WEST VIRGINIA UNIVERSITY HOSPITALS ***Pharmaceutical Services*** ***POLICY AND PROCEDURE MANUAL***	**Policy VII.01** **1st Effective 12/84** **Revised 12/89, 10/84, 11/03, 6/09, 8/12, 11/14, 6/18, 5/19, 2/20, 4/22** **Reviewed 1/02, 1/03, 1/04, 1/05, 1/06, 1/07, 1/08, 1/09, 1/10, 1/11, 1/12, 1/13, 1/14, 1/15, 1/17, 1/18, 5/19, 3/22**

PHARMACY COORDINATED INVESTIGATIONAL DRUG SERVICES

POLICY

All investigational product (IP) in use at West Virginia University Hospitals (WVUH) pharmacy locations is received, stored, distributed, and controlled by the Department of Pharmacy and is used only under the supervision of the authorized study investigator(s).

PROCEDURE

Study Opening

1. The Institutional Review Board (IRB) is responsible for initial approval and ongoing monitoring of all investigational protocols being used at WVU Hospitals.
2. Prior to IRB submission, each oncology protocol must be reviewed and approved at the WVU Hospitals Protocol Review and Monitoring Committee (PRMC).
3. The principal investigator initiating an investigational protocol must do the following to satisfy IRB requirements:
    a. Use the IP only in accordance with the plan of investigation as described in the approved protocol.
    b. Use the IP in patients under his/her supervision or under the supervision of providers who directly report to him/her.
    c. Obtain proper informed consent from the patient or the patient's legal representative.
4. The principal investigator is responsible for providing a copy of approved drug study protocol and study literature to the Investigational Drug Services (IDS) pharmacist. The IDS pharmacy staff will assess if each patient has been consented for study procedures prior to the utilization of IP.
5. The principal investigator must be a member of the institution's professional staff and is responsible for the following:
    a. Submitting proper information and documentation to the IRB to obtain protocol approval
    b. Obtaining the written, informed consent of the patient to participate in the study
    c. Maintaining case report forms, and all other records required in the study by the drug sponsor, institution, or FDA
    d. Informing the IDS Pharmacist(s) of study completion

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6. The WVUH Department of Pharmacy will store all IP being utilized in clinical trials at WVUH and satellite locations and will be responsible to ensure proper storage of all IP.

7. The pharmacy shall reorder IP as necessary and maintain a perpetual inventory of all IP by utilizing an approved web-based accountability record within the Vestigo® platform.

    a. Data will include IP name, amount received, amount dispensed, subject codes (when applicable), batch/serial numbers, expiration dates (if applicable), amount currently on hand and the return to sponsor or alternative disposition of unused product(s).

    b. Investigators will maintain records that adequately document that the subjects were provided the doses specified by the protocol and reconcile all IP received by the sponsor.

IRB Requirements for Expanded Access

1. A physician may petition the IRB for expanded access/compassionate use of a drug or IP.

2. Once IRB approval is obtained, pharmacy will properly store and maintain accountability for IP. This written petition must include a detailed explanation of the reason for using the drug or biologic for the patient and have as an attachment:

    a. The approved FDA protocol

    b. A copy of the consent form signed by the patient or their representative, the physician, and appropriate witnesses

3. The notification must include the following in a narrative developed by the physician administering the IP:

    a. The chemical and commercial name of the IP

    b. The name of the company manufacturing the IP

    c. The date and time the IP was initially administered

    d. The Investigational New Drug (IND) number

    e. The name of the organization that supplied the IP (i.e., NCI, drug company, etc.)

    f. A discussion of the reason this IP was employed as opposed to an approved drug or treatment regimen

    g. The risks or side effects associated with the use of the IP

    h. The signature of the physician administering the IP

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Receiving

1. The product is delivered to the pharmacy and the order is checked against the packing list by the IDS pharmacy team.
    a. If there is a discrepancy between the order and packing slip, the supplier will be notified.
2. After verification that an order is correct, the IDS pharmacist will file all shipping information with the coordinating study materials in the Vestigo® system under the corresponding trial.
3. Receipt of a Schedule II drug shall be checked against the original DEA order form and signed and dated by the IDS pharmacy representative.
4. Products that were damaged upon receipt, proper temperature control was not maintained, are short-dated, or if a discrepancy is found relating to the packing slip will be reported to the sponsor and compensatory action will be taken to correct shortages and return items that were received, but not ordered.
    a. IP must have an expiration date greater than 60 days upon receipt unless approved by the IDS pharmacy team. IP not meeting criteria will be returned immediately.

