**Purpose:** This template provides a recommended structure for recording and tracking protocol deviations for a research study.

**Responsibility:** To be used byPrincipal Investigators and study team members who are delegated to record and track protocol deviations for a research study.

**Procedure:**

* This template contains two types of text: instruction/explanatory and example text.
* **Instruction/explanatory text** are indicated by italics and should deleted. Footnotes to instructional text should also be deleted. This text provides information on the content that should be included.
* **Example text** is included to further aid in document development and should either be modified to suit the drug, biologic or device (study intervention), design, and conduct of the planned clinical trial or deleted. Example text is indicated in [brackets in regular font]. Within example text, a need for insertion of specific information is notated by <angle brackets>. Example text can be incorporated as written or tailored to a particular document. If it is not appropriate to the document, however, it too should be deleted.

Subject-Specific Protocol Deviation Log Template

**Study/Protocol ID:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Site Name/Number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Subject ID:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PI:**

# *This log is cumulative and captures protocol deviations (including protocol violations) for all participants throughout the study. If deviations are entered into a database and are important to final data quality, consider adding a column for deviation code and creating a list of codes at the bottom of the table (i.e. consent deviation, missing data deviation, safety deviation, out-of-visit window deviation, equipment malfunction deviation, etc.). This will allow you to analyze the types of deviations that occurred and assess how seriously the data were affected at the end of the study.*

\*Please review Reporting Local Information Requirements: <https://rgw.arizona.edu/compliance/human-subjects-protection-program/guidance-researchers>

| ****Protocol Version #**** | ****Date of Deviation**** | ****Date Identified**** | ****Deviation Description**** | ****Resulted in AE?********(Yes/No)**** | ****Did Subject Continue in Study?********(Yes/No)**** | ****\*Meets IRB Reporting Req.?(Yes/No)******If yes, list date submitted to IRB** | ****PI Initials and Date****  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |   |   |   |   |   |   |  |
|  |   |   |   |   |   |   |  |
|  |   |   |   |   |   |   |  |
|  |   |   |   |   |   |   |  |
|  |   |   |   |   |   |   |  |
|  |   |   |   |   |   |   |  |
|  |  |   |   |   |   |   |  |
|  |   |   |   |   |   |   |  |
|  |   |   |   |   |   |   |  |
|  |   |   |   |   |   |   |  |
|  |   |   |   |   |   |   |   |
|  |  |  |   |   |   |   |   |
|  |  |  |   |   |   |   |   |
|  |  |  |   |   |   |   |   |
|  |   |   |   |   |   |   |  |
|  |   |   |   |   |   |   |  |