Protocol: _____ **ADVERSE EVENT LOG** **PI:** _____

Subject's Initials: _____ **Subject's ID:** _____

ADVERSE EVENT **Make a separate entry for:** ➢ **All new adverse events** ➢ **All AEs with increased severity** ➢ **All AEs with changes in study drug relationship** ➢ **All medical conditions present at study drug initiation which have worsened**	**√ if AE meets definition of serious***	**Grade / Intensity** **Asymptomatic** **Mild** **Moderate** **Severe**	**Start Date**	**End Date**	**Relationship to study intervention** **Related** **Possibly** **Not Likely** **Not Related**	**Was Action Taken?** **(Circle One)**	**Action(s) Taken^:**	**Outcome:** **Recovered** **Not Recovered** **Recovered w/Sequelae** **Fatal** **Unknown**	**PI Initials / Date**
						Yes / No			
						Yes / No			
						Yes / No			
						Yes / No			
						Yes / No			
						Yes / No			
						Yes / No			
						Yes / No			
						Yes / No			
						Yes / No			
						Yes / No			
						Yes / No			
						Yes / No			
						Yes / No			
						Yes / No			
						Yes / No			
						Yes / No			

*SAE Criteria:
1 Death
2 Life-threatening
3 Requires or prolongs hospitalization
4 Persistent or significant disability/incapacity
5 Congenital Anomaly/Birth Defect
6 Other Medical Importance

^Examples of Actions Taken:
A. Study drug dosage adjusted
B. Study drug interrupted
C. Study drug permanently discontinued
D. Concomitant medication taken (record on Con Med page)
E. Non-drug therapy given (record on Non-Drug Therapy page)
F. Hospitalized/prolonged hospitalization*

Any event that meets SAE or Unexpected Adverse Event must be reported to the IRB (See IRB SOP #1401 for further information on reporting). There may be additional reporting requirements to Sponsor or other regulatory agencies.