Summary: This procedure covers identification, storage, and dispensing parameters for investigational medications as well as non-FDA approved medications.

Purpose: To provide pharmacists, physicians, nurses, and patients full information regarding medications that are not FDA approved. The purpose is to maintain proper storage of the medication as per investigational policy or other reference. The medications are to be dispensed only by the HRMC pharmacy after full identification of the medication and knowledge of the protocol or other information available about the medication.

Scope: This procedure applies to all hospital departments of HRMC that administer medications to patients. (Inpatients and Outpatients). This only applies to investigational and non-FDA approved medications that can be identified. Herbal medications are NOT considered a part of this policy, and are restricted from use at HRMC.

Responsibilities:

Physician: order stating the full medication name, dosage, route, and frequency. If the medication is from an investigational protocol outside of HRMC or a non-FDA approved medication, the physician must write an order that patient may 'use own medication' from the protocol. If an investigational medication, the physician should contact the lead investigator or contact of the investigational protocol to inform them of the patient's admission and is responsible for obtaining protocol information to disseminate to pharmacy and nursing staff involved in the patients care.

Pharmacist: the pharmacy shall retrieve such medication to be identified (to its fullest extent). A copy of the investigational protocol should be made available to the pharmacy, whether provided from the physician or directly from the protocol investigator. After identification, the med should be properly labeled and stored in the pharmacy until dispensed. The medication should be dispensed as single-dose, or in no more than 24 hour supplies. All information regarding the medication's side effects, drug interactions, and clinical use should be disseminated to the nurse and physician (if known).

Nurse: the nurse caring for the patient should have a medical consent form signed by the patient, with a fact sheet attached stating that the patient understands the risks/benefits of such medication. A copy of the fact sheet should be given to the patient, and the consent with fact sheet should be placed in the medical record.

Lead investigator: (if HRMC protocol) the lead investigator should coordinate all physician, pharmacist, and nurse activities, and provide all information available to all involved regarding the use of the medication.

Equipment and Supplies:

Physician order:
Investigational or non-FDA approved medication
Consent form
Fact sheet
Investigational protocol or other information regarding the product

Procedure:

1. Obtain order for medication
2. Obtain all pharmacologic information about medication and/or investigational protocol. Disperse this information to all involved with patient's care.
3. Obtain medication; Identify medication and storage parameters
4. Document consent of patient to receive medication: Include Medication fact sheet & Protocol
5. Dispense medication in single dose increments or in $\leq$ 24 hour supplies; Record dispensing.
6. Upon discharge, return all medication in original containers to patient

INVESTIGATIONAL DRUG STOCK CONTROL & DISPENSING RECORD

Patient Name:_____ **Account #:**____-____-____ **MRN:**_____

Name of Drug:_____ **Dosage Form:**_____ **Dosage:**_____

☐ Consent signed by patient ☐ Investigator contacted
☐ Protocol /pharmacologic info received ☐ Primary physician aware (& in contact with investigator)

Manufacturer:_____ (if known) Protocol name/number:_____ Lot number:_____
☐ Placebo-controlled (blinded)? ☐ Phase_____(I-IV, if known)
Storage:_____ Investigator(s): _____ Ordering Physician:
_____ _____
Phone #(s) for contact(s)_____ _____ @ HRMC

Pharmacologic information:
☐ **See attached information**; Received by_____RPh
If not attached,
→Usual dosage: →Side effects: →Adverse effects:

→Pharmacokinetic/dynamics: →Drug interactions: →Controlled?

RECEIVED on	Amt per tab/cap/etc.	Starting #	Identified by:	Dosage: (note if dosage change)
DATE	**# Dispensed**	**# Remaining**	**Dispensed by:**	**Notes:**