UGANDA CANCER INSTITUTE RESEARCH AND ETHICS COMMITTEE

Date received: _____

REC Form 103

REQUEST FOR AMENDMENT/MODIFICATION OF APPROVED RESEARCH.

Please complete this form and submit both hard and soft copies .The soft copy should be submitted to this email address: **"ucirec@uci.or.ug"**

Table 1: STUDY IDENTIFYING INFORMATION AND PI CONTACTS

UCIREC REF #: (*The REC will not process requests without this number*.)	Date of Request:
Principal Investigator Name Phone # Email	Contact Person (if other than PI) Phone # Email
Title of Study:	

1. Description of proposed changes and the rationale for each: Please submit copies of the approved document (s) with track changes of sections you would like to amend and any other relevant documents. Also submit a clear copy (ies) for stamping incase the amendments are approved.

_____

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Table 2 : MODIFICATIONS

Does the modification involve changes to any of the following aspects?

(please check all that apply)

Research design and /resources	☐
Risks to participants or others in relation to Anticipated benefits	☐
Participant selection and recruitment approach /process	☐
Consent process and /or compensation	☐
Methods for documentation of consent	☐
Monitoring of the data being collected	☐
Privacy research participants and /or confidentiality of research participants 'data	☐
None of the above	☐

1. If you checked any of the boxes in table I above other than "None", Please summarize the changes in the space provided below (Attach another sheet if space is not enough):_____
_____
_____
_____
_____
_____
_____

2. What documents are being added or updated with this modification? (Check all that apply. For each document, submit one (1) "track changes version clearly showing the changes from the version along with one (1)"clean "version with the changes incorporated. For new documents, submit one (1) "clean "version.

Table 3: MODIFIED DOCUMENTS

Document type	Version
Protocol ☐	
Consent form ☐	
Questionnaire ☐	
Advertisement ☐	
Investigator's Brochure ☐	
Other study material (Please Specify)☐	

Note: if multiple Versions of one type of document are being added or updated (e.g. different consent forms), please list them below:

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_____

_____

If the investigational Brochure is being modified, is there new risk information in the updated brochure which should be communicated to current or past participants?

☐NA→Changes in the brochure do not contain any new risk information

☐ No→New risk information in the brochure is already described in the consent form. Submit acopy of the new consent form

☐ No→New risk information does not need to be communicated to participants (Please Explain why).

☐ Yes→Describe your plan to communicate the new risk information to participants.

3. If protocol is amended are there changes made to the Consent Form?

No ☐ Yes ☐

a) If yes, attach new consent form or information sheet that will be used to notify participants.

b) If no give a justification

_____
_____
_____
_____
_____
_____

c) If consent form is amended do you plan to re-consent the participants on study follow-up? Yes ☐ No ☐

d) If no how do you plan to make them aware of the changes?

_____
_____
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_____

Signature assurance sheet

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

Approval of Changes /Modifications by UCIREC

Approval Option	Authorization		
Approved	Name: (chairperson)	Signature:	Date:
Disapproved			

If disapproved briefly explain the reason

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