
POLICY

Investigational Drug Service Transport

Purpose

- A. This policy establishes procedures for the packaging and transport of investigational drug product to various University of Utah Health (UUH) locations and non-UUH locations. All procedures outlined in this policy are congruent with applicable federal, state and local laws and regulations governing the handling and transportation of investigational and/or hazardous drug products.

Definitions

- A. **Drug accountability:** Drug storage, handling, dispensing, and documentation of administration, return and/or destruction of the drug.
- B. **Hazardous drug:** Any drug identified as causing cancer, teratogenic effects, developmental impairment, reproductive toxicity, organ toxicity, or genotoxicity at low doses in humans or animals. Includes any new drug that is similar to an existing hazardous drug in chemical structure or spectrum of toxicity.
- C. **Investigational drug:** A new drug or biological drug that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms "investigational drug" and "investigational new drug" are deemed to be synonymous for purposes of this part. Any drug which has not received FDA approval for use in humans. Also refers to any drug, which is FDA approved and is being used under protocol for human research, possibly outside of FDA approved labeling.
- D. **Investigational product (IP):** a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled in a way different from the approved form, or when used for an unapproved indications, or when used to gain further information about an approved use
- E. **Investigational drug service (IDS):** A function of the Department of Pharmacy and provides support to ensure the safety and efficiency of trials at University of Utah Health that use investigational product(s)/investigational drug(s). Pharmacy personnel that perform investigational drug accountability at UUH satellite locations approved for conducting research protocols are considered an extension of the IDS.
- F. **Principal Investigator:** A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team.
- G. **Research Staff:** Individual(s) involved in clinical investigation. This includes the study coordinator, principal investigator, study monitor, study sponsor.
- H. **Satellite:** A UUH facility that that is not physically adjoined or connected to the University of Utah Hospital or the Huntsman Cancer Hospital and performs drug accountability for IP.

- I. **Send-out inventory:** Inventory not dispensed within Vestigo® but transferred to another location (e.g. if the IDS Pharmacy is acting as the central pharmacy for a multi-site study and prepares IP for non-institutional offsite location for dispensing)
- J. **Sponsor:** An individual, company, institution, or organization that takes responsibility of the initiation, management, and/or financing of a clinical trial
- K. **Sponsor-Investigator:** An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual.
- L. **Transport:** the physical moving of product dispensed by the Investigational pharmacy to another site for administration to a specific patient
- M. **Transfer:** transfer of a product in Vestigo® accompanied by the physical transport of IP to a satellite location within the institution for dispensing to a specific patient
- N. **Vestigo®:** A 21 CFR Part 11 compliant electronic accountability software application designed specifically for investigational pharmacy use and utilized by University of Utah Health IDS. Refer to www.mccreadiegroup.com/vestigo/ for additional information.

Scope

- A. Standard for all entities within University of Utah Health (UUH) locations and non-UUH locations, when investigational product is prepared and transported through the IDS Pharmacy at UUH.

Description

- A. To facilitate use of IP at all University of Utah Health (UUH) locations and non-UUH locations, transportation of IP or supplies is occasionally necessary
 - 1. Transport of IP must be pre-approved by the sponsor and IRB for any location in accordance with federal and state regulations.
 - 2. Only full and intact vials of IP to be used in preparation for dispense will be transferred between the IDS pharmacy and satellite sites if authorized by the sponsor and/or principal investigator.
 - 3. Full or partial bottles of capsules or tablets of IP for oral administration may be transported between the IDS pharmacy and satellite sites if authorized by sponsor and/or principal investigator.

Implementation

- A. Initiation of transport
 - 1. The IDS Pharmacy is responsible for the transfer and transportation of IP and determines the appropriate mode of transportation based upon geographic location.
 - 2. See **Procedure: Investigational Product Transport to CCTS** and **Procedure: Investigational Product Transfer to and from Satellites** for additional workflow details.
- B. Preparation of investigational product(s) for transport
 - 1. Investigational products must be packed and transported in accordance with the specific storage requirements for the IP as directed by individual protocol (eg, protect from light, within temperature parameters)

- a. Temperature and humidity monitoring devices will be used to establish when temperature excursions or humidity excursions occur during transport that could affect the viability of the IP as necessary.
 - b. See **Procedure: IDS Transport of Medications with Temperature & Humidity Monitoring** for additional details.
 - 2. Investigational products known to be hazardous should be packed in impervious plastic.
 - 3. Products that are known to be biohazardous should also be labeled as such.
 - 4. Packages for transport should be accompanied with an Investigational Product Transportation and Monitoring Form if temperature and/or humidity monitoring is required. See **Procedure: IDS Transport of Medications with Temperature & Humidity Monitoring** for additional details.
- C. Arrangement for transportation of investigational product
 - 1. IDS personnel should arrange the transportation with the identified groups as determined by the location where the IP is to be dispensed to patient on study protocol.
 - a. Clinical research coordinators
 - i. Huntsman Cancer ambulatory clinics
 - ii. University Hospital ambulatory clinics
 - b. Pharmacy personnel
 - i. Huntsman Cancer Hospital inpatient units
 - ii. Huntsman Cancer Infusion areas
 - c. Transporter services
 - i. An electronic request system is used for planned transport of IP with date and time specifications included in the request
 - ii. University of Utah Hospital (inpatient units, infusion areas, clinics)
 - iii. University of Utah School of Medicine
 - iv. Inpatient units at Primary Children's Hospital
 - v. Clinical Neuroscience Center
 - d. University Hospital Courier Services
 - i. This is the first choice of transport method for locations that are not physically adjoined or connected to the University of Utah Hospital or the Huntsman Cancer Hospital
 - A. Research Park
 - 1. Center for Clinical and Translational Science (CCTS)
 - 2. Beddu Kidney Clinic
 - 3. Pain Management Center
 - 4. Imaging and Neurosciences Center (INC)
 - B. Eccles Primary Children's Outpatient Services Building
 - C. South Jordan Health Center
 - D. Farmington Health Center
 - E. University Neuropsychiatric Institute
 - F. Investigational Drug Service Pharmacy (when IP needs transported from satellite location)
 - ii. If unable to pick-up product within 15 minutes of finished preparation of the product, an outside courier may be contacted for a 'stat' delivery
 - iii. See **Procedure: Investigational Product Transport to CCTS** and **Procedure: Investigational Product Transfer and Transport**

