

## **APPENDIX B:**

### Sample Adverse Event Form

## SAMPLE ADVERSE EVENT FORM

Study Name \_\_\_\_\_

Site ID: \_\_\_\_\_

Participant ID: \_\_\_\_\_

Has the participant had any Adverse Events (AEs) during this study?       Yes     No    *(If yes, please list all AEs below)*

Severity	Study Intervention Relationship*	Action taken with Study Intervention due to AE	Outcome of AE	Expected*	Serious
1 = Mild 2 = Moderate 3 = Severe	1 = Definitely related 2 = Possibly/Probably related 3 = Not related	1 = None 2 = Discontinued permanently 3 = Discontinued temporarily 4 = Dose decreased 5 = Dose increased 6 = Dose delayed 7 = Other, specify	1 = Recovered, without treatment 2 = Recovered, with treatment 3 = Still Present, no treatment 4 = Still Present, being treated 5 = Residual effect(s) present-no treatment 6 = Residual effect(s) present-being treated 7 = Subject Died	1 = Yes 2 = No	1 = Yes 2 = No  (If yes, complete SAE form)

Event	AE Onset Date	AE Stop Date	Severity	Relatedness	Action taken with study intervention due to AE	Outcome	Expected?	Serious?	Initials

\*Please note if an AE is unexpected **and** is related/possibly related **and** suggests that the research places participants or others at a greater risk of physical or psychological harm than was previously known or recognized (if the AE is serious, then the answer to the third criteria is always yes) it is an **unanticipated problem**.