

## **STANDARD OPERATIONAL PROCEDURE (SOP)**

### **INVESTIGATIONAL DRUG TRANSPORT TO AND FROM SATELLITES**

Investigational product (IP) that is to be dispensed from a University of Utah Health (UUH) satellite should be shipped directly from the sponsor/manufacturer to the UUH satellite location.

When shipment of IP to multiple sites is not permitted by the sponsor, IP will be shipped to the IDS Pharmacy and transferred and transported to UUH satellite location(s) per procedure described below:

- A. Investigational product will only be transferred and transported to UUH satellites when the following has been met:
  - 1. Approval from the sponsor
  - 2. Receiving site is trained and delegated (i.e. SIV has taken place)
  - 3. Protocol that uses the investigational product(s) has been authorized to conduct IRB approved clinical research at the satellite. Refer to **Policy: Investigational Drug Service Transport** for additional details.
- B. For investigational product that is shipped directly to the satellite location from the sponsor/manufacture see **Policy: Investigational Drug Service Pharmacy** for details related to drug accountability.

#### Implementation

- A. It is the responsibilities of the clinical research coordinator (CRC) to do the following:
  - 1. Identify when a patient will need have IP dispensed at a satellite location
  - 2. Contact the IDS Pharmacy using an Outlook meeting request to the Investigational Pharmacy email a minimum of 2 business days prior to when IP needs dispensed for patient use with the following information in the meeting request:
    - a. IRB number and study name
    - b. Subject number and patient initials
    - c. Investigational product name
    - d. Location of satellite where drug is to be dispensed
    - e. Date and time of patient appointment where IP is to be dispensed for patient use
  - 3. Ensure the order for the investigational product and any necessary IVRX/IWRS information is sent to the appropriate pharmacy in a timely manner that allows efficient transfer and transport of IP by IDS pharmacy to the satellite
- B. Transfer and transport of investigational product from IDS pharmacy to satellite
  - 1. It is the responsibility of IDS personnel to do the following after patient has been identified for needing IP dispensed at a satellite location:
    - a. Transfer the appropriate IP from the IDS Pharmacy to satellite location using the "Transfer Inventory" function in Vestigo®

- i. Bottles or vials and quantity to be dispensed must reflect the bottles indicated for dispense in the IVRX/IWRS provided by the study coordinator, if applicable
      - ii. "New location" in Vestigo® is specific to each receiving satellite location and IP storage requirements
    - b. Scan and upload the items listed below into the "Documents" section for the specific protocol in Vestigo®, when applicable, so that the documents are visible by pharmacy personnel at the receiving satellite location:
      - i. Prescription from the electronic health record
      - ii. IVRX/IWRS summary
  2. For investigational products being sent to satellites, investigational product will be packaged according to the protocol and transported with temperature and humidity monitoring, as applicable, according to the **Procedure: IDS Transport of Medications with Temperature & Humidity Monitoring**.
  3. IDS personnel will complete an Investigational Product Transportation and Monitoring Form to be sent with the IP during transport
  4. After the IDS personnel transfers the investigational product in Vestigo®, the Investigational Pharmacy will prepare the IP for transport and arrange courier services to complete the transport of the IP. See **Policy: Investigational Drug Service Transport** for details.
  5. Upon receipt of transported IP at satellite location, the receiving satellite pharmacy personnel must:
    - a. Receive transferred inventory in Vestigo® in the appropriate protocol
    - b. Sign the Investigational Product Transportation and Monitoring Form and then scan and upload the completed form into the "Documents" section for the specific protocol in Vestigo® so that the documents are visible by all pharmacy personnel that utilize Vestigo® for drug accountability.
- C. Transfer and transport of investigational product from satellite to IDS pharmacy
1. See **Policy: Investigational Drug Service Transport** for when IP would be transferred from a satellite back to the IDS pharmacy
  2. It is the responsibility of satellite pharmacy personnel to do the following after IP has been identified for needing transferred and transported back to the IDS pharmacy:
    - a. If the IP initially transferred and transported was never admixed/dispensed by the satellite pharmacy the IP can be returned to the IDS pharmacy and satellite pharmacy personnel would do the following
      - i. Transfer the appropriate IP from the satellite location to the IDS Pharmacy using the "Transfer Inventory" function in Vestigo®
        - A. Bottles or vials and quantity to be returned must match the bottles or vials and quantity of IP originally transferred and transported
        - B. "New location" in Vestigo® is specific to IDS space and IP storage requirements; satellite pharmacy personnel are to confirm with IDS personnel which location to select prior to selecting the "new location" in Vestigo® during the transfer process
      - ii. Print the Investigational Product Transportation and Monitoring Form from the "Documents" section for the specific protocol in Vestigo® and fill out the form appropriately in preparation for the transport back to IDS pharmacy (refer to the section above for required information), and send the form with the IP back to the IDS pharmacy using the appropriate courier service. See **Policy: Investigational Drug Service Transport** for details.

- b. If the IP initially transferred and transported was dispensed by the satellite for patient use this would be defined as a return and satellite pharmacy personnel would do the following
    - i. Document the return in Vestigo®. See the **Procedure: IDS: Disposal, Return, Destruction of Investigational Drug** for more details.
    - ii. 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. When applicable for transport back to the IDS pharmacy, after the satellite pharmacy personnel transfers the investigational product in Vestigo®, satellite pharmacy personnel will prepare the IP for transport and arrange courier services to complete the transport of the IP to the IDS pharmacy. See **Policy: Investigational Drug Service Transport** for details.
- 4. Upon receipt of transported IP at the IDS pharmacy, the receiving pharmacy personnel must:
  - a. Receive transferred inventory in Vestigo® in the appropriate protocol
  - b. Sign the Investigational Product Transportation and Monitoring Form, and then scan and upload the completed form into the "Documents" section for the specific protocol in Vestigo® so that the documents are visible by all pharmacy personnel that utilize Vestigo® for drug accountability.

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