I. **PURPOSE**

To assure safe and accurate acquiring, labeling, storing, administration, documentation and disposition of investigational drugs.

II. **DEFINITION**

Investigational medication is defined as any research medication which will be administered under a specific research protocol even if the medication is approved for marketing by the FDA.

III. **POLICY**

A. Investigational medications may be administered per a research protocol by authorized licensed staff pursuant to the order of a study specific-authorized prescriber.

B. All investigational medications must be under the control of Pharmacy.

C. Prior to administration of the investigational medication, study approval must have been granted by the Human Subjects Review Committee (Institutional Review Board, or IRB) and other regulatory bodies as appropriate (e.g. Sponsored Projects Administration).

IV. **PROCEDURE**

<table>
<thead>
<tr>
<th>RESPONSIBLE PERSON(S)/DEPT</th>
<th>PROCEDURE</th>
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<tbody>
<tr>
<td>Authorized Licensed Staff and Pharmacist</td>
<td>A. Checks chart to be sure a copy of the signed consent form copy of the IRB approved protocol summary, with current approval date and required signatures, has been placed under the Medical-Legal section. Copy of consent may be sent to Pharmacy.</td>
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<tr>
<td>Pharmacy Staff or Authorized Staff</td>
<td>B. Inservice concerning the protocol and medication usage information for the licensed staff who will administer the</td>
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medication or will be involved with direct patient care. 
Inservice should include:

1. pharmacology  
2. method of administration  
3. usual dosage range and schedule  
4. indications  
5. potential known adverse effects and interactions as appropriate.

Licensed Staff  
C. Administers medications per hospital Medication Administration policy and procedure pursuant to the order of an authorized, study specific, prescriber.

D. Returns unused medication to the Pharmacy and/or discards study medications in a container designated for the incineration of medications, as directed by the research staff in compliance with the protocol.

The Pharmacy shall be responsible for receiving, storing, dispensing, returning/destroying all research medications.

Pharmacy  
E. Investigational medications shall be labeled, stored, distributed and controlled in accordance with each research protocol’s requirements and shall comply with all state and federal laws concerning drug maintenance.

F. Records of the receipt, dispensing, administration, return to Pharmacy, destruction, or return to study sponsor of research medications shall be maintained.

PATIENT ADMITTED ON A NON-UCI APPROVED STUDY  
A. Patient’s admitted on a study protocol not approved by the UC IRB require the following:

1. The outside treating study physician must be notified immediately of the patient’s hospitalization.

B. If the patient is to be maintained on the outside protocol:

1. Direct communication concerning the patient occurs between the treating
2. A copy of a signed, current consent and study protocol is provided and placed in the patient’s chart.

3. Pharmacy checks the medication to ensure it is appropriately labeled and in good condition. Pharmacy assumes the responsibility for the medication. Necessary pharmacy documentation is provided by the outside agent. Any specific instructions necessary for patient well-being and safety are provided.

4. Staff who will administer the medication is inserviced by the treating physician or the Pharmacy Department.

RELATED POLICIES AND PROCEDURES:

Medication Mgmt: Maintenance and Administration of Medications
Informed Consent, Research Protocols

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Director, Pharmacy Services

Approvals:

MUPIT January 16, 2007
P & T Committee February 7, 2007
Policy Review Committee February 6, 2007
Performance Improvement Committee February 14, 2007
Med Exec Committee February 26, 2007
Governing Body February 26, 2007