

SEVERE ADVERSE EVENT (SAE) REPORT FORM

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STUDY TITLE			
PROTOCOL NO.		SITE NO.	
SITE			
PATIENT ID		DATE OF REPORT	

1.	SAE Date of Onset:		
2.	SAE Date Stopped:		
3.	Location of SAE:		
4.	Was this an unexpected adverse event?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5.	Brief description of participants (do not include personal identifiers):	Gender	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other, identify
		Age	
		Diagnosis for study participation	
6.	Brief description of the nature of the SAE: <i>attach description, if applicable</i>		
7.	Category of SAE:	<input type="checkbox"/> Date of Death: <input type="checkbox"/> Life threatening <input type="checkbox"/> Congenital anomaly, birth defects <input type="checkbox"/> Life threatening <input type="checkbox"/> Required intervention to prevent impairment (permanent) <input type="checkbox"/> Hospitalization <input type="checkbox"/> Disability <input type="checkbox"/> Other:	

8.	Describe intervention type:			
9.	Relationship of event to intervention:	<input type="checkbox"/> Unrelated	<input type="checkbox"/> Possible	<input type="checkbox"/> Definite
10.	Was the study intervention discontinued due to the event?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
11.	What steps were taken to treat the SAE?			
12.	List relevant tests, lab data, history, and pre-existing medical conditions:			
13.	Report type:	<input type="checkbox"/> Initial	<input type="checkbox"/> Follow-up	<input type="checkbox"/> Final

Print Name of Principal Investigator

Signature of Principal Investigator

Date

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