



STANDARD OPERATING PROCEDURES (SOPs): TRANSPORTING INVESTIGATIONAL AGENTS FROM MAIN CAMPUS IDS PHARMACIES TO LOCATIONS WITHIN THE MEDICAL CENTER

Policy: The investigational pharmacy provides service for drug-related research protocols and is responsible for overseeing the dispensing, labeling, management of inventory and accounting for study drugs associated with research protocols on-site and at participating off-grounds University of Virginia affiliated clinics. If subjects are seen at University of Virginia clinics, it may be necessary to transport investigational agents to various on-site locations. In these instances, the investigational pharmacy staff is to utilize a standard procedure for transporting investigational product in accordance with all applicable federal and state regulations, good clinical practice guidelines, and institutional and departmental policies.

Definitions:

- **Control:** site to which investigational agent is originally shipped. In the context of this SOP, the control pharmacies are located on the main campus of the University of Virginia Health System (Main Hospital IDS and Cancer Center IDS).
- **On-site Clinic:** affiliated site away from the control pharmacy that is located within the Medical Center, such that the transporter may walk to the location from the pharmacy while remaining indoors.

Procedure:

A. Transporting investigational products within the UVA Medical Center:

1. Investigational products are to be dispensed from the main campus investigational pharmacies following the site's standard procedure for proper dispensing, labeling, and accountability of investigational product.
2. Once properly labeled, the product may be picked up from the pharmacy by designated UVA staff members – either a member of the study team or a member of the patient care team. If appropriate, the product may be sent to the receiving agent via the pneumatic tube system.
3. Transport of investigational product must remain in the receiving institution's immediate control, therefore, unless permitted by the study sponsor, investigational agents must NOT be re-shipped by mail or third-party delivery services to another institution, site or study subject.
4. Upon hand-off to designated UVA staff, the following information must be documented:
 - a) Subject name, medical record number, or other subject identifier
 - b) Investigational product name and/or study number (lot number, bottle number, etc will be captured in electronic accountability

- record. No need to replicate information).
- c) Name of study staff who will transport the investigational drug
 - d) Time and date of drug pick up
 - e) Target clinic location
5. If for any reason drug is not dispensed at the on-site clinic or if any unused patient returns remain at the on-site clinic, designated UVA staff must return the product to the control pharmacy.
 6. Upon receipt of returned investigational products, the control pharmacy is to document all patient returns in the site's electronic accountability system and follow the site's procedure for final disposition of the drug.

Applicable Regulations & Guidelines:

- PMB, CTEP, DCTD, NCI Policy and Guidelines for 'Investigational Agent Distribution' Version 06/14
- Joint Commission Standard MM.06.01.05
- ICH GCP 5.14.2
- 21 CFR 312.57(a)
- 21 CFR 312.60-62(a)

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