**NIMH Study-Specific Protocol Deviation Log Template**

***Tool Summary*** *(Remove Tool Summary before finalizing and distributing the document)*

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

***Audience/User:*** *Site Monitors, Principal Investigators, and study team members who are delegated to record and track protocol deviations for a research study*

***How to Use This Template***

*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.*

***Version control*** *is important to track document development, revisions, and amendments. It is also necessary to ensure that the correct version of this document is used by all staff conducting the study. With each revision, the version number and date located in the header of each page should be update.*

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

NIMH Subject-Specific Protocol Deviation Log Template

# *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.*

| ****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 so, list date**** | ****PI Initial and Date**** |
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