UGANDA CANCER INSTITUTE RESEARCH AND ETHICS COMMITTEE

Date received……

REC Form 102

APPLICATION FOR ANNUAL REVIEW (RENEWAL) OF RESEARCH ACTIVITY

Note: Apply two months prior to expiry of approval

For continued protection of the rights and welfare of the human subjects, the UCIREC policy mandated annual review of study progress throughout the study conduct. UCIREC follows, at minimum, the regulations set forth in the CIOMS Guidelines as the criteria for continuing review. The Continuing Review process is synonymous to the initial review.

The Principal Investigator is responsible for timely submission of a continuing review application to prevent any lapse in REC approval. UCIREC 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 both Soft copy and hard copies .Soft copies should be submitted to this email address: "ucirec@uci.or.ug"

A. STUDY INFORMATION		
REC Protocol #	Expiration date of current approval period:	
Study /Project Title		
Principal Investigator		
Institution:		
Phone:		
email		
Contact person (If applicable)		
Role on study		
Phone		
email		

B. STUDY / PROJECT FUNDING	
Funding:	☐ Self- funded ☐ Un funded ☐ Funded If funded Specify funding Agency……

C. STUDY IMPLEMENTATION SITES
List all performance sites for this study (In Uganda and other countries. (i) _____ (ii) _____ (iii) _____ (iv) _____

D. TYPE OF STUDY	Yes	No
Cross-sectional/Survey	☐	☐
Secondary data review	☐	☐
Program/Project evaluation	☐	☐
Clinical /community trial	☐	☐
Case control	☐	☐
Longitudinal study	☐	☐
Record review	☐	☐
Course activity	☐	☐
Use of stored samples	☐	☐
Other (specify)	……	

E. INTERVENTION	Yes	No
Drug	☐	☐
Device	☐	☐
Radiation Use	☐	☐
Genetic study	☐	☐
Tissue	☐	☐
Survey/questionnaire	☐	☐
Medical records	☐	☐
Other briefly explain:		

F. STUDY PROGRESS REPORT		
1. Status of the study (check all that apply)	**Yes**	**No**
Active study	☐	☐
Recruitment/enrollment continues	☐	☐
Accrual complete, research intervention continues	☐	☐
Long-term follow-up	☐	☐
Data analysis only, data collection complete	☐	☐

2. Enrolment and Demographic Information : (leave no line blank)

Total number of subjects indicated in the initial approved protocol	
Total number of subjects enrolled since the start of the study	
Number of subjects enrolled since last progress report:	

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Withdrawn from study	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

3. **Adverse Events, Complications, Study Withdrawals:**	Yes	NO
In the past approval period, did any subject suffer an unanticipated or serious adverse event or death? ***If yes, please attach the Adverse Event Report(s) if adverse events not already reported to UCIREC.***	☐	☐

Has anything occurred since the last IRB review that may have altered the risk/benefit relationship? Briefly Explain

_____

_____

_____

_____

	Yes	No
Based on your knowledge of the adverse events for this study, do you feel that there is a significant increase in risks to subjects?	☐	☐
Did you withdraw any subject(s) from your study because of a problem or complication?	☐	☐

If yes explain reason why subject(s) were withdrawn from the study

_____

_____

_____

_____

Did any subject(s) withdraw themselves from your study? Explain	☐ Yes	☐ No

If yes explain reason why subject(s) were withdrew consent for study participation (if known)_____

_____

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_____

Did any problems occur in obtaining or documenting informed consent (i.e., problems with subject understanding, high refusal rate, etc.)	☒ Yes	☐ No

If yes explain the problems encountered when obtaining informed consent

_____

_____

_____

_____

4. **DSMB Outcome / Preliminary/final Study evaluation reports.**

Please attach - a brief summary of findings obtained in the study, a summary of recent literature or relevant information, especially information about risks associated with the study. 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).

Are there any proposed amendments in the protocol ***If no end the form, sing the form and complete the submission process***. If Yes complete UCIREC form 103 – to apply for modification concurrently	☐ Yes	☐ No

A. APPLICATION SUBMISSION CHECKLIST		
The following must be included in the submission for continuing review:	Yes	No
Continuing Review Application, complete with signature of PI and Co-investigators	☐	☐
Progress Report, attached to application	☐	☐
Include the following only if applicable:		
Current copy of Consent Form(s) stamped with approval date	☐Yes ☐ No ☐ N/A	
Clean copies of Consent Form(s) with revisions if necessary (for new approval stamp)	☐Yes ☐ No ☐ N/A	
Informational letters used in place of consent form (cover memo), and other	☐Yes ☐ No ☐ N/A	
recruitment materials (Ads, Web postings, letters etc., if modified from	☐Yes ☐ No ☐ N/A	
originally approved recruitment materials).	☐Yes ☐ No ☐ N/A	
Adverse Event Summary Table	☐Yes ☐ No ☐ N/A	
Current Approval letters from other foreign sites with UCIREC	☐Yes ☐ No ☐ N/A	
Complete protocol including modifications previously approved by the UCI REC (if submitting an amendment or modification to original protocol)	☐Yes ☐ No ☐ N/A	
Additional information PI considers important for review by UCIREC		

Principal Investigator's Assurance Statement:

I certify that the information given by me is correct to the best of my knowledge; I am familiar with and understand the REC's policy concerning research involving human subjects (CIOMS Guidelines or Helsinki Declaration) and I agree:

(Please check all that applies)

1. ☐To accept responsibility for the scientific and ethical conduct of this research study;

2. ☐To obtain prior approval from the UCIREC as well as the UNCST before amending or altering the research protocol or implementing changes in the approved consent form;

3. ☐To immediately report to the UCIREC and the UNCST any serious adverse reactions and/or unanticipated effects on subjects which may occur as a result of this study;

4. ☐To complete and submit the Continuing annual Review Form annually (when due) as well as the Final/Study termination form at the end of the proposed study (if applicable).
5. ☐To submit the final study report to the UCIREC using a standard form.

Principal Investigators'	**Primary ; Co – Investigators'**
Signature :	Signature:
Print Name :	Print Name:

OFFICIAL USE ONLY

Comment:

(i) ☐Application Submission requirements are complete

(ii) ☐Application Submission requirements are incomplete

If Incomplete document action taken and advise given to the investigator and the response

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Name	**Signature:**	**Date**

REC staff that received application