PROTOCOL DEVIATION LOG

Study Title:	Investigator Name:
Protocol ID Number:	Site Name & Number

*See Attached Key

PD #	Subject ID	Date of Deviation	Deviation Description	Type of Deviation	Resulted in AE	Subject W/D	IRB Reporting Req'd	Date Reported to IRB	PI Initial & Date
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									

_____
Study Personnel Signature

_____/_____/_____
Date

***DEVIATION CATEGORIES:**

A. Informed Consent
B. Eligibility
C. Protocol implementation
D. Reporting
E. Other, specify in log

Informed Consent (Category A)

1. Failure to obtain informed consent
2. Consent form used was not current IRB-approved version
3. Consent form does not include updates or information required by IRB
4. Consent form missing
5. Consent form not signed and dated by participant
6. Consent form does not contain all required signatures
7. Other, specify in log

Eligibility (Category B)

8. Participant did not meet eligibility criterion
9. Randomization of an ineligible participant
10. Participant randomized prior to completing Baseline Assessment, etc.
11. Randomization and/or treatment of participant prior to IRB approval of protocol
12. Other, specify in log

Protocol implementation (Category C)

13. Failure to keep IRB approval up to date
14. Participant receives wrong treatment
15. Participant seen outside visit window
16. Use of unallowable concomitant treatments
17. Prescribed dosing outside protocol guidelines
18. Missed assessment
19. Laboratory tests not done
20. Missed visit
21. Other, specify in log

Reporting (Category D)

22. Not submitting reportable information to the IRB within 7 days
23. Failure to respond to the NSI stipulations in the requested timeframe
24. Other, specify in log

Other (Category E)

25. Other, specify in log