sponsored by KATH /Unit Budgets	(US\$100.00) or Cedi Equivalent	(US\$30.00) or Cedi Equivalent
Studies Sponsored by Local Ghanaian Organisations	(US\$500.00) or Cedi Equivalent	(US\$50.00) or Cedi Equivalent
Studies with International Funding (US\$15,000.00 – 500,000.00)	(US\$1000.00) or Cedi Equivalent	(US\$100.00) or Cedi Equivalent
Studies with International Funding (<US\$15,000.00)	(US\$500.00) or Cedi Equivalent	(US\$50.00) or Cedi Equivalent
Studies with Substantial International Grants/Contracts Research (>US\$500,000.00)	(US\$ 2000.00) or Cedi Equivalent	(US\$200.00) or Cedi Equivalent
Non-Ghanaian Investigators with no External Support	(US\$100.00) or Cedi Equivalent	(US\$10.00) or Cedi Equivalent
Ghanaian Lecturers/Professionals (Non-KATH Employees Without Funding)	Gh¢500.00	Free
Ghanaian Lecturers/Professionals (KATH Employees Without Funding)	Gh¢200.00	Free
Post Graduate Students with International Funding	(US\$100.00) or Cedi Equivalent	(US\$10.00) or Cedi Equivalent
Post Graduate Students with Local Funding	(US\$50.00) or Cedi Equivalent	Free
Post Graduate Students (Without Funding)	Gh¢100.00	Free
Undergraduate Students	Gh¢25.00	Free
Non-Ghanaian Students with no External Support	(US\$50.00) or Cedi Equivalent	Free
Continuing Review Application		Free

### **BANK DETAILS**

**Account Name:** Komfo Anokye Teaching Hospital Service Account  
**Bank:** Fidelity Bank  
**Account Number:** 1070031981539  
**Branch:** Ridge Tower  
**Currency:** **Ghana Cedis**

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**Bank Name:** Societe Generale, Ghana  
**Branch:** Kumasi Central  
**Branch Code:** 90602  
**Account Name:** Komfo Anokye Teaching Hospital  
**Account Number:** 332510003094  
**IBAN:** GH2880000990602332510003094  
**Swift Code:** SSEBGHAC  
**SWIFT No.** **SSEBGHAC**  
**Currency:** **US DOLLAR**