National Jewish Health®

Clinical Research Services

Protocol Deviations Log

Protocol: _____

Investigator: _____

Participant ID: _____

Description of Deviation	Deviation Category *	Deviation Code **	Date of Deviation *(DD-MMM-YYYY)*	Date of IRB Notification *(If Applicable)*	Corrective Action Code ***	PI Signature and Date *(DD-MMM-YYYY)*

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Protocol: _____

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***DEVIATION CATEGORIES**

- **A.** Safety
- **B.** Informed Consent
- **C.** Eligibility
- **D.** Protocol Implementation protocol
- **E.** Other, specify in log

****DEVIATION CODES**

Safety (Category A)

1. Not reporting an SAE within 24 hours
2. Laboratory tests not done
3. AE/SAE not reported to IRB on time
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 subject
10. Consent form does not contain all required signatures
11. Other, specify in log

Eligibility (Category C)

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

Protocol Implementation (Category D)

17. Failure to keep IRB approval up to date
18. Subject received wrong treatment
19. Subject 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

*****CORRECTIVE ACTION CODES**

1. Rescheduled subject
2. Re-consented subject
3. Reviewed protocol
4. Requested Extension
5. Other, specify in log or attach CAPA form