APPDENIX D:

SERIOUS ADVERSE EVENT REPORT

Protocol Title:

Investigator(s):

Sponsor:		**Drug/Device/Procedure:**	
# of SAE's at this site:	**Total # of SAE's (all sites):**	**# Of subjects enrolled at this site:**	**Total # of subjects enrolled to date (all sites):**
Patient ID #:		**Date of event:**	

Evaluation classification: ☐ Serious ☐ Unexpected

Intensity: ☐ Mild ☐ Moderate ☐ Severe

Relationship to treatment: ☐ Unlikely ☐ Possible ☐ Probable

Narrative description of the event, including all pertinent clinical history and data associated with the event:

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