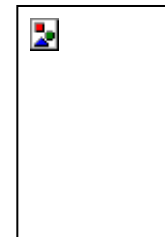




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UNIVERSITY OF PERPETUAL HELP SYSTEM- JONELTA  
INSTITUTIONAL ETHICS REVIEW BOARD**

Biomedical Research Institute,  
Upper Basement, Upper Basement, Tamayo Tower, UPHDMC  
Alabang Zapote Road, Las Piñas City, Tel. No. (632) 874-8515 local 631



Form 3.4 (A) 2018  
Serious Adverse Event Report

**Serious Adverse Event Report**

Principal Investigator:..... SAE Report No: .....

Study Title:..... IERB Protocol Code:  
.....  
.....

Name of the study  
medicine/device.....

Sponsor:.....  
.....

Report Date :..... <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up Onset date: ..... Date of first use: .....
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Subject's initial/number:	Age:	<input type="checkbox"/> Male	<input type="checkbox"/> Female
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Subject's history:	Laboratory findings:

SAE:	Treatment:
	Outcome: <input type="checkbox"/> Resolved <input type="checkbox"/> On-going

Seriousness: <input type="checkbox"/> Death <input type="checkbox"/> Life Threatening <input type="checkbox"/> Hospitalization ○ Initial ○ Prolonged <input type="checkbox"/> Disability / Incapacity <input type="checkbox"/> Congenital Anomaly <input type="checkbox"/> Other.....	Relation to ○ Drug ○ Device ○ Study <input type="checkbox"/> Not related <input type="checkbox"/> Possibly <input type="checkbox"/> Probably <input type="checkbox"/> Definitely related <input type="checkbox"/> Unknown
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Changes to the protocol recommended?     No     Yes , attach proposal

Changes to the informed consent form     No     Yes , attach proposal  
recommended?

Comment:

**RECOMMENDED ACTION: (for IERB use only)**

NO FURTHER ACTION

REQUEST FURTHER INFORMATION

WITHDRAWAL OF ETHICAL APPROVAL OF THE STUDY

<b>PRIMARY REVIEWER</b>	Signature	_____
Date: <dd/mm/yyyy>	Name	<Title, Name, Surname>