

MAKERERE UNIVERSITY SCHOOL OF HEALTH SCIENCES RESEARCH & ETHICS COMMITTEE (MakSHS-REC) COLLEGE OF HEALTH SCIENCES	For Office Use Only MakSHS-REC/A/.....
REC FORM 106	Date received

FINAL REPORT REQUIRED FOR
STUDY CLOSE OUT WITHDRAWAL OF IRB APPROVAL/STUDY TERMINATION

This form will constitute your notice of study termination and final study close-out report to the (MakSHS-REC) and UNCST. Submit this form and the information requested prior to the expiration date for the protocol.

Note: In order to terminate (MakSHS-REC) approval, all research related to this protocol must have ceased, including subject enrollment, subject follow-up, and work with identifiable information related to the study subjects, including medical or research records. Data analysis utilizing identifiable data collected from study subjects requires (MakSHS- REC) approval. If you are performing data analysis, you must submit the Continuing Review application.

It is the responsibility of the Principal Investigator to notify all study personnel associated with this protocol that the study has been terminated or closed/completed.

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

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

MAKSHSREC Research protocol reference number <i>(application will not be reviewed without this number)</i>		Effective Date of withdrawal or close out: Must be on or before expiration date.	
Initial approval date			
Previous renewal approval date if applicable			
Expiry date of initial approval or renewal approval			
Project Title:			
Study site			
Principal Investigator :			
Phone:		Email:	
Co-Investigator (s)			

STUDY INFORMATION

Total number of subjects enrolled since start of the study? (May be for more than one year)	
How many subjects have voluntarily withdrawn participation at their own request?	
How many subjects have withdrawn participation at the request of the PI?	
How many serious adverse events have occurred at your site(s)? (deaths, serious incidents, significant adverse events) if applicable	
How many serious adverse events have occurred for entire study? (If multi-site) and if applicable	
Have there been any significant new findings (either good or bad) that should be disclosed to subjects who participated in the study. <u>If yes</u> , attach a brief rationale and any plans for informing subjects.	Check one: <input type="checkbox"/> Yes <input type="checkbox"/> No
Signature of Principal Investigator	Date
Print Name of Principal Investigator	