Severe Adverse Event* Form #: Visit #: Subject #: Initials: Date: (mm-dd-yyyy) "Report to your institution's IRB 1. Patient Datails Date of Birth: (mm-yyyy)						
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Date of Birth: (mm-yyyy)	*Report to your institution's IRB					
Height cm	1. Patient Details					
Weight	Date of Birth: (mm-yyyy) - Sex: (M=Male; F=Female)					
Race: AM = American Indian/Alaskan Native AS = Asian UN = Unknown or not reported NH = Native Hawaiian/Other Pacific Islander BL = Black/African American WH = White 2. Principal Investigator Details Name: Phone: Address: Onset date: (mmddyyyy) 3. State Main Adverse Event Phone: (mmddyyyy) Phone: (mmddyyyy) Noset date: (mmddyyyy) Phone: (mmddyyyy) Resolved? (Y=Yes; N=No) If yes, resolution date: (mmddyyyy) Does the patient have prior history of this type of event? (Y=Yes; N=No) If yes, please describe: (Y=Yes; N=No) Phone: (Y=Yes; N=No) If yes, resolution date: (Y=Yes; N=No) If yes, please describe: (Y=Yes; N=No)	Height cm Ethnicity: Hispanic/Latino? (Y=Yes, N= No)					
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5. Classification D=death; L=life threatening; H=hospitalization; I=incapacity; C=congenital anomaly/birth defect; R=req.intervention; OT=other					
If hospitalization, I=Initial; P=Prolonged Admission D	Date: (mmddyyyy)				
Discharge D	Pate:				
6. Relevant Medical History (include primary diagnosis, pre-existing medical conditions, and allergies)					
 7. Outcome of Event R=recovered without sequelae; S=recovered with sequelae; N=not yet recovered; Q=died-due to AE; U=died-cause unspecified 8. Additional Comments and Relevant Diagnostic Tests 					
9. Relevant Laboratory Values					
Test	Date (mmddyyyy)	Result (Units)	Normal Value		
ecorder Signature Initials Date (mm/dd/yyyy)					
Investigator Signature	Initials Dat	e (mm/dd/yyyy)			