

Department of Pharmaceutical Care
University of Iowa Hospitals and Clinics

Section Research

Related Policy None

Operating procedure RES-NP003

INVENTORY MANAGEMENT OF INVESTIGATIONAL
PRODUCTS

Definitions:

Vestigo: A web-based platform used by the University of Iowa Investigational Drug Service to manage investigational drug products used in studies conducted at the University of Iowa Hospitals and Clinics. It allows tracking of details such as trial status, study team members, patient enrollment, drug dispensing, temperature monitoring, etc.

General Procedures:

- I. Drug Accountability
 - A. Investigational Drug Service (IDS) will ensure that the receipt, accountability, disposition, and all record keeping concerning the Investigational Product (IP) complies with FDA and institutional requirements as well as state and local guidelines.
 - B. No sponsor-based forms will be utilized by IDS for master drug accountability.
 - C. IDS does not complete subject-specific accountability logs.

- II. Ordering of Drug Supply
 - A. IP is typically obtained from:
 - National Cancer Institute/Cooperative Group Studies
 - Pharmaceutical Industry/Sponsor
 - Wholesaler
 - B. Inventory must be received in IDS before the pharmacy's study activation can occur. Exceptions include those protocols in which patient registration/screening is required prior to the shipment of inventory by the sponsor or supplier.

- C. IP shipments are to be delivered directly to the IDS pharmacy location at the following address:

University of Iowa Hospitals and Clinics
Investigational Drug Service
01284 PFP
200 Hawkins Drive
Iowa City, IA 52242

- D. If IP is inadvertently shipped directly to a physician's office, or other location, it is the responsibility of the individual receiving the shipment to arrange prompt delivery to IDS and to notify Sponsor of the correct shipping address.

III. Ordering IP from NCI

- A. Ordering IP from the NCI will be based on identification of a patient that will potentially enroll in the study and may be restricted by the NCI until the patient is in screening or enrolled in the study.
- B. Coordinators for NCI studies will provide IDS with information about their study patient's upcoming visits to ensure adequate stock of IP is available.

IV. Ordering IP from the Pharmaceutical Industry

- A. For IP from pharmaceutical companies, the ordering process will be discussed with the sponsor at the site initiation visit (SIV) or coordinated through the study monitor.
- B. Once notified that inventory is to be ordered (typically occurs after full IRB approval has been received), pharmacy personnel will initiate the ordering process. An IDS member will place the order for IP through the sponsor's preferred mechanism.
- C. In cases where the initial supply of IP is sent automatically from the sponsor, an IDS member will inform the internal (University of Iowa) study team when IP is on site.
- D. IDS will be responsible for securing and reordering drug supplies for all research studies with inventory managed by IDS. This does not include inventory managed outside of IDS (sponsor uses an electronic system that automatically generates orders), studies where the IP is filled by an outside pharmacy or studies where the coordinator orders IP.

- V. Ordering Commercially Available IP from a Wholesaler
- A. Purchases will be based on package size.
 - B. The study will be charged for the entire package ordered at the time of purchase.
 - C. A University of Iowa-generated invoice will be provided upon request – invoices from third party suppliers will not be provided.
 - D. At study closure an attempt may be made to return remaining inventory to the supplier and the study reimbursed for the cost. However, there is no guarantee that this can or will occur.
- VI. Standard of Care Medications
- A. All standard of care medications will be dispensed from regular hospital supply and processes will be in place for the study to provide reimbursement of the patient charge to UIHC. Lot number, expiration date and drug accountability will not be tracked for the study.
 - B. The product will not be labeled “for investigational use” as it is commercially supplied and is used for Standard of Care purposes.
- VII. Receipt of IP
- A. Upon receipt of a shipment of IP, an IDS staff member will verify the following items against the protocol and shipping invoice:
 - Drug name
 - Strength
 - Formulation
 - Quantity
 - Manufacturer name and address
 - Lot or Batch number
 - Expiration/Retest date
 - Storage conditions
 - Patient-specific information, if applicable
 - B. If any discrepancies are noted upon receipt, an IDS member will notify the study sponsor immediately and appropriate actions will be taken according to the instructions provided by the sponsor and/or protocol.
 - C. Upon receipt of a shipment of IP, the IDS staff member will acknowledge the shipment by following the steps outlined by the sponsor. The information noted in (A) above will be maintained on paper drug accountability logs or in Vestigo.
 - D. Investigational products that do not contain an expiration date or retest date are deemed in date and acceptable for use until notice of an expiration is received from the sponsor or supplier.

- VIII. Temperature monitoring Devices During shipment (e.g., TempTrak)
- A. IDS staff will follow sponsor instruction regarding reporting of in-transit temperature.
 - B. The temperature monitor device should enable staff to retrieve the necessary information and submit as outlined on the shipping documentation.
 - C. Steps for reporting the temperature data must be outlined on the shipping documentation.
 - D. If a temperature monitoring device is noted to be out of range, the IP will be placed in quarantine in appropriate storage conditions until otherwise directed by the sponsor.
 - E. A printed copy of the temperature report will be maintained in the IDS shipping folder or is scanned into Vestigo.
 - F. IDS will not retain any temperature monitor devices after shipment for review by study personnel at a later time.
 - G. Should the sponsor require return of the temperature monitoring device, a prepaid shipping method must be provided at the time the IP is shipped.
- IX. Maintaining Inventory of Drug Supply
- A. Under no circumstances shall any IP bearing the label “Investigational Drug: Limited by Federal Law to Investigational Use” be used as regular pharmacy stock.
 - B. If the sponsor is controlling IP re-supply, it is the sponsor’s responsibility to ensure that the IDS pharmacy has adequate supply on hand for trial continuation and future enrollment. The sponsor is responsible for communicating with IDS the amount of product they will ship to ensure that adequate storage room is available.
 - C. IP physical inventory and review of expiration/retest date is completed monthly.

Approved by the Pharmacy Administrative Staff: 1/2022.

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Reviewed: