COLLEGE OF SURGEONS OF EAST, CENTRAL AND SOUTHERN AFRICA
(ASSOCIATION OF SURGEONS OF EAST AFRICA)

East, Central and Southern Africa Health Community (ECSA-HC)
Plot No 157 Olorien-Njiro Road
P.O.Box 1009 Arusha – Tanzania
Phone: +255 27 2549362/5/6
Web: www.cosecsa.org
Email: coo@cosecsa.org
IRB Registration Number: 00011122

Submitting a COSECSA IRB application

1. Prospective applicants should direct their initial inquiry to the COSECSA IRB Secretary regarding submission procedures and committee meeting dates.

2. The COSECSA IRB secretary forwards the following to the applicant:
    - An application form (National REC Standard Application Form)
    - Guidance notes on completing the National REC Standard Application Form
    - A submission checklist
    - A declaration and signature page
    - A list of closing dates and meeting dates for the current year
    - A copy of the COSECSA IRB operating procedures (this document)

3. A response to an inquiry will be received within one week. The COSECSA IRB always endeavors to meet this target.

4. Upon receipt of an application, the details are processed by the COSECSA IRB Secretary and entered onto the database maintained by the Secretary.

5. If the application is complete and meets the requirements under this document / SOP, it is put forward for review at the next scheduled COSECSA IRB meeting.

6. Applications for consideration by the COSECSA IRB must include: (See Appendix II – Applicant's Checklist)
    - A completed application form and a signed declaration and signature page
    - Patient / subject study explanation leaflet
    - Insurance indemnity
    - Invitation letters
    - Informed consent form – if applicable
    - Questionnaires – if applicable
    - Current CV of the applicant

7. If the research application has been submitted to another REC/IRB, copies of letters of favorable ethics review, review with modifications or rejection should be included with the application

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8. Before submitting an application, the Principal Investigator of the research study to be reviewed should:
    - Be aware of and adhere to the procedures outlined in this Guideline
    - Ensure that there is adequate clinical indemnity for their research activity before embarking on it.
    - Where research is sponsored by external organisations such as pharmaceutical companies, researchers must be clear on their own liability, the liabilities of their employing organisation and the liabilities of external organisations, and must make sure there is adequate indemnity for all liabilities.
    - Know and understand the provisions of the Data Protection legislation in their jurisdiction.

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For the Ethical Review of Health-Related Research Studies, which are not Clinical Trials of Medicinal Products For Human Use as defined in S.I. 190/2004

Please DELETE "Yes; No; N/A" as appropriate

Application to include		**Document Version/ Date**		
Covering letter to the committee on headed paper	YES			
Application Checklist	YES			
Ethics application (**original** application signed and dated by Chief Investigator with **original** signature)	YES			
Consent Form (s) on headed paper	YES		NO	N/A
Information Leaflet / Sheet (s) on headed paper	YES		NO	N/A
Letter to Family Doctor on headed paper	YES		NO	N/A
Recruitment material/advertisement	YES		NO	N/A
Questionnaire / Interview Prompts	YES		NO	N/A
Genetic Consent Form (s) on headed paper	YES		NO	N/A
Consent Form (s) for Tissue or Organ Retention on headed paper	YES		NO	N/A
Research Proposal or Study Summary	YES		NO	N/A
Proof of Insurance for investigators. For researchers who are students in an academic institution proof of the insurance cover by the academic institution is required	YES		NO	N/A
CV of Principal Investigator, **signed and dated**	YES		NO	N/A
Other Documents: please list				