

Protocol Deviation Log

Protocol ID/Number:					Site Name/Number:				
Protocol Title (Abbreviated):									
Principal Investigator:					Page number [1]:				
Ref No.	Subject ID	Date of Deviation	Date Identified	Deviation Description	Dev. Type [2]	Resulted in Adverse Event?	Did Subject Continue in Study?	Meets IRB Reporting Req. (Yes/No)	IRB Reporting Date
1									
2									
3									
4									
5									
6									

7									
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Investigator Signature: _____

Date: _____

Form Instructions:

[1] Each page should be separately numbered to allow cross-referencing (e.g., deviation #2 on p. 7).

[2] Deviation Type: (A-J) See codes below—enter the appropriate deviation code from the list.

Protocol Deviation Codes:

A – Consent Procedures

B – Inclusion/Exclusion Criteria

C – Concomitant Medication/Therapy

D – Laboratory Assessments/Procedures

E – Study Procedures

F – Serious Adverse Event Reporting/Unanticipated Adverse Device Effect

G – Randomization Procedures/Study Drug Dosing

H – Visit Schedule/Interval

I – Efficacy Ratings

J – Other