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| **Study Stage:**  Conduct |

**Purpose:** This template is intended for use in tracking the dispensing to and return of study drug from research participants, after they have been given by the Research Pharmacy to the research team. This does not cover drug accountability from the Sponsor to the research team because it is expected that the Research Pharmacy will receive study drug(s) from the Sponsor and manage any necessary returns or destruction of the study drug(s). For devices, please see the device accountability log on the MICHR site.

**Useful to:** Research staff responsible for tracking the dispensing of study drug to research participants and the return of study drug to the research pharmacy.

**Instructions:**

* Customize the template based on your study specifics (for example, 1 unit equals 20 pills)
* Use a separate log for each participant
* Each time study drug is given to a participant, document it in this log.
* Add columns about drug storage to the log if it is a controlled substance or if it will be stored between pick up from research pharmacy and dispensing to participant in order to document drug location at all times. Include columns for each person involved in each transfer of the drug. If returned drug is stored before going to the research pharmacy add additional columns. Of note, because this form meets the requirements of the regulations, it should be used as it is written when conducting clinical trials using controlled substances (i.e. opiates).
* Include information about storage conditions (including temperature and access information). Note: See reference below for regulatory definition of locked and secure.
* Each time a study drug is returned by the research participant, document in this log.
* Pages may be added to the template as needed.
* Each time the log is used ensure that the individual initials the document personally.
* For study teams with members who have similar initials revise the log to use names rather than initials.

**Best Practice Recommendation:**

* If your study Sponsor provides a chain of custody template and controlled substances are involved, use both forms if this forms information is
* not captured in the form provided by the sponsor.

**Template History:**

**Last Updated:** 6/07/202

Version: 2.3

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| **Reference(s):**  **FDA** 21CFR 312.69 Handling of controlled substances  <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.69> |

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| **Study Name:** | **IRB HUM#:** |
| **Principal Investigator:** | **Study Drug Name:** |
| **Locked & Secure Storage location 1 (if applicable):**  **Storage Condition:**  Room Temperature (RT) Cold 2 to 8◦ C (C) Frozen -15 to -25◦ C (F) | **Locked & Secure Storage location 2 (if applicable):**  **Storage Condition:**  Room Temperature (RT) Cold 2 to 8◦ C (C) Frozen -15 to -25◦ C (F) |
| **Participant ID:** |  |

| **Lot #/Bottle #/Kit#** | **Dosage/ Strength** | **Person storing drug must initial here**  **(list date and time)** | **Person removing drug from storage must initial here (list date and time)** | **Date and time Dispensed to Participant**  (DD/MM/YY) | **Quantity Dispensed to Participant** | **Person dispensing drug must initial here** | **Date and time Returned by Participant** | **Quantity Returned by Participant** | **Receiver must initial here** | **Person storing drug must initial here**  **(list date and time)** | **Person removing drug must initial here (list date and time)** | **Person returning drug to pharmacy must initial here and list date and time** |
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|  |  | Initials:  Date:  Time: | Initials:  Date:  Time: | Date:  Time: |  | Initials: | Date:  Time: |  | Initials: | Initials:  Date:  Time: | Initials:  Date:  Time: | Initials:  Date:  Time: |
|  |  | Initials:  Date:  Time: | Initials:  Date:  Time: | Date:  Time: |  | Initials: | Date:  Time: |  | Initials: | Initials:  Date:  Time: | Initials:  Date:  Time: | Initials:  Date:  Time: |