UGANDA CANCER INSTITUTE RESEARCH AND ETHICS COMMITTEE

REC FORM 104

ADVERSE EVENT REPORTING FORM

Complete entire form. Do not leave any blanks and the soft copy should be sent to this email address: ucirec@uci.or.ug

UCIREC Protocol #:		
Study Title**:**		
Principal Investigator: Name : Phone: email:		
Site/Institution Principal: investigator: Name: Phone: email:		
Study Sponsor:		
Report prepared by:		
Date of Adverse Event:	**Subject's Initials or Study #:**	**Type of Report:** ☐ Initial ☐ Follow-up
Brief Description of the Adverse event (including your diagnosis) :		

Location of Adverse Event: _____ **Research involves a:** ☐ Drug ☐ Device ☐Procedure **Name of Drug, Device or Procedure:**	☐ Not related ☐ Unlikely ☐ Possibly related ☐ Probably related ☐ Related ☐ Unknown **Expectedness:** ☐ Expected ☐ Not expected **Severity of Adverse Event:** ☐ Mild ☐ Moderate ☐Severe ☐ Fatal **Outcome of Adverse Event:** ☐ Death (due to event) ☐ Death (due to other causes) ☐Hospitalization ☐ Extended Hospitalization ☐Congenital Abnormality ☐ Recovered ☐Not yet recovered
Is the drug/device investigational: ☐Yes ☐No **Has the Adverse Event been reported to:** ☐ Sponsor, Date of report ---------- ☐ REC, Date of report _____	**Recovery of Subject:** ☐ Complete ☐Moderate ☐ Minimal ☐ None ☐ resolved ☐ Unknown

Was this Adverse Event addressed in the protocol and consent form? ***Was this Adverse Event addressed in Investigators Brochure?*** ***Are changes required to the protocol?*** ***Are changes required to the consent form?*** *If changes are **required**, please attach a copy of the revised protocol/consent form with changes highlighted with a bright coloured highlighter.* *If changes are **not required**, please explain as to why changes to the protocol /consent form are not necessarily based on the event.* _____ _____ _____ _____ _____	☐ *Yes* ☐ *No* ☐ *N/A* ☐ *Yes* ☐ *No* ☐ *N/A* ☐ *Yes* ☐ *No* ☐ *N/A* ☐ *Yes* ☐ *No* ☐ *N/A*
From the data obtained or from currently available information, do you see any need to reassess the risks and benefits to the subjects in this research? ☐ *Yes* ☐ *No* *P.I. Signature* _____ *Date* _____	

Note: Serious adverse events should be reported within 7 days while minor adverse events may be submitted in the annual report.