CONTRACTUAL AGREEMENT BETWEEN THE RESEARCH PHARMACY AND PRINCIPAL INVESTIGATOR FOR INVESTIGATIONAL PROTOCOL

1. This document constitutes the contractual agreement between the Research Pharmacy and Principal Investigator for Protocol. The Investigational Drug shall be stored under double lock in room number and under the direct care of the Study Coordinator and/or the Principal Investigator and under supervision of the Principal Investigator.

2. The Principal Investigator conducting this study protocol is responsible for the following:

a. The Principal Investigator will supply the Research Pharmacy with information on patients receiving an investigational drug that experience an adverse drug reaction related to the investigational drug or an interaction with other drug therapy;

b. An investigational drug log will be maintained by the Principal Investigator containing the following information:

(1) Protocol number
(2) Date Protocol Approved
(3) Name of the drug
(4) Dosage form and strength
(5) Manufacturer or other source
(6) Date of receipt of the drug
(7) Quantity received
(8) Expiration date
(9) Control number
(10) Name of patient receiving the medication
(11) Serial Number of the Prescription
(12) Name of authorized practitioner signing the prescription
(13) Quantity dispensed
(14) Balance remaining after the transaction
(15) Documentation that signed informed consent scanned into patient's electronic medical record
(16) Documentation that VA Form 10-9012 scanned into patient's electronic medical record
(17) Recorder's initials
(18) A final entry will be made when the use of the investigational drug is discontinued. This entry will document the date of termination of the use of the drug, the quantity remaining, and the action taken to dispose of the balance on hand

3. This information may be kept on an electronic spreadsheet or on a paper log and made available for review by the Research Pharmacist on a monthly basis.

4. The Research Pharmacist will inspect the storage area to be used before the study begins and randomly during the study.

5. Signatures of those below validate this contractual agreement between the Principal Investigator for this study protocol and the Research Pharmacy and certify each individual understands his or her responsibilities regarding the agreement.

Research Pharmacist	(Date)	Principal Investigator	(Date)
ACOS for Research	(Date)	Chief, Pharmacy Service	(Date)