

January 24, 2012

**BARTTER RESEARCH UNIT (BRU) STANDARD OPERATING PROCEDURES (SOP)
Security and/or Disposition of Drugs Presented by Research Study Participants upon
Admission to The Bartter Research Unit (BRU)**

1. PURPOSE: To establish procedures regarding the security and/or disposition of drugs brought to The Bartter Research Unit (BRU) at South Texas Veterans Health Care System (STVHCS) by research study participants upon admission.

2. POLICY: This policy describes procedure for disposition of drugs brought by research study participants upon admission to the hospital.

3. ACTION:

a. Upon admission of a research study participant to the BRU, the admitting study staff or assigned nurse will verify if the research study participant has brought medications with him/her to the BRU.

b. If the study participant has brought medications with him/her, the admitting study staff or assigned nurse will give them to a relative accompanying the patient, so that they may be taken home.

c. If there is no relative available to take the medications to the study participant's home, the admitting study staff or assigned nurse will forward the medications to the research pharmacy. The research pharmacist will place the medications in a bag, seal the bag, and write on the outside of the bag the study participant's name, social security number, and the research protocol for which the patient is currently enrolled. This bag will remain in the pharmacy until the study participant is discharged. Upon discharge, the research pharmacist will return the sealed bag of home medications to the study participant.

d. In certain cases, it may be necessary to use a research study participant's own medication for therapy while the individual is an inpatient of the BRU. Examples of such cases include previously dispensed investigational medications as part of an active VA-approved protocol and admitted patients involved in an active VA-approved protocol that are non-veterans. Non-veteran research study participants may be instructed to bring any prescribed medications they are currently taking in their original containers containing pharmacy labels if the principal investigator determines continuation of this drug therapy is indicated while admitted.

e. Medications will not be stored in Personal Effects, nor in the clothing room with other personal property. The assigned nurse will store and secure the participant's own medication(s) in a cassette in the medication cart located within the medication room and labeled with the research study participant's name. This cassette will not be changed out by inpatient pharmacy.

f. The Principal Investigator will create a note in Computerized Patient Record System (CPRS) that explicitly orders the patient's own medications to be administered while in this hospital. Procedures for identification and labeling the medication presented by a research study participant upon admission to the BRU include:

- (1) The Principal Investigator or study physician designee, assigned nurse, or Research Pharmacist will attempt to positively identify the medications presented by the research study participant upon admission. The identification process should include a visual examination to ascertain medication identity, integrity, and expiration date(s). If medications cannot be identified, or if the expiration date(s) is not available, they may not be administered.
- (2) Medications presented by research study participants upon admission, which are investigational drugs, will be identified by the Research Pharmacist.
- (3) Identification information will be documented on the drug container with an auxiliary label (Attachment 1), which will include the identification of the medication and the initials of the identifying investigator or designee, nurse, or pharmacist.
- (4) The nurse or pharmacist will inform the investigator or designee and the participant when medication presented by the participant upon admission will not be permitted for use (due to problems with integrity of the medication, expiration date, etc).

g. Procedures for use of a patient's own medications:

- (1) Medications will be inventoried by nursing staff and witnessed by the research study participant on the Patient Personal Medication Inventory Form (Attachment 2) upon arrival to the BRU.
- (2) The beginning inventory will be signed by the research study participant, assigned nurse and research pharmacist.
- (3) Medications will be stored under nursing staff control within a participant specific labeled cassette of the medication cart in the locked medication room. This will ensure the stored medications are under double lock.
- (4) The administration of medications not dispensed by the Research Pharmacy will be recorded by Nursing staff on a hardcopy Medication Administration Record (MAR) (Attachment 3), and in a note by Nursing staff in CPRS.
- (5) Nursing staff will use a hardcopy medication administration record and/or VA Form 10-2638, Controlled Substance Administration Record to document administration of controlled drugs (Attachment 4).
- (6) Controlled drugs will be counted with a witness at the end of each shift and documented on VA Form 10-1043 (Attachment 5).
- (7) Medications will be returned to the study participant upon discharge, unless otherwise authorized by the investigator or designee.

(8) Return of medication will be documented and witnessed by the research study participant on the Patient Personal Medication Inventory Form (Attachment 2).

(9) If directed by the Principal Investigator or study physician designee, the medication will be disposed of in accordance with Pharmacy's disposition process.

(10) The medication administration record(s) and inventory sheet will be filed and maintained by Nursing for a period of not less than three years.

(11) The Controlled Substance Coordinator will conduct a monthly audit of controlled drugs stored and administered.

