Protocol Deviation Log

Project Identification			
Study number:		**Principal Investigator Name:**	

Deviation Type	Resulted in Adverse Event	Did Subject Continue in Study	Reported to IRB
1 = Consent Procedures 2 = Inclusion/Exclusion Criteria 3 = Medication/Therapy 4 = Laboratory Assessments/Procedures 5 = Study Procedures 6 = Serious Adverse Event Reporting/Unanticipated Adverse Device Effect 7 = Randomization Procedures/Study Drug Dosing 8 = Visit Schedule/Interval 9 = Other	1 = Yes 2 = No	1 = Yes 2 = No	1 = Yes 2 = No

Subject #	Date of Deviation	Date Identified	Deviation Description	Deviation Type	Resulted in Adverse Event	Did Subject Continue in Study?	Reported to IRB?	Date Investigator Notified	Investigator Initials & Date

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