SAE REPORTING FORM ADDENDUM

Participant ID

Report Date

Type of Report:  ○ Initial  ○ Follow-up  ○ Final  (Note: If this report is for a prior event that is now resolved, please mark as "Final" not "Initial")

Date of Onset: 

Date of Resolution: (if any)

Categorization:

○ Death  ○ Disability  ○ Other
○ Life threatening event  ○ Congenital anomaly/birth defect
○ Overnight hospitalization (or prolongation)  ○ Medical intervention required to prevent death/disability

Grade of Risk:

○ None  ○ Severe
○ Mild  ○ Life-threatening or disabling
○ Moderate  ○ Fatal

Attribution of relatedness to study:

○ Unrelated/Not  ○ Unlikely/remote  ○ Possibly  ○ Probably  ○ Definitely

Attribution of expected nature given study or population:

○ Anticipated  ○ Anticipated but greater than expected  ○ Unanticipated

Resolution:

○ Recovered/resolved  ○ Not recovered/resolved
○ Recovering/resolving  ○ Fatal
○ Resolved with sequelae  ○ Lost to follow-up/unknown

Study action:

○ No action/change  ○ Alter study procedure  ○ Other
○ Discontinue permanently  ○ Other
○ Discontinue temporarily

explain:

explain:

Signature of study PI

Date

Comments: