Investigational Title: ______________________________ COMIRB #____________________

Principal Investigator: ______________________________

Participant ID: ______________________________

Seriousness Criteria	Action Taken	Outcome
1. Life Threatening 2. Hospitalization 3. Congenital Anomaly/Birth Defect 4. Persistent or Significant Disability or Incapacity 5. Other Medically Important Event 6. Death	1. None 2. Concomitant medication (add to ConMeds) 3. Procedure 4. Subject discontinued 5. Other, specify	1. Ongoing 2. Recovered 3. Recovered with sequelae 4. Death 5. Not Recovered 6. Unknown

ADVERSE EVENT and INTERCURRENT ILLNESS LOG

AE # (1, 2, 3…)	Adverse Event /Intercurrent Illness (enter diagnosis)	Start Date (dd/mmm/yyyy)	Stop Date (dd/mmm/yyyy)	Serious	Seriousness Criteria	Severity	Relationship to Study Drug/Device	Action Taken (list all that apply)	Outcome	PI Initials & Date
				o Yes o No		oMild oModerate oSevere oLife Threatening oDeath	oNot Related oPossible oProbable oDefinite			
				o Yes o No		oMild oModerate oSevere oLife Threatening oDeath	oNot Related oPossible oProbable oDefinite			
				o Yes o No		oMild oModerate oSevere oLife Threatening oDeath	oNot Related oPossible oProbable oDefinite			
				o Yes o No		oMild oModerate oSevere oLife Threatening oDeath	oNot Related oPossible oProbable oDefinite			

To be signed by Principal Investigator at End-of-Study or once all events have stabilized/resolved.
Principal Investigator Signature:___________________________Date:________________