

# Documenting Drug Accountability for Oral Investigational Agents

## Conducting and Documenting Drug Accountability for Oral Investigational Agents that are Self-Administered by Patients

SOP #: PM-8	Next Review Date: 07/2012
Version #: 2.1	Review Interval Period: Annual
Approved Version #: 2.1 Date: 07/2011	Policy Reference: DDM-1

Purpose: To identify all activities associated with drug accountability for participant self-administration of oral investigational agents, ensuring error-free drug accountability for clinical trials which involve participants receiving oral investigational agents.

### STEP 1: Dispensing of Investigational Agents

1. Investigational agents are dispensed from the Clinical Center Pharmacy Department to a participant or to a Patient Care Unit for self medication.
2. A record of dispensed investigational agents is generated by Pharmacy personnel and documented in the Pharmacy Department's Investigational Drug Management System (IDMS).

### STEP 2: Self-Administering Oral Investigational Agent

1. A participant self-administers investigational agents according to protocol directions.

### STEP 3: Return of Unused Oral Investigational Agent

1. As per protocol, a participant will return unused oral investigational agents, along with their completed patient diary (if applicable per protocol), to a Research Nurse.
2. If a participant goes off study while at home, the Research Nurse will ensure and document the return of the unused oral investigational agents from the participant.
3. If applicable, the Research Nurse reviews and validates the completeness and accuracy of the participant's diary (or other document as specified in the protocol) with the participant.

### STEP 4: Counting of Returned Oral Investigational Agents

1. Assemble the following equipment and supplies (may be obtained from inpatient floor supply rooms) for counting returned oral investigational agents (tablets and capsules) by patients:
  - Plastic specimen bags marked, "Biohazard"
  - Covered, plastic, double-lined Medical Pathological Waste (MPW) box
  - Absorbent, disposable pads (example: Chux™)
  - Disposable pharmaceutical "weighing trays" (may be obtained from the Clinical Center Pharmaceutical Development Section, Pharmacy Dept., Building 10, Room 1C230)
  - Sterile, disposable tongue blades
  - Clean, non-sterile gloves
2. Wash hands.
3. Don gloves.
  - If at any time gloves are torn, punctured, or contaminated with Hazardous Drug, remove the gloves, rewash your hands and replace the gloves with a fresh pair. Gloves should also be replaced between handling different medications for a single subject and before handling another subject's medication.
4. Place a disposable plastic-backed absorbent pad on a flat, clean, washable surface.
5. Place weighing tray on pad.
  - Use a new weighing tray for each subject and for each different oral investigational agent to avoid cross contamination between objects /agents.
6. Pour tablets or capsules out of their container onto weighing tray.
  - Use more than one weighing tray if the quantity exceeds what one tray can hold or more than can be accurately counted on a single tray.
  - If any tablets or capsules are damaged or crushed, count the intact capsules or tablets and return all products to the Pharmacy.
7. Manipulate and count the medications on the weighing tray using a disposable tongue blade.
8. Return tablets or capsules to the containers in which they were received.
9. Seal container using the same closure.
  - Do not break seals on unopened containers. Read and record the count printed on the product label.
10. Discard used weighing trays, tongue blades, and absorbent pad into a MPW box.
11. Remove gloves and discard in a MPW box.
12. Wash hands.

### STEP 5: Documenting Oral Investigational Agents, Returning Counted Agents To Patients, or Disposing of Returned Medications

1. The amount of investigational drug dispensed in the CRIS (under Orders), the amount taken by the patient, and the amount of returned unused agent is reconciled and documented in the medical record.
  - Reconciliation will ensure that all dispensed doses are properly accounted for, with explanation for any inadvertently lost or destroyed medications.
2. If the sponsor has not provided a Pill Count Form or Log, staff should use the following CCR forms:
  - [Patient Self-Administered Study Agent Interim Compliance Form](#). This form is used if a patient is bringing back their study drug but it will not be returned to the pharmacy. The patient will be taking it back home with them.
  - [Patient Self-Administered Study Agent Compliance Log](#). This log is used to capture the entire study drug compliance.

3. The completed Patient Self-Administered Study Agent Interim Compliance Forms are retained in the Research Folder to ensure proper record of drug accountability per patient at the clinical site.
4. If dictated by the protocol, remaining counted investigational agents are re-dispensed to the participant for self-administration, a note is entered in the medical record, and a new Patient Self-Administered Study Agent Interim Compliance Form is initiated.
5. Unused investigational agents that are not re-dispensed to the patient for future administration are counted and recorded on the Patient Self-Administered Study Agent Interim Compliance Form.

#### STEP 6: Disposing of Unused Investigational Agents

1. Obtain an Oral Investigational Agent Disposal kit from the 6th floor Pharmacy Repository (Rm 6C417, ACRF) door pocket.
  - The kit includes a Biohazard bag which contains an Investigational Drug Return Form.
2. Complete an [Investigational Drug Return Form](#).
3. Make a copy of the Investigational Drug Return Form and place it in the Research Record.
4. Put all returned oral investigational agent containers in a Biohazard specimen bag with the Investigational Drug Return Form.
5. Deliver the Biohazard bag containing the unused investigational agent to the 6th floor Pharmacy Repository (Rm 6C417, ACRF) and place in the designated drop slot located on the wall to the right of Room 6C417.
  - Messenger or Escort Services may be contacted to perform the delivery function.

#### STEP 7: Accounting for Discarded Unused Investigational Agents

1. Investigational agents are counted by Pharmacy personnel.
2. The total amount of investigational agent returned to the Pharmacy is entered into the NIH Clinical Center Pharmacy's Investigational Drug Monitoring System (IDMS) database.
3. Pharmacy personnel will contact, via email, the study Principal Investigator (or personnel identified on Investigational Drug Return Form) to report the final count of unused investigational agent, (the patient's initials, the protocol number, and the drug name will be included in the email) within two (2) weeks of receiving returned investigational drugs.
4. The Research Nurse will compare the Pharmacy's final count of investigational agents with the amount recorded in the corresponding CCR Pill Count Case Report Form and, if necessary, reconcile any discrepancies.
5. The Research Nurse will document in the medical record any discrepancies and reconciliation processes if the Research Nurse's total pill count total and the Pharmacy's final count are not the same.
6. Investigational Agents are saved for inspection or retrieval by drug company monitors, returned to the drug Sponsor, as required, or destroyed as per Pharmacy procedure.