ADVERSE EVENT LOG

Study Title	Investigator/Site ID#	Participant ID #	Date/ Visit

Did any AEs occur? ☐ Yes ☐ No

- *If concomitant medication was given, please update the Concomitant Medication Log accordingly.*
- *If an SAE, please remember to report event to the IRB*
- *Collection begins from time of consent.*
- *Ensure only the PI or sub-I determine causality relationship*

AE #	Adverse Event Verbatim Term	Severity	Start Date: (DD/MMM/YYYY)	Date Site Became Aware of AE: (DD/MMM/YYYY)	SAE Y/N	Study Condition Related? Y/N	Relationship to Study Procedures	Action Taken with Respect to Study Procedures	Was Conmed given for this AE? Y/N	Primary Outcome of AE	Sequela(e)	Outcome Date: (DD/MMM/YYYY)	Investigator Initials / Date

Investigator Signature*: _____ ***Date:*** _____

Not to be signed by investigator until page is complete (all items resolved)/end of study participation.

Severity/ Highest Severity Attained:	Relationship to Study Procedures:	Action Taken With Respect to Study Treatment:	Primary Outcome of AE:
1. Mild	0. Not Related 3.Possible	0. None 3. Hospitalization	1. Recovered/resolved 4. Not resolved
2. Moderate	1. Definite 4. Unlikely	1. Medication Therapy 4. Unknown	2. Recovered/resolved with sequela (e), Specify 5. Fatal
3. Severe	2. Probable	2. Medical Procedures 5. Other	3. Recovering/resolving 6. Unknown