

Protocol Deviation Tracking Log

Purpose: To record all protocol deviations that occur at a study site for both observational and interventional clinical research studies.

IMPORTANT: This log is maintained in the Study Binder (Synonyms for this binder include Investigator Binder, Regulatory Binder, Investigator Site File [ISF], and Study File.) and should be made available upon request for review by the IRB and the Sponsor's monitor. Deviations should be reported to the IRB of record as per the IRB Standard Operating Procedures. See OHRE/IRB SOP 1401 for reporting requirements for deviations to the UNC IRB.

Audience/User: Study coordinators, principal investigators (PIs), other site staff, clinical monitor

- Best Practice Recommendations:**
- Record protocol deviations in the tracking log as they occur, to ensure completeness and accuracy of the data.
 - The site PI should sign each form after it has been completed or immediately prior to a monitoring visit. If it has been signed with fewer than five deviations entered into it, the next identified deviation should be reported on a new page to ensure that all deviations have been reviewed by the PI.
 - Number each page and identify the final page of the log by indicating FINAL in the page number field.
 - Store pages in reverse chronological order, with the newest pages of the log placed at the front of the section.
 - Remove this page before using the log.

- Log Instructions:** [1] Each page should be separately numbered to allow cross-referencing (e.g., deviation #2 on p. 7)
[2] Deviation Type: (A-E) See categories and codes below—enter the appropriate deviation code from the list.
E.g. missed assessment outlined in the study protocol = 18

***DEVIATION CATEGORIES:**

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

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

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

Protocol Deviation Tracking Log

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

7									
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Investigator Signature: _____

Date: _____