MAKERERE UNIVERSITY
SCHOOL OF HEALTH SCIENCES
RESEARCH AND ETHICS COMMITTEE (MakSHS-REC)
COLLEGE OF HEALTH SCIENCES

REC FORM 102

APPLICATION FOR ANNUAL REVIEW (RENEWAL) OF RESEARCH ACTIVITY

Note: Apply two months prior to expiry of approval

STATEMENT OF POLICY

It is the policy of the School of Health Sciences Research and Ethics Committee that, in the continuing review of on-going research, the entire study will be reviewed to ensure the continued protection of the rights and welfare of the human subjects. The (MakSHS-REC) follows, at minimum, the regulations set forth in the CIOMS Guidelines as the criteria for continuing review. The Continuing Review process must be no less stringent than the initial review.

The Principal Investigator is responsible for timely submission of a continuing review application to prevent any lapse in (MakSHS-REC) approval. (MakSHS-REC) regulations do not provide for exceptions to the requirement for continuing review. Therefore, failure by the Principal Investigator to ensure timely review is a serious matter that may lead to suspension or withdrawal of approval. **NO EXTENSIONS CAN BE GRANTED.**

If applying for **re-approval for long-term follow-up or data analysis only**, complete sections A, C,D,E, F, and H only.

Note submit application online: https://nrims.uncst.go.ug/

Also, send application to healthsciences.irb@gmail.com

A. STUDY INFORMATION

MAKSHSREC Research protocol reference number (Submission will not be reviewed without this number)			
Initial approval date			
Previous renewal approval date (if applicable)			
Expiry date of initial approval or renewal approval			
Project Title:			

Principal Investigator:			
Institution:			
Phone:		Email:	
Contact Person: (If applicable)			
Role on Project:			
Phone:		Email:	

B. PROJECT FUNDING

Funding:	☐ Unfunded ☐ Self-funded
	☐ Funded
	Agency/Company Name:

C. PERFORMANCE SITE(S)

List all performance sites for this study (including names of foreign countries with sites).

D. STATUS OF STUDY (check all that apply)

Active study

- ☐ Recruitment/enrollment continues
- ☐ Accrual complete, research intervention continues
- ☐ Long-term follow-up
- ☐ Data analysis only, data collection complete

E. ADDITIONAL INFORMATION

Intervention:

- ☐ Drug
- ☐ Device
- ☐ Genetic study
- ☐ Tissues
- ☐ Survey/Questionnaire
- ☐ Radiation Use
- ☐ Medical Record Review

☐ Other, Briefly explain

Drug/Device name:

F. PROGRESS REPORT

1. Enrollment and demographic information: LEAVE NO LINE BLANK

Total number of subjects requested in original SHS-REC application:

Number of subjects enrolled since last progress report:

Total number of subjects enrolled since the start of the study

Please report the number of subjects in Uganda in the following categories: (Numbers must add up and make sense. Please check before submitting form)

	Currently active in study		Withdrawn from study
	Follow-up data collection only		Deaths related to study
	Completed intervention and any follow-up		Deaths unrelated to study
	Lost to follow-up		

2. Adverse Events, Complications, Study Withdrawals:

In the past approval period, did any subject suffer an unanticipated or serious adverse event or death? ☐Yes ☐ No

If yes, please attach the Adverse Event Report(s) if adverse events not already reported to MakSHS-REC.

Adverse events/overall risk: **Answer every question**.
Based on your knowledge of the adverse events for this study, do you feel that there is a significant increase in risks to subjects? Has anything occurred since the last IRB review that may have altered the risk/benefit relationship? Explain.

Did you withdraw any subject(s) from your study because of a problem or complication? Explain.

Did any subject(s) withdraw themselves from your study? Explain.

Did any problems occur in obtaining or documenting informed consent (i.e., problems with subject understanding, high refusal rate, etc.) Explain.

3. Progress Report:

Please attach a SEPARATE brief summary of findings (preliminary or final) obtained in the study, a summary of recent literature or relevant information, especially information about risks associated with the study, completed activities and pending activities. Begin with a 1-2 sentence description of the purpose of the study. **If there are no findings at this time, this should be stated and explained.**

G. AMENDMENT / REVISION REQUEST

Complete **ONLY** if Amendment or Revision is requested.

HIGHLIGHT CHANGES TO THE REVISED CONSENT FORM WITH A BRIGHT COLOURED HIGHLIGHTER.

Proposed Amendment(s): List the proposed Amendments and briefly describe the nature of the proposed changes and their rationale. Please attach an amended version of the protocol and/or the Informed Consent if applicable.

Human Subject Population: Has the human subject population changed? If yes, explain. Indicate if there are new performance sites or any changes in selection criteria.

Risks/Benefits: Describe if and how the risks/benefits have changed.

Note: Attach separate sheet if space is not enough.

Principal Investigator's Assurance Statement:

I understand the MakSHS-REC 's policy concerning research involving human subjects and I agree:

1. To accept responsibility for the scientific and ethical conduct of this research study,
2. To obtain prior approval from the Institutional Review Board (MakSHS-REC) and the UNSCT before amending or altering the research protocol or implementing changes in the approved consent form,
3. To immediately report to the MakSHS-REC and the UNSCT any serious adverse reactions and/or unanticipated effects on subjects which may occur as a result of this study,
4. To train study personnel in the proper conduct of human subjects research,
5. To complete the Continuing Review and Final Report Forms.

Signature of Principal Investigator Date

Write/Typed Name of Principal Investigator

H. APPLICATION ENCLOSURES CHECKLIST

Check all that are included in your submission for continuing review.

The following **must be included** in the submission for continuing review:

☐ Continuing Review Application form 102, complete with signature of PI
☐ Progress Report -pending activities inclusive in the report, attach the report to application form 102

Include the following only **if applicable**:

☐ Current copy of Consent Form(s) stamped with approval date
☐ Clean copy of Consent Form(s) with revisions if necessary (for new approval stamp)
☐ Informational letters used in place of consent form (cover memo)
☐ Adverse Event Summary Table
☐ Current Approval letters from another foreign sites withMakSHS-REC
☐ Complete protocol including modifications previously approved by the MakSHS-IRB (if submitting an amendment or modification to original protocol)
☐ Recruitment Information (Ads, Web postings, letters etc., if modified from originally approved recruitment materials)
☐ Additional information PI considers important for review by MakSHS-REC