LOS ANGELES COUNTY DEPARTMENT OF HEALTH SERVICES
HARBOR-UCLA MEDICAL CENTER

SUBJECT: INVESTIGATIONAL DRUGS **POLICY NO.** 325F

CATEGORY: Provision of Care	**EFFECTIVE DATE:** 2/19
POLICY CONTACT: Jennie Ung, PharmD	**UPDATE/REVISION DATE:**
REVIEWED BY COMMITTEE(S): Pharmacy and Therapeutics	

PURPOSE:
To outline handling procedures of investigational drugs.

POLICY:
All Investigational Drugs for Harbor-UCLA Medical Center (HUMC) patients shall be handled by the onsite Lundquist Institute Investigational Drug Services (IDS) Pharmacy and Harbor-UCLA Medical Center Pharmacy.

PROCEDURE:
1. The Pharmacy and Therapeutics Committee is the governing body for authorization of any investigational studies after review and approval by the Institutional Review Board (IRB).
2. A copy of the drug protocol shall be maintained on file in the Pharmacy Department and in the unit where the drug is administered. Basic drug information of the investigational drugs shall be available in the Pharmacy and at the nursing stations where the drugs are being administered.
3. Patient's signed consent shall remain in the patient's chart. Copies of signed consent will be distributed to the principal investigator (PI) or authorized designee(s) and the patient.
4. The Study personnel educate the staff administering the study drugs on the basic pharmacological information of the drug (e.g., potential adverse drug reactions, side effects, monitoring parameters).
5. The staff administering the study drugs demonstrate an understanding of the basic pharmacologic information about the investigation drug.
6. Prior to administration of an investigational drug, the PI or designee shall place an order in the medical record.
7. The following requirements of the investigational drugs must be met:
   a. Their use shall be in accordance with applicable State and Federal laws and regulations and policies adapted by the Hospital.
   b. Such drugs shall be used only under the supervision of the principal investigator who must be a member of the Professional Staff Association (PSA) and be responsible for assuring that informed consent is obtained from the patient.

REVISED: 1/22
REVIEWED: 2/19, 1/22

APPROVED BY:

Anish Mahajan, MD
Chief Executive Officer
Chief Medical Officer

Griselda Gutierrez, MD
Associate Chief Medical Officer

Jason Black, MBA, DNP, RN
Chief Nursing Officer

c. The IDS pharmacist shall be responsible for proper storage, labeling, and dispensing of such drugs pursuant to the order of the PI.

8. When patient is involved in an investigational protocol that is independent of the hospital (Patient's own study drug from outside), the hospital (attending physician and pharmacist) evaluates and, if no contraindication exist, accommodates the patient's continued participation in the protocol.
9. IDS Pharmacy's responsibilities:
   a. IDS will obtain, receive, store, compound and control all investigational drugs in accordance to its policies and procedures.
   b. Drug accountability and dispensing records will be maintained.
   c. Subject randomization and blinding will be performed per protocol.
   d. IDS Pharmacy will ensure all applicable licensure (pharmacy and compounding) are current and other applicable rules and regulations are followed.
   e. Quality Assurance (QA):
      i. Internal audits of study drug preparation, usage, storage and record keeping will be performed by IDS to ensure compliance with applicable legal and regulatory requirements.
      ii. Compliance audit will be conducted biannually by Lundquist Institute Compliance Office team.
      iii. Study sponsor audit will be conducted by the sponsor at their discretion.
      iv. All records of QA review will be readily retrievable by IDS.
      v. QA reports must be submitted to HUMC P&TC for quarterly review.

10. HUMC responsibilities:
    a. Investigational drugs to be administered to a patient in house (inpatient, ED or Infusion Center) must be dispensed by Harbor-UCLA Pharmacy.
       i. Medication order must be viewed.
       ii. All products received from IDS Pharmacy must be re-labeled with a Harbor patient specific label and delivered to the unit for administration.
    b. Administration must be charted in the patient's medical record.
    c. Unused investigational drugs must be returned to IDS for reconciliation and destruction.
    d. Harbor-UCLA's medication supply is never to be used in lieu of one provided by IDS Pharmacy.

Reviewed and approved by:
Medical Executive Committee on date 01/2022

Beverley A. Petrie

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