

**POLICY AND PROCEDURE MANUAL  
PHARMACY SERVICES**

SECTION: **INPATIENT PHARMACY SERVICES**

SUBJECT: **ORDER ENTRY AND DISPENSING FOR  
INVESTIGATIONAL DRUGS**

CODE: 3.25.5  
DATE: 11/17/04  
REVISED: 4/19/22  
APPROVED: Tinh Tran, Pharm. D.  
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POLICY

The Investigational Drug Service Pharmacist (IDSP) processes physician orders to administer investigational drugs (study drugs) to the patient. This occurs once authorization is received and the admitting physician writes the order to administer the study medication. In the absence of the IDSP an inpatient pharmacist may dispense enough emergency doses to the nursing unit to last until the IDSP's next scheduled shift. Communication to the Nursing unit via the Medication Administration Record (MAR) is required. Inventory control via the controlled drug procedure will be utilized

PROCEDURES

I. Order Entry

A. Receipt of all documents and approval for the administration of the investigational drug as per Pharmacy Policy 1.14.1

B. Processing the physician order to administer the investigational drug(s)

C. Selecting the following drug codes, which are dependent on the number of medications in the study

1. RS1: Rancho Study Drug #1
2. RS2: Rancho Study Drug #2
3. RS3: Rancho Study Drug #3

D. Entering the directions (sig) utilizing the following format: the sig followed by the study medication name in brackets.

Example: Study with a single drug:  
Rancho Study Drug #1  
2 tablets daily [TEST1 Study Drug]

Example: Study with multiple drugs (3):  
Rancho Study Drug #1  
1 cap bid [TEST2 Study Drug A]

Rancho Study Drug #2  
1 tab qAM [TEST2 Study Drug B]

Reviewed: 8.20.2014 II, 4/19/2022 TT

Approved By: 

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Rancho Study Drug #3  
1 tab qAM 30 min. before Drug A&B [TEST2 Study Drug D]

II. Dispensing

A. Prepare a pharmacy notebook for tracking the medication, the notebook containing:

1. Copy of the protocol (or an electronic document file stored on the Investigational Drug computer)
2. Copy of all amendments (or an electronic document file stored on the Investigational Drug computer)
3. Copy of the consent form (or location for easy access)
4. Information concerning the study drug
5. All correspondence concerning the study drug
6. Copies of the Proof of Use Record sheets outstanding
7. Completed Proof of Use Record sheets returned from the nursing unit

B. Prepare a second notebook for the nursing unit, the notebook containing:

1. Current Proof of Use Record Sheet(s) for the medication sent to the nursing unit
2. Information concerning the study drug

C. Generate Proof of Use Record sheet(s) by entering the appropriate study drug code(s) into the controlled drug computer program

D. Pyxis Medstation will be loaded with unit of use oral medications for use on the unit. Intravenous medications will be delivered directly to the nurse caring for the patient.

E. Record on each Proof of Use Record sheet the following:

1. Name of the Study Drug
2. The patient's name: AFOR\_\_\_\_\_A
3. The patient's medical record number