National Center for Complementary and Integrative Health

Tool Summary Sheet

Tool: Protocol Deviation Tracking Log

Purpose: To record all protocol deviations that occur at a study site

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

Details: This tracking log should provide a comprehensive list of all protocol deviations that occur at a study site. It is required for both observational and interventional clinical research studies.

This tool is complementary to, and does not replace, the form reporting individual protocol deviations to the institutional review board (IRB). Deviations should be reported to the IRB and others (e.g., the program official, the NCCIH clinical director), as required.

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 maintain this log in the Essential Documents Binder, behind the Protocol Deviations tab. (Synonyms for this binder include Investigator Binder, Regulatory Binder, Investigator Site File [ISF], and Study File.)
- Store pages in reverse chronological order, with the newest pages of the log placed at the front of the section.
- At the conclusion of the study, identify the final page of the log by checking the box in the footer.
- Remove this Tool Summary Sheet before use of the log.

Tool Revision History:

Version		
Number	**Date**	**Summary of Revisions Made:**
1.0	15Aug2012	First approved version
2.0	24Apr2013	Created tool summary sheet and changed log from individual to study-wide format

Protocol Deviation Tracking 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 AE?**	**Did Subject Continue in Study?**	**Meets IRB Reporting Req. (Yes/No)**	**IRB Reporting Date**
1									
2									
3									
4									
5									
6									
7									

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