RESEARCH STANDARD OPERATING PROCEDURES (SOP)
Pharmacy Procurement of Investigational Drugs, Investigational Devices, and Supplies

1. **PURPOSE**: To establish a policy and standard operating procedure for research pharmacy to procure investigational drugs, devices and supplies.

2. **POLICY**: The Research Pharmacist will work in collaboration with Pharmacy Procurement and Principal Investigators to obtain investigational drugs, investigational devices, and supplies to provide support of VA-approved research protocols.

3. **ACTION:**

a. **Responsibilities**

(1) **<u>The Research Pharmacist</u>**

(a) The Research pharmacist is responsible for ensuring that all investigational studies have received initial approval prior to ordering, receipt, storage, or dispensing of investigational drugs or devices.

(b) For medications and supplies not provided by the sponsor, the research pharmacist will place an order with pharmacy procurement and obtain these supplies or medications from pharmacy procurement once received.

(c) The principal Investigator will be billed for medications or supplies purchased via the pharmacy service budget.

(d) Procedure in Case of Loss of Shipment of Investigational Medication or Device

(1) Any suspected theft, diversion, or loss of investigation drugs or devices must be reported to Pharmacy Chief, Associate Chief of Pharmacy Clinical Programs, Administrative Officer Research, and Associate Chief of Staff for Research.
(2) VHA medical center Police Service will be notified of losses not accounted for by the close of business day will be VHA medical center Police Service.

(2) **<u>Pharmacy Procurement</u>**

(a) Pharmacy procurement will initiate purchases for medications at the request of the research pharmacist.

(b) Pharmacy procurement will provide the research pharmacist with pricing information for medications or supplies at the request of the research pharmacist.

(3) **Principal Investigator (PI)**

(a) Prior to notifying sponsor to ship investigational drug, verifies that the research pharmacist has obtained IRB approval letter, R&D approval letter, and Interactive Web Response System (IVRS/IWRS) access.

(b) Ensures Pharmacy Services obtains reimburse for medications and supplies purchased on the pharmacy service budget.

4. **REFERENCES**: None

5. **RESPONSIBILITY**: Chief, Pharmacy Service (119)

6. **RESCISSIONS**: *RESEARCH STANDARD OPERATING PROCEDURES (SOP) Research Pharmacy Drug and Supply Procurement,* November 16, 2011

7. **RECERTIFICATION**: October 2019

PETER T. TRANG, RPh, MBA
Chief, Pharmacy Service