Protocol Deviations Log

STUDY NAME	
Site Number: _____ **Pt_ID:** _____	**Visit Date:** ___ ___ / ___ ___ ___ / 2 0 ___ ___ d d m m m y y y y

Did this participant have any protocol deviations? ☐ Yes ☐ No

Description of Protocol Deviation:	Deviation Category*	Deviation Code**	Date Deviation Occurred: (dd/mmm/yyyy)	Date IRB Notified (if applicable):	Principal Investigator's Signature	Date Signed (dd/mmm/yyyy)

Protocol Deviations Log

*DEVIATION CATEGORIES:

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

**DEVIATION CODES: Numbers listed by the sample protocol deviations

Safety (Category A)

1. Not reporting an SAE within 24 hours
2. Laboratory tests not done
3. AE/SAE is not reported to IRB
4. Other, specify in log

Informed Consent (Category B)

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

Eligibility (Category C)

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

Protocol implementation (Category D)

17. Failure to keep IRB approval up to date
18. Participant receives wrong treatment
19. Participant seen outside visit window
20. Use of unallowable concomitant treatments
21. Prescribed dosing outside protocol guidelines
22. Missed assessment
23. Missed visit
24. Other, specify in log