- to/from Satellites** for additional workflow details on transport to these UUH facilities
- e. Salt City couriers
 - i. Available for stat deliveries as well as routine medication pickups from the Huntsman Cancer Hospital Outpatient Pharmacy hourly between 0900-1300, and 1400-1600 Monday through Friday
 - D. Transportation of investigational product to specific UUH entities
 - 1. See **Procedure: Investigational Product Transfer and Transport to and from Satellites** for additional details
 - 2. See: **Procedure: Investigational Product Transport to CCTS** for additional details
 - E. Transportation of IP to non-UUH entities as send-out inventory
 - 1. The IDS pharmacy will transfer medication in Vestigo® to a send-out location when sent to a non-UUH entity for further dispensing by that entity's pharmacy.
 - a. An example of a non-UUH entity to which a send-out location would be used could be when transporting drug to Primary Children's pharmacy to be dispensed by the pharmacy personnel at Primary Children's to a study participant being treated at Primary Children's.
 - 2. For multi-site investigator initiated trials, transport to off-campus or non-UUH entities is permitted when the sponsor-investigator is located at the University of Utah and the following criteria are met:
 - a. An active IND exists
 - b. According to 21 CFR 312.6, the immediate packaging of the investigational drug must be labeled: "Caution: New Drug - Limited by Federal law to investigational use".
 - c. The sponsor-investigator must maintain adequate records showing the receipt, shipment, and other disposition of the investigational drug including:
 - i. Name of the investigator to whom the drug is shipped
 - ii. Date, quantity, and batch number of each shipment
 - iii. Return, destruction, or other appropriate disposition of unused study drug
 - 3. The sponsor-investigator, or delegated coordinator, is responsible for packaging, labeling, shipping, and maintaining of adequate records as noted in subsection c above.
 - F. Use of courier and transporter services
 - 1. All couriers and transporters should be trained by their department on proper handling of investigational drug product, and how to address hazardous-drug spills in accordance with institutional policies and procedures. See **Policy: Safe Handling of Hazardous Drugs: Overview and General Procedures** subsection A for additional details.
 - 2. Investigational products must be packaged and labelled separately, but deliveries may be bundled in order to facilitate the most efficient delivery and best use of resources
 - 3. The courier/transporter signs the Investigational Medication Pick-up Log for each investigational drug prior to leaving the Investigational Pharmacy or satellite pharmacy
 - 4. Investigational products must be secured during transport and never left unattended in a vehicle or at any other point during transportation
 - G. Documentation

1. The transferring "from" location initiates a "send-out" or "transfer" in Vestigo® to the receiving "to" location and prints a chain of custody form (IDS Investigational Product Transportation and Monitoring Form)
 2. Upon receipt of investigational product, the chain of custody form (IDS Investigational Product Transportation and Monitoring Form) should be completed by receiving personnel.
 3. The completed transport IDS Investigational Product Transportation and Monitoring Form should be emailed to the IDS. The group receiving the IP may keep the original; the emailed copy should be filed in IDS electronic records
 - a. Completed forms should be emailed to investigational.pharmacy@hci.utah.edu; faxed forms are accepted, although it is strongly preferred that forms are emailed.
 4. The courier/transporter signs the Investigational Medication Pickup Log for each investigational drug prior to leaving the Investigational Pharmacy or satellite pharmacy; this log should be electronically maintained by the IDS pharmacy
- H. Transport of returned IP
1. Investigational product that has been dispensed for patient use will be returned by the patient or research staff to the pharmacy from which it was dispensed
 2. Once returned to the dispensing pharmacy the following will be done:
 - a. The return will be documented in Vestigo®. See the **Procedure: IDS: Disposal, Return, Destruction of Investigational Product** for more details.
 - b. Investigational Product dispensed for patient use will NOT be transported and will remain at the location at which it was returned for disposal, return or destruction.
 3. Investigational product that was transferred and transported from IDS to a satellite, but was never admixed or dispensed for patient use may be transferred and transported back to the IDS pharmacy
 4. For details about the transfer and transport process see **Procedure: Investigational Product Transfer and Transport to and from Satellites**
- I. Shipment or mailing of investigational product
1. Investigational products will NOT be shipped by IDS pharmacy or satellite pharmacy personnel via postal delivery or other third-party delivery services as a dispensing function.
 2. Investigational products may be shipped to sponsors by IDS pharmacy or satellite pharmacy personnel by postal delivery or other third-party delivery services as a return function if provided with required shipping packaging.
 - a. See **Procedure: IDS: IP Transport between UUH Sites and Study Participants** for further details.
 - b. See **Procedure: IDS: Disposal, Return, Destruction of Investigational Product** for additional information.

Owner: IDS manager
Last updated: 12/30/2020
Previous updates: 4/11/2018

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