# Logo for the National Institutes of Health. National Institute of Dental and Craniofacial Research

# Tool Summary Sheet: Protocol Deviation Tracking Log

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

## Audience/User

Completed by Study Coordinators, Principal Investigators (PIs), other site staff; reviewed by Clinical Monitors

## 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 according to the IRB reporting requirements and others per the protocol and Manual of Operating Procedures (MOP), if applicable. For studies with NIDCR additional oversight, deviations are included in the Safety Oversight Committee Reports and/or Medical Monitor Oversight Reports. NIDCR may request additional protocol deviation reporting if warranted.

## Best Practice Recommendations

* Record protocol deviations in the tracking log as they occur to ensure completeness and accuracy of the data.
* Number each page and maintain this log in the Essential Documents Binder. The form should be positioned 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** | **Version Date** | **Summary of Revisions Made:** |
| --- | --- | --- |
| 1.0 | 16Nov2011 | First approved version |
| 2.0 | 14Mar2012 | Updated Tool Summary Sheet and added check box to footer |
| 3.0 | 17Sep2013 | Added columns: Deviation Identified By, Action Taken, and Impact / Initials; removed signature requirement. |
| 4.0 | 19Oct2015 | Updated Tool Summary Sheet and deviation impact items, and added Comments field. |
| 5.0 | 20Oct2020 | Updated instructions on the Tool Summary Sheet related to reporting events to NIDCR, added an impact code. |

# Protocol Deviation Tracking Log

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| --- | --- | --- | --- |
| **Protocol Number**  **and Abbreviated Title:** |  | **Site Name / Number:** |  |
| **Principal Investigator:** |  | **Page number [1]:** |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Ref No.** | **Subject ID** | **Date of Deviation** | **Date Identified** | **Deviation Identified By** | **Deviation Description** | **Dev. Type [2]** | **Resulted in AE (Yes/No)** | **Did Subject Continue in Study?** | **Meets IRB Reporting Req. (Yes/No)** | **IRB Reporting Date** | **Action Taken  (if any)** | **Impact [3]** | **Initials [4]** | **Comments** |
| **1** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **2** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **3** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **4** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

Check if final page of log: 🗆

## 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:

1. Consent Procedures
2. Inclusion/Exclusion Criteria
3. Concomitant Medication/Therapy
4. Laboratory Assessments/Procedures
5. Study Procedures
6. Serious Adverse Event Reporting/Unanticipated Adverse Device Effect
7. Randomization Procedures/Study Drug Dosing
8. Visit Schedule/Interval
9. Efficacy Ratings
10. Other
11. Impact: (A-D) See codes below – Enter the appropriate impact code from the list.

Impact Codes:

1. Study Validity
2. Safety
3. Outcome Measures
4. Other (briefly describe)
5. Insert the initials of the person completing the log entry.

Version 5.0 2020-10-20