

November 10, 2010

**RESEARCH STANDARD OPERATING PROCEDURES (SOP)
Pharmacy Logbook for Securing Protected Health Information (PHI)**

1. **PURPOSE:** To establish a policy and standard operating procedure for maintaining and securing logbook(s) containing Protected Health Information (PHI) within the research pharmacy.

2. **POLICY:** Current regulatory requirements mandate that the research pharmacy maintain logbook(s) to track enrollment and drug accountability in accordance with VHA Handbook 1108.04.

3. **ACTION:**

a. Logbook(s) will be maintained provided any of the following conditions apply:

- (1) Required by protocol sponsor
- (2) Individual research subject dispensing logs when more than one medication is dispensed to the subject from the research pharmacy
- (3) Randomization schemes maintained in research pharmacy
- (4) Inpatient medications required to document individual picking up medication

b. The following PHI may be recorded in the logbook(s):

- (1) Patients name;
- (2) Last four of SSN;
- (3) Birth date;
- (4) Assigned randomization number or other unique patient identifying number;
- (5) Date of randomization, prescription dispensed or returned;
- (6) Prescription number; and
- (7) Kit number or container number;

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- c. All logbook(s) will be secured within a locked file cabinet located within the research pharmacy, Room D705.
 - (1) During working hours, Monday – Friday 8am-4:30pm, the cabinet will not be locked when the research pharmacist is within the research pharmacy.
 - (2) If the research pharmacist leaves the research pharmacy at any time during those hours, the file cabinet will be locked.
 - (3) During off hours when the research pharmacy is closed, the file cabinet will be locked.

- d. The research pharmacy is equipped with controlled access via an electronic card reader and pin number unique to each individual granted access.
 - (1) Access to the research pharmacy is limited only to research pharmacy personnel.

4. **REFERENCES:** VHA Handbook 1108.04 Investigational Drugs and Supplies

5. **RESPONSIBILITY:** ACOS for Research and Development (151)

6. **RESCISSIONS:** None

7. **RECERTIFICATION:** November 2015


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