WVUH Department of 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 personnel.

WVUH location is defined as any hospital or clinic operating under WVUH.

PROCEDURE

Study Opening

1. The Institutional Review Board (IRB) is responsible for initial approval and ongoing monitoring of all investigational protocols being used at WVUH.
2. Prior to IRB submission, each oncology protocol must be reviewed and approved at the WVUH 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 team 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
6. The WVUH Department of Pharmacy will store all IP being utilized in clinical trials at WVUH and will be responsible to ensure proper storage of all IP. The IDS Pharmacy team will prioritize involvement with clinical trials utilizing an EPIC research module and clinical trial management system (e.g. OnCore™).
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. 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
4. Once IRB approval is obtained, pharmacy will properly store and maintain accountability for IP.

Purchasing Commercial Medications for Research Purposes

1. All requests for commercially available pharmaceutical agents with intent to be used for research purposes are directed to the WVUH IDS Pharmacy team.
2. Orders for such IP will be placed through the WVUH Inpatient Pharmacy Inventory group for procurement within 30 days.
3. Researcher(s) will be invoiced for the cost of IP.
4. Medication procurement areas:
    a. Animal researchers
        i. Researcher(s) must submit an approval letter from the Institutional Animal Care and Use Committee (IACUC) supporting the use of the requested IP within an approved research protocol.
        ii. Researcher will be appropriately credentialed.
        iii. For controlled medications, the researcher must hold a valid WV controlled substance permit. The university or hospital DEA number may be used.
        iv. A copy of the IACUC approval letter will be stored with the invoice for IP and made available for Board of Pharmacy inspections.
    b. Inpatient clinical trial use or infusion center use
        i. Commercial medications may be obtained for a WVU IRB approved research protocol if the sponsor is unable or unwilling to successfully supply.
        ii. For controlled medications, the researcher must hold a valid WV controlled substance permit. The university or hospital DEA number may be used.
    c. Medications for outpatient clinical trial use
        i. WVUH IDS will not procure commercial medications for use in an outpatient clinical trial.
        ii. The researcher may work with the Medical Center Pharmacy to obtain commercial medications for outpatient utilization.

Receiving

1. The product is delivered to the pharmacy and the order is checked against the packing list by the IDS pharmacy team.
    a. IP is delivered to the designated pharmacy receiving area.
    b. IDS technician is alerted to package arrival via paging system.
    c. Within the receiving area, IP package is opened, and IP is inspected.
    d. IP is immediately placed within the designated storage requirements.
    e. Packing slip is checked against IP received.
    f. Packing slip is initialed or signed and dated by receiving IDS technician.
    g. If there is a discrepancy between the order and packing slip, the supplier and sponsor will be notified.
2. After verification that an received order is correct, the IDS pharmacy team will file all shipping information with the coordinating study materials in the Vestigo® system under the corresponding trial.
    a. Staffing and patient scheduling may not permit inventory and/or shipping documents to be entered into the Vesitgo® system the same day they are received.
3. Receipt and storage of IP deemed a controlled substance (Schedule I-V) will follow WVUH Pharmaceutical Services Controlled Substances and Drug Diversion Management Policy, which complies with all applicable federal and state regulations.
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 90 days upon receipt unless approved by the IDS pharmacy team. IP not meeting criteria will be returned immediately.

5. All IP is physically inventoried on a monthly basis by the IDS pharmacy technician(s). During inventory, IP is counted to verify the quantities match those recorded in Vestigo®. Additionally, IP expiration dates are confirmed during the monthly physical inventory. No formal documentation of monthly inventory will be maintained.

Storage and Dispensing

1. All IP shall be stored and dispensed by the IDS pharmacy team at WVUH. The IDS pharmacy team at WVUH will distribute product to patients enrolled in clinical trials at WVUH and associated clinics. 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 or 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 and pharmacy technicians 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. All trained team members will fall under the purview of the lead pharmacist who signed the study delegation of authority (DOA). Team members will not need to additionally sign the DOA.
    c. IDS pharmacy team will sign the master DOA, maintained by site regulatory staff, and will not maintain a separate unblinded or pharmacy-specific DOA, responsibility, or training log.

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 may co-sign destruction of IP via Vestigo® credentials.
6. Vestigo® will maintain physical and digital documents as certified copies as directed by the Food and Drug Administration (FDA). Certified copies will show all details of the original document with legible text, clear images, and the full size of the paper maintained.
    a. WVUH IDS maintains copied document certification via:
        i. Physical: all pages, front and back and in the correct order of the original document will be stamped with "certified true copy of original", dated, and signed by the endorsing WVUH IDS team member.

ii. Digital: all pages, front and back and in the correct order of the original document, will be marked as certified within the Vestigo® system by the endorsing WVUH IDS team member. The first page of certified digital copies will be stamped with "certified true copy of original".

b. The individual who certifies the copy as an accurate and complete representation of the original will be the same person who makes the copy from the original or completed the certification step within Vestigo®.

c. Certified digital copies will be stored electronically within the Vestigo® system.

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 appropriate 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 WVUH, the attending physician will decide whether to accommodate the patient's continued participation in the protocol if no contraindications exist during the inpatient stay.
    a. A copy of the patient's consent to the study participation and Investigator's Brochure for patient supplied IP will be provided for clinical team's review.

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

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

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