

## Transportation of Study Drug to Off Site Locations

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**DEPARTMENT:** Investigational Drug Services, University of Minnesota Medical Center

**DATE:** 15 October 2007

**LAST REVISED:** 07 January 2016

**Approved:** 

### **PURPOSE:**

This SOP explains the process of transporting study medication to a location outside of the East Bank Medical Center Complex

### **PROCEDURE:**

- 1) Research subjects may receive doses of study drugs in locations other than the East Bank Medical Center Complex, necessitating the transport of doses to other buildings.
- 2) If the dose is to be prepared in an off-site pharmacy, written approval for transferring study medication to the off-site pharmacy will be obtained from the Sponsor.
- 3) IDS will prepare study specific paperwork the for off-site pharmacy
  - a. DARFs (IDS developed or sponsor required)
  - b. Master Patient Log
  - c. Kit/Bottle/Vial roster forms
  - d. Drug Datasheet
- 4) Sponsor will indicate how medication will be delivered to off-site pharmacy
  - a. Medication will be sent by commercial courier
  - b. Medication will be brought to off-site pharmacy by IDS Pharmacy staff
- 5) Transfer of any product to a location that does not involve exiting the East Bank Medical Center Complex will be transferred at the discretion of the IDS staff.
- 6) Transfer of any product that involves leaving the medical center complex will be handled as outlined below:
  - a) Products stored at ambient temperatures will be transferred in a cooler accompanied by temperature data logger and receipt to document the product's temperature and condition upon arrival. The data logger will be programmed to alarm according the sponsor's specifications. The data logger and completed receipt will be returned to the IDS Pharmacy where the data from the logger will be printed and attached to the completed receipt.

- b) Products stored under refrigeration will be transferred in a cooler with the appropriate refrigerator packs accompanied by temperature data logger and receipt to document the product's temperature and condition upon arrival. The data logger will be programmed to alarm according the sponsor's specifications. The data logger and completed receipt will be returned to the IDS Pharmacy where the data from the logger will printed and attached to the completed receipt.