OLIVE VIEW-UCLA MEDICAL CENTER
POLICY & PROCEDURE

NUMBER: 1593
VERSION: 3

SUBJECT/TITLE: **INVESTIGATIONAL DRUGS**

POLICY: The pharmacy director or designee is responsible for ensuring that Olive View-UCLA Medical Center's administration and management of investigational drugs is in accordance with applicable laws standards and protocols.

PURPOSE: To define pharmacy's role in investigational drugs service and ensure that investigational drugs are procured, distributed, administered, and monitored in accordance with federal and state laws as well as hospital rules and regulations.

DEPARTMENTS: All

DEFINITIONS: Investigational drugs are those that have not yet been approved by the FDA. Research drugs are those that are used in research projects. They encompass both investigational and approved drugs.

PROCEDURE:

A. Approval of Investigational Drugs

1. Investigational studies involving the pharmacy department must be reviewed by the research pharmacist and approved by the pharmacy director.

2. All investigational drug studies must be approved by the Institutional Review Board (IRB) before being conducted. The IRB evaluates investigational drug studies in terms of their compliance with recognized ethical, legal, and scientific practice standards.

3. Investigational drug studies must contain adequate safeguards for the institution, the staff, the scientific integrity of the study, and the patient.

4. A copy of the approved research protocol, in which the pharmacy participates, is kept on file, at the pharmacy, for a period of time that is required by the FDA.

5. Investigational and research drugs must be prescribed by the principal investigator(s) or an authorized prescriber. Principal investigators, as per Medical Staff policies, must be members of Olive View-UCLA Medical Center faculty.

6. The research pharmacist prepares an Investigational Drug Data Sheet, if

requested, and distributes it to the pharmacy and nursing staff who are participants in the dispensing and administration of the investigational drug.

7. Before receiving investigational or research drugs, patients must have consented to the treatment on an IRB-approved consent form.

8. The Principal Investigator(s) and/or designees are responsible for supervision and monitoring of investigational drugs administered to subjects according to the study protocol.

9. Upon request from administration, the pharmacy shall prepare a summary report of active, completed, and pending investigational studies.

10. The pharmacy shall be fairly reimbursed, by the sponsor/principal investigator, for drug and personnel costs in addition to any other expenses associated with conducting investigational drug studies.

B. Investigational Drugs Protocol Binder

1. The research pharmacist prepares a binder (manual) for each research protocol the pharmacy is involved in.

2. The binder contains the following sections:
    a. Overview of the protocol (objectives of the study, principal investigator, sponsor, patient sample, research design and methodology, drugs used, etc.)
    b. Dispensing procedures for each investigational drug studied
    c. Randomization list, if applicable
    d. Shipment records for each investigational drug
    e. Accountability logs for each investigational drug
    f. Patient profile, if applicable
    g. The full version of the protocol
    h. Relevant correspondence and miscellaneous section

3. Each participating pharmacist is required to read the manual.

4. The manual is available for review by the principal investigator, sponsor, or the FDA. However, the principal investigator or the blinded team is not permitted access to un-blinded documents of double-blind studies.

5. The manual is kept at the pharmacy or with investigator study file for at least two years, FDA requirement, or whatever the sponsor requires,

after the study is completed.

C. Storage of Investigational Drugs

1. At the pharmacy, all investigational drugs shall be stored in a clearly marked area, separate from regular stock. Only the research pharmacist or a pharmacist working in this capacity shall have access to such drugs.

2. Investigational drugs are stored according to the storage requirements of the sponsor in terms of light, temperature, moisture, ventilation, security, and sanitation.

3. Investigational drugs are not to be stored on nursing units or other areas unless an approval is granted by the Medical Staff Committee (P&T and/or IRB). When permission is granted, storage requirements described above shall apply here also.

D. Dispensing of Investigational Drugs

1. Investigational drugs are dispensed through the pharmacy pursuant to an order by the principal investigator(s) or his/her designee(s).

2. The research pharmacist, or a pharmacist working in this capacity, prepares and dispenses investigational and research drugs in accordance with the protocol requirements as detailed in the "dispensing procedures" of the manual.

