

APPENDIX C:

Sample Serious Adverse Event Report Form

SAMPLE SERIOUS ADVERSE EVENT REPORT FORM

Protocol Number:	Protocol Title:
1. a. Principal Investigator Name: b. Site Investigator Name: c. Site ID #: d. Site Phone #: e. Site Fax: f. Site E-mail:	
2. Participant ID: _____	3. Participant Age: _____
4. Participant gender: a. <input type="checkbox"/> Male b. <input type="checkbox"/> Female	5. Type of report: a. <input type="checkbox"/> Initial b. <input type="checkbox"/> Follow-up # _____
6. Serious Adverse Event (SAE) name or diagnosis: <i>(one or two words, full description is provided in Question 7)</i> a. _____	
7. Brief narrative summary of the event including: <i>(A brief but clear description of relevant signs, symptoms, and objective findings. The current best assessment resulting from the findings and the plan including any appropriate further diagnostic workup to be undertaken and plan of treatment including if it should be started immediately or based on further workup. The planned timing for the workup and any decision points about treatment should be included. The investigators current (working) diagnosis with rationale which can then be modified based on additional workup to a final diagnosis)</i> (Attach description if more space needed).	

8. Date of report: _____/_____/_____ d d m m m y y y y	9. Date discovered: _____/_____/_____ d d m m m y y y y
10. SAE onset date: _____/_____/_____ d d m m m y y y y	11. SAE stop date: _____/_____/_____ d d m m m y y y y or check if Ongoing <input type="checkbox"/>
12. Did the participant receive the study intervention prior to this SAE? a. <input type="checkbox"/> Yes; If yes, last date study intervention given _____/_____/_____ d d m m m y y y y b. <input type="checkbox"/> No c. <input type="checkbox"/> N/A	
13. Action taken with the study intervention due to SAE: a. <input type="checkbox"/> None b. <input type="checkbox"/> Dose decreased c. <input type="checkbox"/> Dose increased d. <input type="checkbox"/> Dose delayed e. <input type="checkbox"/> Discontinued permanently f. <input type="checkbox"/> Discontinued temporarily g. <input type="checkbox"/> Other, brief description: _____	
14. What medications or other steps (i.e., procedures, tests) were taken to treat participant due to this SAE? (Note: please list or provide separately with concomitant medications/treatments and laboratory results if there are too many to record here) (Please provide medical records if possible)	
15. Was this SAE unexpected? (An unexpected event is one that is not described in the protocol, informed consent or package insert/Investigator Brochure): a. <input type="checkbox"/> Yes b. <input type="checkbox"/> No	

