SERIOUS ADVERSE EVENT REPORT

To the Principal Investigator, use this form to report the following adverse events, according to the recommended submission timelines:

- ***All SAEs that result to death***
  - ***On-site, within 24 hours that Principal Investigator/site is informed of the event***
  - ***Off-site, within 24 hours that Principal Investigator/site receives report from the Sponsor***
    Note: SAEs that occur on weekends/holidays may be reported to the IEC via email to iec@dlshsi.edu.ph. The duly accomplished Form 3F/V2/2014 may be submitted on the next working day.

- ***Other on-site SAEs must be reported within 7working days that Principal Investigator/site is informed of the event***
  - ***SAEs that are related and expected***
  - ***Adverse events that are serious, related and unexpected (SUSARs)***

- ***All SAEs that change the study risks and necessitate modification of the IEC-approved protocol /ICF must be reported within 7 working days from date that Principal Investigator/site receives report from the Sponsor***

Use the ADVERSE EVENT SUMMARY REPORT (Form 3G/V1/2012) for adverse events that are not covered by the foregoing reporting criteria.

Please obtain an electronic copy of this Form, fill-out the requested information, and make your submission both in electronic version and hard copy. Print in letter-sized paper with printer default set at A4.

I. PROTOCOL INFORMATION	**IEC Protocol Tracking No.**
Study Protocol No.	Protocol Approval Date: <dd/mm/yy>
Study Initiation Date: <dd/mm/yy>	Expected End Date: <dd/mm/yy>
Title:	Version Number, Date
Name of Principal Investigator	Contact Nos.:
Sponsor/CRO	
Study Site	
Type of Review (*To be determined by IEC*) ☐ Full Board ☐ Expedited	

1. What Is Being Reported? ☐ SAE ☐ SUSAR ***Seriousness Criteria:*** ☐ Death ☐ Life-threatening ☐ In-patient hospitalization/ prolongation ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect	2. Report Type ☐ Initial ☐ Follow-Up Follow-up Report No. ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ ____
3. Has the Sponsor been notified? ☐ No ☐ Yes (explain/give reasons)	3. Number of similar SAEs that occurred previously at: 3.1. DLSMHSI site <number> 3.2. Other site(s) <number>

4. In the opinion of the PI, will amendments be required to:	Study Protocol? ☐ Yes ☐ No	Informed Consent Form? ☐ Yes ☐ No	Participant Information? ☐ Yes ☐ No
5. If Yes, will already enrolled patients be re-consented? ☐ Yes (*If YES, append revised document*) ☐ No (*If No, why not?)*			

II. INFORMATION REQUIRED		**SAE REPORT SUBMISSION DATE** <dd/mm/yy>		
1. **PATIENT INFORMATION**				
Patient Case No.	Date of Birth <dd/mm/yy>	Age	Gender ☐ Male ☐ Female	Weight <kg/lbs>: Height: <cm/in>
2. EVALUATION OF EVENT				
2.1. Event/Reaction		2.2 Serious? ☐ Yes ☐ No	2.3. Expected? ☐ Yes ☐ No	
2.4. Date PI became aware of SAE/SUSAR <dd/mm/yy>		2.5. Date of Experience <dd/mm/yy>	2.6. End of Experience <dd/mm/yy>	
2.6. Causality/Relatedness Assessment by PI ☐ Certainly ☐ Probably ☐ Possibly ☐ Unlikely ☐ NOT RELATED		2.7. Rationale for the Causality Assessment		

2.8. Action taken with investigational drug ☐ Continued unchanged ☐ Withdrawn ☐ Interrupted ☐ Dose reduced ☐ Dose increased ☐ Others (specify)	2.9. Did the event/reaction abate after stopping the investigational drug? ☐ Yes ☐ No ☐ Not Applicable
2.10. Did the event/reaction reappear after reintroduction of the drug? ☐ Yes ☐ No ☐ Not Applicable	2.11 Have urgent safety measures implemented? I ☐ Yes (*give details*) ☐ No (*explain/give reasons*) ☐ Not Applicable

2.12. Describe the event/reaction (*Summary of s/s, diagnosis. treatment start and stop dates, hospitalization start and stop dates, other relevant laboratory tests and findings, and medical history including concurrent and pre-existing conditions*)

3. CONCOMITANT MEDICATION PRIOR TO EVENT/REACTION

Drug (*to include route of administration*)	**Daily Dose**	**Date Begun**	**Date Stopped**	**Reason for Use**

4. Is there a reasonable possibility that other medications contributed to the event/reaction?
☐ Yes (*specify*)
☐ No

5. Are there other possible contributory factors?
   - ☐ Yes (*specify*)
   - ☐ No

6. OUTCOME OF EVENT/REACTION

6.1. Outcome of the SAE
- ☐ Recovered/Resolved
- ☐ Recovered with sequelae (*specify*)
- ☐ Improving//Recovering/Resolving
- ☐ Deteriorating
- ☐ Not recovered/ Not resolved
- ☐ Death
- ☐ Unknown
- ☐ Others (specify)

6.2. If patient died, was an autopsy performed?
- ☐ Yes (*If Yes, provide date of autopsy <dd/mm/yy>*)
- ☐ No
- ☐ Unknown

6.3. Primary cause of death as determined by the autopsy (*if performed*)

I declare that the above information/statements are true and correct to the best of my knowledge.

_____ _____

Signature Over Printed Name of Principal Investigator ***Date***

III. IEC RECOMMENDATION	**Specifics**
☐ NO FURTHER ACTION REQUIRED ☐ REQUEST INFORMATION *(indicate Information)* ☐ RECOMMENDED FURTHER ACTION *(indicate Action)* ☐ PENDING WITH MAJOR CLARIFICATION	
Reviewer ☐ Primary ☐ Secondary	_____ _____ ***Reviewer's Signature Over Printed Name*** ***Date***