

LOUIS STOKES CLEVELAND VA MEDICAL CENTER  
Medical Research Service  
SOP Cover Page

**Effective Date:** September 1, 2005

**SOP Title:** Utilizing In-Stock Medications for Research Purposes

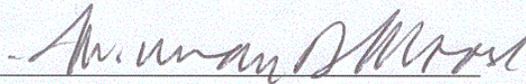
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**Approved By:**

  
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Committee Chairperson/Administrator (if applicable)

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**LOUIS STOKES CLEVELAND VA MEDICAL CENTER**  
**Medical Research Service**  
**Standard Operating Policy and Procedure (SOP)**

**Effective Date:** September 1, 2005

**SOP Title:** Utilizing In-Stock Medications for Research Purposes

**SOP Number:** HSP-012

**SOP Version:** .00

1. **PURPOSE:** To establish guidelines for the utilization of in-stock Medications for research purposes (“In-stock Investigational Drugs”)

2. **POLICY:** When In-Stock medications are used within the context of a research study, the principal investigator must identify that the prescription is being dispensed for research purposes. The Investigational Drugs for Patient Use Policy (MCP 119-019) and all other corresponding regulations are applicable.

3. **DEFINITIONS:**

**a. Investigational drugs:** An investigational drug is defined by one of the following: (i.) a drug in any of the clinical stages of evaluation which has not been released by the FDA for general use or cleared for sale in interstate commerce; (ii.) any commercially available drug proposed for a new use; (iii.) any commercially available drug proposed for a new dosage form or method of administration; (iv.) a commercially available drug which contains a new component such as an excipient or coating; (v.) a new combination of two or more commercially available drugs; or (vi.) a combination of commercially available drugs in new proportions.

4. **RESPONSIBILITIES:**

**a. Principal Investigator (PI) must:**

(1) Obtain the necessary approvals of the Research and Development (R&D) Committee, Institutional Review Board (IRB), Subcommittee on Research Safety (SRS), Pharmacy and Therapeutics (P&T) Committee prior to the commencement of the research project.

(2) Discuss the study with the Research Pharmacist.

(3) Specify that prescriptions for in-stock drugs be being written for research purposes.

(4) Maintain and adhere to all provisions regarding the protection of human rights and safety during the research project.

(5) Ensure that subjects are not paying for research related costs.

**b. Pharmacy Service must:**

(1) Approve the project and then provide a notice to the principal investigator, research pharmacist and to the IRB office. As is customary, the in-stock investigational drugs will be stored under lock and key and dispensed by Pharmacy Service.

(2) Maintain a copy of the authorization document (VA Form 10-9012) that designates the PI and secondary investigator(s) for each investigational drug maintained in the pharmacy.

(3) Maintain a copy of the most recent version of the protocol.

(4) Maintain a copy of the signed informed consent documents.

(5) Maintain all copies of investigational transactions for five (5) years following the termination of a study.

**5. PROCEDURE:**

a. Place order for In-stock drug in CPRS. Insert the following text in the comments' section:  
"This prescription is being filled for research purposes only in relation to the "(insert name of trial) Trial".

b. Work with Tammy Salewsky, Clinical Informatics Clinical Coordinator, to create a "Quick Order" for in-stock drug to be used in clinical trial. Provide Tammy with the following information for each variant of the prescribed drug. Tammy Salewsky is stationed in Brecksville and can be reached at 939-6694.

- (1) Drug Name
- (2) Dosage
- (3) Days Supply, Quantity, Refills
- (4) Route
- (5) Schedule
- (6) Priority (ASAP, Done, Routine, Stat)
- (7) Text for Comments Section "This prescription is being filled for research purposes only in relation to the "(insert name of trial) Trial".

c. IRB will provide Alice Leone, Research Pharmacist, with 10-9012 and the approved protocol.

d. The PI must provide Alice Leone (Wade Park) or Rich D'Atri (Brecksville) with a copy of the subject's signed consent forms. Then, the signed consent forms and protocol will be supplied to the outpatient or inpatient pharmacy for proper referencing.

6. **REFERENCE:** M-2, Part VII, Chapter 6, dated 3/28/91; M-2, Part I, Chapter 3, dated 12/13/93; VHA Handbook 1200.5 and RCS 10-1, dated 5/18/92; IRB SOP Manual; 21 CFR Parts 50, 56 and 312, MCP 119-019 "Investigational Drugs for Patient Use", dated November 5, 2004.

7. **RESCISSION:** September 1, 2008.

8. **FOLLOW UP RESPONSIBILITY:** Research Service Compliance Officer.