SERIOUS ADVERSE EVENT

REFER TO ***STUDY PROCEDURES MANUAL*** FOR DETAILED INSTRUCTIONS.

NAME OF RESPONSIBLE INVESTIGATOR:	
INSTITUTION:	
REPORT COMPLETED BY:	
DATE OF REPORT:	TYPE OF REPORT: ❐ INITIAL ❐ FOLLOW-UP # _____ ❐ FINAL

PATIENT INFORMATION

PATIENT RZ #:	AGE:	SEX: ❐MALE ❐FEMALE	DATE PATIENT STARTED STUDY INTERVENTION:

Event Information

EVENT ONSET DATE/TIME:	NAME OF EVENT:
DATE BECAME AWARE OF EVENT:	

DESCRIPTION OF EVENT:

SERIOUSNESS CRITERIA (CHECK ALL THAT APPLY):
- ❐ DEATH
- ❐ LIFE-THREATENING
- ❐ REQUIRES OR PROLONGS HOSPITALIZATION
- ❐ RESULTS IN PERSISTANT OR SIGNIFICANT DISABILITY/INCAPACITY
- ❐ MAY REQUIRE MEDICAL OR SURGICAL INTERVENTION TO PREVENT ON OF THE OTHER OUTCOMES
- ❐ CONGENITAL ANOMALY OR BIRTH DEFECT
- ❐ OTHER SERIOUS MEDICAL EVENT

OUTCOME:
- ❐ SAE PERSISTING AT TIME OF REPORT
- ❐ COMPLETE RECOVERY/RETURN TO BASELINE
- ❐ RESOLVED (NO SEQUELAE)
- ❐ RESOLVED WITH SEQUELAE, SPECIFY
- ❐ DEATH, SPECIFY DATE/TIME
- ❐ UNKNOWN/LOST TO FOLLOW-UP

IS THE EVENT UNEXPECTED? ❐ YES ❐ NO

RELATIONSHIP OF STUDY INTERVENTION TO EVENT:
- ❐ NOT RELATED
- ❐ UNLIKELY RELATED
- ❐ POSSIBLY RELATED
- ❐ PROBABLY RELATED

Serious Adverse Event

Refer to ***Study Procedures Manual*** for detailed instructions.

Action Taken with Study Intervention: ❒ Study intervention completed at time of event onset ❒ Study intervention ongoing ❒ Study intervention interrupted (temporarily), specify date ___________________________ ❒ Study intervention permanently stopped, specify date ___________________________
Action Taken to Treat the Event: ❒ None ❒ Uncertain ❒ Surgery ❒ Other procedures (non-surgical) ❒ Blood or blood products ❒ Drug therapy ❒ Other
Treatment Details:

Other Report Information

Past medical history/comorbidities:	❒ Separate page attached ❒ Demographic CRF completed
Laboratory tests and investigations related to event:	❒ Separate page attached ❒ None
Other relevant information:	❒ Separate page attached ❒ None
Other event information the investigator wishes to report:	

Signatures

Report Completed by:	Signature:	Date:
Site Investigator:	Signature:	Date: