

**IHSU-RESEARCH ETHICS COMMITTEE
ADVERSE EVENT AND SEVERE ADVERSE EVENT 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		
<u>PROTOCOL AND EVENT TYPE</u>		
IHSU/REC Protocol Number		
Title of the Protocol		
Date of event		
Type of event (please tick appropriately)	<input type="checkbox"/> Expected	<input type="checkbox"/> SAE
	<input type="checkbox"/> Unexpected	<input type="checkbox"/> AE
<u>PERSON REPORTING ADVERSE EVENT</u>		
Name		
Signature		
Date of report		
Contact details	<ul style="list-style-type: none"> • Tel: • Email address 	
<u>PRINCIPAL INVESTIGATOR</u>		
Name of Principal Investigator		
Organizational affiliation		
Signature of Principal Investigator		
Contact of Principal Investigator	<ul style="list-style-type: none"> • Tel: • Email address 	
<u>PARTICIPANT INFORMATION</u>		
Research participant ID number:		
Age:		
Sex	<input type="checkbox"/> Male <input type="checkbox"/> Female	

Article Participant received	
Route of administration	
<u>DETAILED ADVERSE EVENT INFORMATION</u>	
Event type and seriousness of the Event	
<input type="checkbox"/> Definitely; When the event is directly caused by the intervention <input type="checkbox"/> Probably; When the event is most likely explained by the research intervention but when definite proof of causality is not evident <input type="checkbox"/> Possible; When explanation for event is equally due to research intervention or other cause <input type="checkbox"/> Unlikely; When the event is more likely explained by another cause <input type="checkbox"/> Not related; When the event is clearly due to another cause	
Severity of the Event	
<ul style="list-style-type: none"> ● Minimal ● Moderate ● Severe ● Life- Threatening ● Fatal 	
Relationship of the AE to the equipments used in the investigation process	
<input type="checkbox"/> Definitely; When the event is directly caused by the intervention <input type="checkbox"/> Probably; When the event is most likely explained by the research intervention but when definite proof of causality is not evident <input type="checkbox"/> Possible; When explanation for event is equally due to research intervention or other cause <input type="checkbox"/> Unlikely; When the event is more likely explained by another cause <input type="checkbox"/> Not related; When the event is clearly due to another cause	
Was this Event expected in terms of its severity?	<ul style="list-style-type: none"> ● Yes ● No
Description of the Event	
Treatment/management of the Event	
Was this event expected in terms of its specificity?	<ul style="list-style-type: none"> ● Yes ● No
If yes, submit a copy with track changes	
Steps taken to avoid recurrence of future (AE)	