**NIMH Concomitant Medication Log Template**

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

***Purpose:*** *This template may be used to record and track concomitant medications.*

***Audience/User:*** *Principal Investigators and study team members who record and track concomitant medications*

***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 be 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 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 updated.*

**NIMH Concomitant Medication Log Template**

*Customize the following according to the protocol*

*[Check if participant has not taken medications (including OTC) within 30 days of screening visit  None]*

*[Check if participant has not taken medications (including OTC) within 30 days of randomization visit  None]*

| Medication Name  (Generic name) | Indication  (If given for an AE, enter exact term from AE log) | Dose w/Units | Frequency | Route\* | Start Date  (mm/dd/yyyy) | End Date  (mm/dd/yyyy) | Given for an AE?  Y/N | Data Collected By (Initials & Date) | Investigator Initials & Date |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | \_\_\_/\_\_\_ /20\_\_\_ | \_\_\_/\_\_\_ /20\_\_\_  **Or**  Ongoing at End of Study |  |  |  |
|  |  |  |  |  | \_\_\_/\_\_\_ /20\_\_\_ | \_\_\_/\_\_\_ /20\_\_\_  **Or**  Ongoing at End of Study |  |  |  |
|  |  |  |  |  | \_\_\_/\_\_\_ /20\_\_\_ | \_\_\_/\_\_\_ /20\_\_\_  **Or**  Ongoing at End of Study |  |  |  |
|  |  |  |  |  | \_\_\_/\_\_\_ /20\_\_\_ | \_\_\_/\_\_\_ /20\_\_\_  **Or**  Ongoing at End of Study |  |  |  |
|  |  |  |  |  | \_\_\_/\_\_\_ /20\_\_\_ | \_\_\_/\_\_\_ /20\_\_\_  **Or**  Ongoing at End of Study |  |  |  |

*[Check at end of study if participant did not take medications (including OTC) throughout the course of the study*  *None]*

\*Route = Inhaled (RESP), Intramuscular (IM), Intravenous (IV), Nasal (NAS), Oral (PO), Rectal (REC), Topical (TOP), Subcutaneous (SC), Sublingual (SL), Transdermal (TDM), Unknown (UNK), or Other (specify).

*Customize the following according to the protocol*

*[  Medications Confirmed at Baseline by \_\_\_\_\_\_\_\_\_\_\_  Medications Confirmed at V1 by \_\_\_\_\_\_\_\_\_\_\_ ]*