GUIDELINES FOR REGISTERING AND OBTAINING ETHICAL CLEARANCE FOR RESEARCH AT KATH

Obtaining ethical clearance for your research at KATH goes through a **2-step process**. Part 1 is the registration. This **first part** involves **R&D Review and presenting the proposed research to the Directorate/Unit(s)** where the research is intended to be conducted for the research to be certified as being **feasible for its conduct (Scientific and Technical Review)** in the respective Directorate/Unit. **The second part involves the ethical evaluation** of the proposed research by **the KATH-IRB**.

The processes involved have been outlined below as a guide to applicants. Please do not hesitate to contact the R&D Unit on **0322000617** for any clarification on any aspects of the guidelines.

PART1: Research 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.
4. Send your confirmatory submission email print-out to the KATH 's main revenue office behind Block A and collect payment voucher in return.
5. Pay the non-refundable KATH R&D registration/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 R&D registration/IRB fees to R&D for processing. Proposal/Protocol (***sample format on page 3 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, we will notify you by email to proceed to the KATH-IRB (See KATH-IRB application guidelines below).
9. This email does not constitute site approval or ethical clearance for the conduct of the study.

NOTE:

- ***Note that all sponsored research studies to be conducted at KATH must budget administrative charges/Indirect cost/Overheads cost/ Facilities and Administrative Rate in their budget. Consult R&D if you need further clarification(s).***
- ***All research studies to be conducted at KATH must have a collaborator (preferably a senior staff KATH employee) in the respective Directorate/Unit where the study is to be conducted.***
- ***Ethical clearance from the KATH IRB (see Part 2-next page) is required and mandatory for every research to be conducted at KATH even if the work has been approved by other IRBs.***

PART 2: KATH IRB Application Submission Guidelines

1. Complete KATH-IRB Application form and send it with all the required documents to the KATH-IRB Office located at the R&D *(The latest version of the KATH-IRB Application form and other accompanying forms will be sent to applicants via email after the initial registration process is completed as described in Part 1 above).*
2. Submit all the required set of documents (see checklist of attachments on the KATH-IRB Application) in soft and hard copy to the KATH-IRB Office located at the R&D.
   All soft copies should be:
   - exactly the same in content and arrangement order as the signed printed bound hardcopies (see arrangement order below).
   - merged into one file with filename format as "PI's Name plus the study title". e.g., Prof. Kofi Nti_UTI Study in Ghana
   - submitted via email to kathirb@kathhsp.org with copy to kathirb25@gmail.com
   - put either a pen drive or CD to be collected at the IRB office.

   The required number of signed printed hard copies should be:
   - bound in one document
   - submitted with soft copies on a pen drive or CD.
   - submitted to the KATH IRB Office
3. The arrangement **order** of both the soft (merged into one file) and all required hard printed copies (bound in one document) should be as detailed on the KATH-IRB application form.
4. Please note that all documents in submission to the KATH-IRB should be *versioned* and *dated*.
5. 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.
6. Next, the principal investigator notifies KATH-IRB the official start date of the study; and when the study closes.

NOTE:

- ***The principal investigators of all approved research projects are required to submit quarterly report to the R&D Unit.***
- ***All protocol amendment(s) for approved research studies conducted at the hospital should receive KATH-IRB approval prior to implementation.***

Administrative Approval

This kind of approval will be given to students up to undergraduate degree level OR studies undertaken by departments/units that do not require a Full Institutional Review Board (IRB) for the purposes of undertaking operational research. **However, if the results are to be published in a scientific journal, Full IRB approval would be required**. Such applications **will go through Part 1 as indicated above** after which R&D will issue an administrative approval. The R&D Unit may require such studies to undergo IRB review if there are appreciable risks involved.

PROPOSAL FORMAT GUIDELINE

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)

- *Background*
- *General Aim*
- *Methodology*
- *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 multicentre study and indicate the other centres)*
- *Subjects/study population*
- *Inclusion/exclusion criteria*
- *Sample size determination*
- *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, policymakers 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 the site-specific budget with reference to KATH.*

References

Appendix

- Copy(ies) of all regulatory approvals already acquired (e.g., CHRPE, FDA etc)
- Questionnaire (if any)
- CV for the PI (maximum 2 pages)
- Any other attachments