(+256) 0312 307400
rec@ciu.ac.ug
www.rec.ciu.ac.ug

CLARKE INTERNATIONAL UNIVERSITY-RESEARCH ETHICS COMMITTEE
ADVERSE EVENT AND SEVERE ADVERSE EVENT REPORT TEMPLATE

DEFINITIONS **Serious Adverse Event;** refers to an adverse event associated with death, hospital admission, prolongation of a hospitalization, persistent or significant disability or incapacity or otherwise life-threatening condition in connection with a clinical trial **Adverse Event;** is any untoward medical occurrence in a participant during study participation in a clinical trial who has administered a pharmaceutical product or a medical device. The event may or may not be casually related to the treatment or procedure		
PROTOCOL AND EVENT TYPE		
CIU-REC Protocol Number		
Title of the Protocol		
Date of event		
Type of event (please tick appropriately)	[ ] Expected [ ] Unexpected	[ ] SAE [ ] AE
PERSON REPORTING ADVERSE EVENT		
Name:		
Signature:		
Date of report:		
Contact details	• Tel: • Email address:	
PRINCIPAL INVESTIGATOR		
Name of Principal Investigator		

Organizational affiliation	
Signature of Principal Investigator	
Contact of Principal Investigator	• Tel: • Email address
PARTICIPANT INFORMATION	
Research participant ID number:	
Age:	
Sex	[ ] Male [ ] Female
Article Participant received	
Route of administration	
DETAILED ADVERSE EVENT INFORMATION	

Event type and seriousness of the Event

[ ] Definitely; When the event is directly caused by the intervention
[ ] Probably; When the event is most likely explained by the research intervention but when definite proof of causality is not evident
[ ] Possible; When explanation for event is equally due to research intervention or other cause
[ ] Unlikely; When the event is more likely explained by another cause
[ ] Not related; When the event is clearly due to another cause

Severity of the Event

- Minimal
- Moderate
- Severe
- Life- Threatening
- Fatal

Relationship of the AE to the equipments used in the investigation process

[ ] Definitely; When the event is directly caused by the intervention
[ ] Probably; When the event is most likely explained by the research intervention but when

definite proof of causality is not evident [ ] Possible; When explanation for event is equally due to research intervention or other cause [ ] Unlikely; When the event is more likely explained by another cause [ ] Not related; When the event is clearly due to another cause	
Was this Event expected in terms of its severity?	• Yes • No
Description of the Event	
Treatment/management of the Event	
Was this event expected in terms of its specificity?	• Yes • No
If yes, submit a copy with track changes	
Steps taken to avoid recurrence of future (AE	