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Owner **Melanie Joe:**
Chief Pharmacy
Officer

Policy Area **Health**
Enterprise:
Medication
Management

Applicability **UCI Health -**
Orange

MM: Management of Investigational Medications

I. PURPOSE

To delineate policies and procedures relating to assuring safe and accurate acquiring, labeling, storing, administration, documentation, and disposition of investigational drugs utilized in clinical research at UCI Health.

II. DEFINITIONS

- A. **Institutional Review Board (IRB):** an independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.
- B. **Principal Investigator (PI):** an individual in charge of a clinical trial at a trial site. The Principal Investigator prepares and carries out the clinical trial protocol (plan for the study) or research. The principal investigator also analyzes the data and reports the results of the clinical trial.
- C. **Co-investigator (Co-I):** any individual member of the clinical trial team designated and supervised by the Principal Investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions.
- D. **Informed Consent:** process by which a subject voluntarily gives his or her permission to participate in a particular trial after having been in possession of all essential information necessary to make that decision to participate.
- E. **Investigational product(s) (IP):** any research medication, which will be administered under a specific research protocol, even if the medication is approved for marketing by the FDA.

- F. **Drug accountability:** drug receipt, drug storage, handling, dispensing, and documentation of return and/or destruction of the drug
- G. **Investigational Drug Services (IDS):** a function of the Department of Pharmacy and provides support to ensure the safety and efficiency of trials at UCI Health that use investigational product(s)

III. POLICY

- A. All research is approved by the Human Subjects Review Committee (Institutional Review Board or IRB) and other regulatory bodies as appropriate (e.g., Sponsored Projects Administration) prior to study initiation.
- B. Investigators, nursing, pharmacy, study coordinators and other delegated study staff will collaborate to accommodate the dispensing and/or administration of investigational drugs to patients in the outpatient and inpatient settings according to policy.
- C. Investigational product (IP) may be administered per a research protocol by authorized licensed staff pursuant to the order of a study specific-authorized prescriber.
- D. All investigational medications must be under the control of Investigational Drug Services (IDS) Pharmacy. This includes storage, control, and distribution of IP.
- E. All UCI Health personnel who prepare, store, administer, and dispose of IP must comply with all federal, state, and institutional policies and adhere to the following procedures.


IV. PROCEDURES

To manage investigational medications at UCI Health, the following procedures shall occur:

- A. The PI, Co-I, or delegated research staff shall:
 - 1. The PI will ensure study protocol approval by the IRB prior to study initiation.
 - 2. The PI will ensure appropriate training to delegated study staff has been provided for study protocols prior to study initiation.
 - 3. The PI, Co-I, or delegated research staff will provide in-service on the protocol and medication usage information for the licensed staff that will administer the medication or will be involved with direct patient care. In-service will include but not limited to:
 - a. Pharmacology
 - b. Method of administration
 - c. Storage of investigational drug
 - d. Usual dosage range and schedule
 - e. Indications
 - f. Potential known adverse effects and interactions as appropriate
 - 4. The PI, Co-I, or delegated research staff will provide a copy of the current study protocol, Investigator's brochures and other essential documents to research teams so that drug can be safely and appropriately dispensed.

5. The PI, Co-I, or delegated research staff will obtain and provide signed informed consent to research staff involved with dispensing and administration of investigational medication.
6. The PI or Co-I will send Pharmacy a medication order for the investigational medication.
7. The PI will take direct responsibility for oversight of all delegated staff and duties associated with the clinical trial.

B. The IDS pharmacy staff member shall:

1. Under the supervision of the PI, the pharmacist will review the protocol, pharmacy manual, and/or other related research documents to determine feasibility and management of drug-related issues of the clinical trial.
2. The IDS Pharmacy shall be responsible for receiving, storing, dispensing, returning and/or destroying all IP.
3. The IDS pharmacist will document necessary training of ancillary pharmacy staff used to prepare and dispense drugs outside of the main IDS pharmacy location.
4. Upon receipt of an order for an IP, the IDS pharmacist shall verify the following prior to dispensing IP:
 - a. The patient has been appropriately consented by reviewing the signature page of the consent.
 - b. The appropriate IP, dose, and route are ordered for the patient
 - c. The patient is appropriately due for the IP
 - d. The patient meets all appropriate laboratory parameters to receive the IP.
 - e. The patient has not experienced any protocol-specified adverse events deeming the IP inappropriate.
5. The IDS Pharmacy staff will label and distribute all IP in accordance with each research protocol's requirements and shall comply with all state and federal laws concerning drug maintenance.
6. Used injectable vials/syringes shall be discarded immediately after preparation in an appropriate waste container and not saved. Please refer to Drug Disposal/ Destruction Policy for Investigational Products and Medications.
7. Records of the shipment receipt and investigational product accountability shall be maintained for a period of 8 years, or 2 years after FDA approval of investigational drug, if required by the sponsor.
8. The Investigational Drug Pharmacy may be contacted at extension (714) 456-7833 .

Approval Signatures

Step Description	Approver	Date
Governing Body	Governing Body [AR]	05/2024
Med Exec Committee	Medical Executive Committee [AR]	05/2024
Policy & Communications Committee	Policy & Communications Cte [JL]	05/2024
P & T Committee	P & T Committee [SA]	04/2024
Nurse Executive Council	Nurse Executive Council [JW]	04/2024
Nursing Practice Council	Nursing Practice Council [LW]	03/2024

Applicability

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