Storage and Dispensing

1. All IP shall be stored and dispensed by the IDS pharmacy team at WVU Hospitals in accordance with the centralized model. The IDS pharmacy team at WVU Hospitals will distribute product to patients enrolled in clinical trials at WVU Hospitals, outpatient clinics, and other system hospitals. The IDS pharmacy team will be responsible for packaging, labeling, order review, profile maintenance, and delivery of all IP. The following special requirements exist:
    a. The IP is dispensed only upon receipt of an order entered into EPIC by an authorized investigator.
    b. The prescription label is distinguishable from other labels by the legend, “investigational drug”. The study protocol and subject ID will also be recorded on the label.
2. Before the pharmacy will dispense the initial supply of IP:
    a. The pharmacy must have on file the study protocol and must verify subject consent.
3. IP included in an Epic Beacon plan requires a dual verification process that mandates two (2) independent verifications of the medication order within the protocol. The following components are to be verified:
    a. Drug
    b. Kit or vial number

c. Dose

d. Concentration

e. Infusion instructions

f. Route of administration

g. Volume of drug (in syringe or bag)

h. Time of dose

i. Expiration of Beyond Use Date (BUD) and time

j. Documentation in drug accountability records

4. If IP delivered to the nursing unit is not administered to the patient, the IP will be returned to the pharmacy and the following will occur:

    a. The return of unused IP will be recorded on the Drug Accountability Record Form in Vestigo®.

    b. The unused IP will be destroyed per the SOP for Destruction of Drugs.

    c. The destruction will be recorded on the Drug Accountability Record Form in Vestigo®.

5. All pharmacists who will be handling IP will receive study-specific training to ensure accuracy and compliance with the protocol. The following criteria will be met:

    a. Pharmacists assisting in IP dispensations may be trained on the following: review of study protocol; IP dispensing, preparation, and storage; blinding requirements; and required documentation pertaining to the specific study.

    b. Following training, the pharmacist will sign a record corresponding to the study to verify appropriate training occurred.

Vestigo®

1. Vestigo® is a web-based application used to manage IDS inventory through record keeping functions.
2. Vestigo® is used for accountability documentation and no paper records will be kept.
3. Study monitors may request Vestigo® access to review their study specific accountability documents.
4. Temperature logs from refrigerators and freezers that contain IP are uploaded once monthly to Vestigo®.

5. For IP destruction on site, a study sponsor representative must approve the destruction request via Vestigo® credentials.

Patient Monitoring

1. Patient education and monitoring of therapy shall be provided in a coordinated fashion by the pharmacy and nursing staffs, and the authorized investigator(s).

Study Closure

1. At the conclusion of the study, the Pharmacy will return unused IP to the sponsor or dispose of IP as directed by the sponsor.
2. If permission is granted for the destruction of any unused IP, the drugs will be sealed in a plastic bag and placed in the receptacle designated for incineration.
3. Upon completion of the study, pharmacy records regarding drug disposition will be retained within the Vestigo® platform for at least two years, or longer if required by regulation.
    a. Pharmacy files of investigational protocols will be maintained by protocol name.

Patient Own IP

1. When a patient is admitted with a supply of drugs from an investigational protocol that is not associated with WVU Hospitals, the attending physician will review the protocol and will accommodate the patient's continued participation in the protocol if no contraindications exist during the inpatient stay.
    a. A copy of the protocol must be obtained and added to the patient's chart.

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WVU Investigational Drug Services (IDS) Pharmacy Standard Operating Procedures:

1. WVU IDS Pharmacy SOP-01: IDS Centralized Operating Model – Centralized Oversight and Monitoring of Satellite Locations
2. WVU IDS Pharmacy SOP-02: Investigational Drug Pharmacy Staff Training Checklist
3. WVU IDS Pharmacy SOP-03: IDS Notification Process
4. WVU IDS Pharmacy SOP-04: Research Study Medication EPIC Order Build Process
5. WVU IDS Pharmacy SOP-05: IDS Billing for Services
6. WVU IDS Pharmacy SOP-06: Reporting Pharmacy Investigational Products Errors
7. WVU IDS Pharmacy SOP-07: Investigational Product Temperature Monitoring and Excursion Procedures
8. WVU IDS Pharmacy SOP-08: Destruction of Medications and Investigational Product

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