

JOINT CLINICAL RESEARCH CENTRE INSTITUTIONAL REVIEW BOARD/RESEARCH ETHICS COMMITTEE

Requirements for an initial submission:

Application for submission

The Principal Investigator(s) submit(s) a formal application to the IRB Office, asking for the review of the submission. The application is addressed to the IRB Chair. In response, the IRB office will provide a submission package consisting of requirements of the respective submission.

IRB Review fees

A non - refundable review fee of **\$1000** for foreign sponsored clinical trials and basic science studies, and **\$500** for epidemiological and social science studies. A non - refundable review fee of **\$500** for locally sponsored clinical trials and basic science studies, and **\$250** for locally sponsored epidemiological and social science studies.

Please note: the same fee is required if the original proposal/protocol were rejected and required re - submission necessitating full board review.

In addition the protocol should contain the following information:

- Full addresses and qualifications of the investigator (s).
- Full addresses and qualifications of the research assistants
- The address of the sponsor/source of the grant

Protocol Summary

- Protocol and Protocol-Related Documents including the following:
 - ✓ Investigator's brochure
 - ✓ Informed consent document in the language (s) in which it will be administered and how the informed consent will be sought.
 - ✓ Back-translation of the consent documents from the local language
 - ✓ Questionnaires in the language(s) in which they will be administered.
 - ✓ A clear justification of the study.
 - ✓ A justification for the targeted population.
 - ✓ A statement on the anticipated risks.

- ✓ A statement on the expected potential benefits.
 - ✓ A statement on compensation in case of any injuries to the participants as a result of study
 - ✓ Study budget
 - ✓ A statement of agreement to comply with ethical principles set out in the relevant guidelines.
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- ❖ A letter or letters of approval of the same study from the other institution (s) in case of multi centred studies or proposed studies by foreign investigators.
 - ❖ In case of a sub study, a letter or letters of approval of the main study, together with the protocol summary of that study.
 - ❖ A certificate for the competence in research ethics (for foreign investigators)

Note: *The above stated items constitute one copy. Fifteen copies of these will be required on submission.*

Other documents required for submission:

- Review Application Form 1 (attached)
- Review Application Form 2 (attached)

INVESTIGATIONAL NEW DRUG (IND) / DEVICE (IDE):

None IND IDE

If IND or IDE, please complete the information below:

FDA No.:.....
Name.....
Sponsor.....
Holder.....

PROCEDURE USE: Invasive Non-invasive

MULTI-SITE COLLABORATION: YES NO

FINANCIAL DISCLOSURE: YES NO

INSTITUTE RESEARCH CONTACT

Name:.....

Address:.....
.....

Telephone:.....

Fax:.....

E-mail:.....

REVIEW APPLICATION FORM 2

PARTICIPATING INVESTIGATORS:

Name	Institution	Telephone/Fax numbers
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		

TYPE OF REVIEW:

<input type="checkbox"/> Initial Review <input type="checkbox"/> Resubmission for Re-review <input type="checkbox"/> Protocol Amendment <input type="checkbox"/> Expedited Review	<input type="checkbox"/> Annual Continuing Review <input type="checkbox"/> Report Review <input type="checkbox"/> Protocol Termination
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SIGNATURES:

_____ Date:

Protocol Recipient

_____ Date:.....

Applicant/Investigator

APPROVAL:

_____ Date:

Chairman, JCRC-IRB/REC

COMPLETION:

_____ Date:.....

Secretary/Administrator, JCRC-IRB/REC

PROTOCOL NUMBER ASSIGNED: _____

BANK ACCOUNT INFORMATION:

Please Wire money to:

ACCOUNT NAME: JOINT CLINICAL RESEARCH CENTER

ADDRESS: Plot 101 Upper Lubowa Estates
P O Box 10005, Kampala Uganda
Tel: +256 414 201147/8
Fax: +256 414 342632
e-mail: jcrc@jcrc.org.ug

BANK NAME: STANBIC BANK UGANDA LIMITED

ACCOUNT NO: 024/00/637793/01
SWIFT Code: **SBICUGKX**
17 Hannington Road
P.O.Box 7131 KAMPALA, Uganda

Contact Person (at Bank): Catherine Asinde / Patricia Njoroge +256 312 224354 or
+256 312 224456 or +256 312 224600

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When using overseas banks, which are not on the SWIFT network, transfers should be made by telegraphic transfer directly to Stanbic bank Uganda where testing arrangements are in place, or directly to the correspondent bank where they are not. In the latter case the overseas bank must instruct the correspondent bank to SWIFT advise Stanbic Bank Uganda of the transfer. Failure to do this will delay the transfer.