**NIMH Subject Specific Investigational Product Dispensation and Accountability Log Template**

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

***Purpose:*** *This template provides a recommended structure for recording and tracking subject specific investigational product (IP) dispensation and accountability*

***Audience/User:*** *Site Monitors, Principal Investigators and study team members who are delegated to record and track subject specific IP dispensation and accountability*

***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 Investigational Product (IP) Dispensation and Drug Accountability Log Template**

| Lot Number(s) | Randomization Number | Number of Containers Dispensed to Subject | Number of Units Dispensed to Subject | Date Dispensed to Subject | Dispensed by (staff name) to Subject | Expected Date of First Dose to Subject | Number of Containers Returned | Number of units returned by Subject | Date Returned by Subject | Verified by(staff name) | *Actual* number of units used/taken | *Estimated* number of units to be used/taken | % compliance\* |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |

\*Calculation of % Compliance = Actual taken / Estimated to be taken