



STANDARD OPERATING PROCEDURES (SOPs): TRANSPORTING INVESTIGATIONAL AGENTS FROM MAIN CAMPUS IDS PHARMACIES TO OFF-GROUNDS CLINICS

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 multiple University of Virginia clinics, it may be necessary to transport investigational agents to off-grounds 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).
- **Satellite:** affiliated site or pharmacy away from the control pharmacy. Ideally, this site shares staff with the control site and is covered by the same Institutional Review Board.

Procedure:

A. Transporting investigational products to off-grounds UVA affiliated clinics or satellite pharmacies:

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 logged out of the site's electronic accountability system and labeled, the product may be picked up by designated UVA research staff or institutional courier for transport to the clinic.
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 clinical research staff or institutional courier, 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. Investigational products are to be packed and transported in accordance with specific storage requirements for the drug (with coolant if refrigerated, protected from light, etc).
6. Investigational products are to be packed in a designated, secured, hard sided, leak-proof container that is visibly labeled to denote its contents are investigational and may be hazardous. Known hazardous agents must be packed in a hazard bag and the outside of the container must be labeled with an orange biohazard sticker.
7. The investigational agents must be secured during transport and must never be left unattended in the vehicle.
8. If for any reason drug is not dispensed at the satellite location or if any unused patient returns remain at the satellite, designated UVA clinical research staff must return the product to the on-grounds primary location (control pharmacy) following the same transport procedures listed above.
 - a) In addition, the satellite is to document the date the drug was returned on the product label or bag and hold in a designated cabinet/storage area for UVA clinical research staff to pick up and transport back to the control pharmacy.
 - b) Under no circumstances is study drug to be destroyed at the satellite location. It must be returned to the control pharmacy for final reconciliation.
9. 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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