4. REFERENCES: VHA Handbook 1108.01, Pharmacy Service Policy Memorandum Security and/or Disposition of Drugs Presented by Patients upon Admission to System Health Care Facilities

5. RESPONSIBILITY: BRU Nurse Manager

6. RESCISSION: None

7. RECERTIFICATION: January 2017


MARY S. MOORE, MSN, RN
Nurse Manager

Patient's Own Medication

Pt. Name: _____ Last 4 _____

Med: _____

Drug identified by: _____ (R.N./M.D./R.Ph.)

Date: _____

Patient's Own Medication

Pt. Name: _____ Last 4 _____

Med: _____

Drug identified by: _____ (R.N./M.D./R.Ph.)

Date: _____

Patient's Own Medication

Pt. Name: _____ Last 4 _____

Med: _____

Drug identified by: _____ (R.N./M.D./R.Ph.)

Date: _____

Patient's Own Medication

Pt. Name: _____ Last 4 _____

Med: _____

Drug identified by: _____ (R.N./M.D./R.Ph.)

Date: _____

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Med: _____

Drug identified by: _____ (R.N./M.D./R.Ph.)

Date: _____

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Med: _____

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Date: _____

Patient's Own Medication

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Med: _____

Drug identified by: _____ (R.N./M.D./R.Ph.)

Date: _____

Patient's Own Medication

Pt. Name: _____ Last 4 _____

Med: _____

Drug identified by: _____ (R.N./M.D./R.Ph.)

Date: _____

Patient's Own Medication

Pt. Name: _____ Last 4 _____

Med: _____

Drug identified by: _____ (R.N./M.D./R.Ph.)

Date: _____

Patient's Own Medication

Pt. Name: _____ Last 4 _____

Med: _____

Drug identified by: _____ (R.N./M.D./R.Ph.)

Date: _____

Patient's Own Medication

Pt. Name: _____ Last 4 _____

Med: _____

Drug identified by: _____ (R.N./M.D./R.Ph.)

Date: _____

BARTTER RESEARCH UNIT
Patient Personal Medication Inventory Form

Patient Name: _____

Last 4: _____

Admission Date: _____

Study Name: _____

	Medication	Dosage Form (pill, injection, liquid, patch, etc.)	Dosage	Directions	Use (scheduled or PRN)	Expiration Dates	Qty	
							Adm	D/C
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								
15.								
16.								

Upon Admission:

Nurse: _____ Date: _____

Study Participant
Signature: _____ Date: _____

Research Pharmacist
Signature: _____ Date: _____

Upon Discharge:

Nurse: _____ Date: _____

Study Participant
Signature: _____ Date: _____

Department of Veterans Affairs	STAT AND ONE TIME MEDICATION/TREATMENT RECORD										MONTH(S):	YEAR:						
MEDICATION TREATMENT DOSE/ROUTE INSTRUCTIONS				ADMINISTRATION				RESULTS				ADMINISTRATION		RESULTS				
ORDER DATE	DATE			INIT	DATE			INIT	DATE			INIT	DATE	TIME	INITIALS	DATE	TIME	INITIALS
REASON	TIME			INITIALS	TIME			INITIALS	TIME			INITIALS	INITIALS	INITIALS		INITIALS		
REASON	INITIALS			REASON	INITIALS			REASON	INITIALS			REASON	INITIALS		INITIALS		INITIALS	
ORDER DATE	DATE			INIT	DATE			INIT	DATE			INIT	DATE	TIME	INITIALS	DATE	TIME	INITIALS
REASON	TIME			INITIALS	TIME			INITIALS	TIME			INITIALS	INITIALS	INITIALS		INITIALS		
REASON	INITIALS			REASON	INITIALS			REASON	INITIALS			REASON	INITIALS		INITIALS		INITIALS	
ORDER DATE	DATE			INIT	DATE			INIT	DATE			INIT	DATE	TIME	INITIALS	DATE	TIME	INITIALS
REASON	TIME			INITIALS	TIME			INITIALS	TIME			INITIALS	INITIALS	INITIALS		INITIALS		
REASON	INITIALS			REASON	INITIALS			REASON	INITIALS			REASON	INITIALS		INITIALS		INITIALS	
PATIENT IDENTIFICATION				ALLERGIES				IM OR SQ INJECTION SITES				RESULTS						
<input type="checkbox"/> NKA				INDICATE RIGHT (R) OR LEFT (L) 1 = ABDOMEN 4 = GLUTEAL AREA 2 = ARM 5 = THIGH 3 = ILIAC CREST				E = EFFECTIVE I = INEFFECTIVE (RECORD OBSERVATION) A = ADVERSE REACTION (RECORD OBSERVATION) NO = NOT OBSERVABLE										

