**Tool Summary Sheet**

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| --- | --- |
| **Tool:** | Protocol Deviation Tracking Log  |
| **Purpose:** | To record all protocol deviations that occur at a study site.  |
| **Audience/User:** | Study Coordinators, Principal Investigators (PI), 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 IRB. Deviations should be reported to the IRB and others (e.g., the program official, the NIDCR clinical director), as required. The set of columns are suggestions and can be customized to meet the needs of the study. |
| **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, 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.
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**Tool Revision History:**

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| --- | --- | --- |
| **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.  |

Protocol Deviation Tracking Log

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| --- | --- | --- | --- |
| **Protocol ID/Number:** |  | **Site Name/Number:** |  |
| **Protocol Title (Abbreviated):** |  |
| **Principal Investigator:** |  | **Page number [1]:** |  |
| **RefNo.** | **SubjectID** | **Date of Deviation** | **Date Identified** | **Deviation Identified By** | **Deviation Description** | **Dev. Type [2]** | **Did Subject Continue in Study?** | **Meets IRB Reporting Req.(Yes/No)** | **IRB Reporting Date** | **Action Taken** **(if any)** | **Impact [3]** |
| **Resulted in AE (Yes/No)** | **Initials [4]** |
| **1** |  |  |  |  |  |  |  |  |  |  |  |
|  |  |
| **2** |  |  |  |  |  |  |  |  |  |  |  |
|  |  |
| **3** |  |  |  |  |  |  |  |  |  |  |  |
|  |  |
| **4** |  |  |  |  |  |  |  |  |  |  |  |
|  |  |
| **5** |  |  |  |  |  |  |  |  |  |  |  |
|  |  |

# 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

[3] Impact: (A-D) See codes below – Enter the appropriate impact code from the list.

Impact Codes:

A – Study Validity

B – Safety

C – No Impact

D – Outcome Measures

[4] Insert the initials of the person completing the log entry.