3. Investigational drugs and research drugs are not dispensed to patients who are not enrolled in that specific protocol.

E. Labeling of Investigational Drugs

1. Investigational and research drugs, ready to be dispensed to the patients, must be labeled in accordance with statutory and protocol labeling requirements. The following information must appear on the label in most cases:
    a. Patient name or patient initials
    b. Subject study identification number
    c. Medical record number or financial identification number and location, if inpatient
    d. Principal investigator
    e. Date of dispensing
    f. Research protocol name or protocol number
    g. Study arm, if applicable

h. Drug name, if not blinded
i. Drug strength, dosage form, and quantity
j. Name and amount of other ingredients (i.e. diluent name and volume)
k. Direction for use, infusion time, etc.
l. Expiration date
m. Investigational drug label: "Caution: New drugs-Limited by Federal (or United States) law to investigational use" or its equivalent
n. Other auxiliary labels as required by the protocol or as appropriate
o. Pharmacist's initials

F. Administration of Investigational Drugs

1. Investigational drugs are administered to patients who have already consented to participate in the protocol according to Medical Staff rules and regulations.

2. Registered nurses may administer investigational drugs after they have demonstrated to the principal investigator or his/her designee, an understanding of the basic pharmacological information about the drugs.

3. Investigational drugs are administered to enrolled patients pursuant to an order from the principal investigator(s) or his/her designee.

4. Investigational drugs are administered in accordance with the approved protocol.

G. Accountability for Investigational Drugs

1. The pharmacy maintains a perpetual inventory system for all investigational drugs.

2. As part of the perpetual accountability system, the pharmacy uses an accountability form supplied by the sponsor, or made in-house. In most cases, the form contains the following information:

a. Drug name
b. Dosage form and strength
c. Name of the sponsor
d. Date of dispensing
e. Patient initials and subject number
f. Amount dispensed/received

g. Current balance
h. Lot number
i. Pharmacist's initials

3. Accountability records are available to the Federal and State regulatory agencies, IRB, study monitor, and the principal investigator upon request.

4. At the conclusion of the study, the pharmacy shall return all unused drugs to the pharmaceutical facility designated by the sponsor or destroyed per hospital pharmaceutical waste policy as authorized by the sponsor.

H. Investigational New Drugs

1. Investigational New Drug protocols shall be approved by the IRB prior to dispensing by the pharmacy.

2. Pharmacy shall dispense Investigational New Drugs (IND) to Olive View-UCLA patients pursuant to a proper order from an authorized physician.

3. Record keeping and other procedures stated above shall also apply here.

I. Investigational Drugs for Compassionate Use

Attending physicians may prescribe, and pharmacy may dispense, investigational drugs for compassionate use after the physician has secured the approval from the Institutional Review Board (IRB), as specified in Medical Staff rules and regulations. These approvals are on a patient by patient basis.

Pharmacy shall keep records of all patients receiving investigational drugs for compassionate use.

J. The Use of Outside Investigational Drugs

When an investigation medication protocol is being conducted independent of the hospital, the hospital will review and accommodate, as appropriate, the patient's continued participation in the protocol. A physician/nurse will notify the pharmacy of his/her patient, who is participating in the outside study and is being admitted to our facility. If the contact number is available, a pharmacist will contact the principal investigator (PI) and notify him/her that his/her patient has been admitted. The pharmacist will also request protocol information in order to continue the study medication in pursuant to the protocol, if the PI requests.

The information will be conveyed to the primary physician and documented on the

study log. Olive View-UCLA Medical Center personnel will then follow the procedures of patient's own medication policy for dispensing outside investigational drugs.

After the primary physician writes an order for the patient to use his/her home medication, a pharmacist must verify the identity and integrity of these medications prior to administration. The drug administration records will be kept in accordance with study protocol.

References: Guideline for Industry E6 Good Clinical Practice: Consolidated Guidance, 21 CFR 312.6; 312.59; 312.60; 312.61; 312.62	
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