



POLICY AND PROCEDURE

Title: Drug Transport	
Policy Number: 4.6	Version: 02/01/2023

CENTRAL RECEIVING LOCATION

For studies managed by IDS, the majority of drug shipments are received in the primary IDS location, EUC Building A, Suite AT111, 1365 Clifton Road, NE, Atlanta, GA 30322. For studies conducted at the Hope Clinic, IP shipments are sent directly to the Hope Clinic, 500 Irvin Court, Suite 200, Decatur, GA 30030.

DISTRIBUTION

Inpatient

For inpatient studies at EUH or EUH Tower, doses are prepared following a physician’s order for investigational medication, and are transported directly to the nursing unit by study or IDS personnel. Prepared doses requiring refrigeration are placed in the refrigerator until time of administration.

Outpatient Winship Cancer Institute

For outpatient hematology/oncology studies, IV doses administered in the Winship Infusion Center or the Phase I unit are prepared by IDS personnel in Emory Clinic, Building A, and transported to the Infusion Center or to the Phase I Unit by IDS personnel. For outpatient studies involving take-home study drug, study personnel pick up the medication from IDS to deliver to the study participant. If refrigerated doses are to be sent home with the participant, they are dispensed in a cooler or other container with refrigerator packs.

Outpatient Emory Clinics

For outpatient and infusion studies conducted in EUC Building A or B, doses are prepared and transported by study or IDS personnel to the area where the participant will receive the medication.

Emory Children’s Center

For outpatient vaccine studies of the Emory Children’s Center (ECC), doses are prepared and delivered by IDS or study personnel to the ECC along with a Chain of Custody form to document delivery. The study product is transported at ambient temperature unless specified otherwise by the sponsor. The chain of custody documents the temperatures at pickup and min/max at delivery, if required by the sponsor.



Hope Clinic of Emory Vaccine Center

Hope Clinic maintains two buildings, 500 Irvin Court and 484 Irvin Court which are adjacent to each other and located in Decatur, GA. An IDS satellite facility is located in the 500 Irvin Court building where doses are prepared for all outpatient and infusion studies. For subject visits conducted at 500 Irvin Court, study personnel directly pick up the prepared doses from the pharmacy. No chain of custody is required. For subject visits conducted at 484 Irvin Court, doses are delivered by IDS or study personnel to the visit room along with a Chain of Custody form to document delivery. The study product is transported at ambient temperature, and the chain of custody documents the temperatures at pickup and min/max at delivery, unless specified otherwise by the sponsor.

Offsite Locations

For studies conducted at Executive Park, Emory University Hospital Midtown and Infusion Center, Emory St. Joseph’s Hospital and Infusion Center, and Emory John’s Creek, IDS personnel prepare doses and transport them STAT via local commercial courier, Apple Courier, www.appleatlanta.com.

Prior to sending a shipment via commercial courier, IDS confirms with the research coordinator that study personnel are available to receive it. All shipments sent via commercial courier are placed in a container for transport which is sealed with a tamper evident seal, and a Chain of Custody form is sent with it. If the study medication is a controlled substance, the outside package shall bear no indication of contents.

Approximate travel distance from 1365 Clifton Road to each location is as follows:

Executive Park	12 Executive Park	2.7 miles
EUHM	550 Peachtree Street	4.9 miles
Emory St. Joseph’s	5665 Peachtree Dunwoody Road	8.0 miles
Emory John’s Creek	6325 Hospital Parkway	25 miles

If asked by a sponsor to supply inventory to the Grady Memorial Hospital IDS, Emory IDS will package and transport inventory STAT via Apple Courier to the following address:

Grady Health System
80 Jesse Hill Jr. Drive, SE
Investigational Drug Service
Room BE115
Atlanta, GA 30303
(404) 616-3045

If the study sponsor requires that temperature be monitored during transit, IDS uses the AcuTemp PX1L carrier with a min/max thermometer, at controlled ambient or refrigerated temperature, for



transport. The prepared dose or drug inventory is placed in the carrier and the thermometer is reset so that the minimum and maximum temperatures during transit are recorded. IDS uses the Chain of Custody form described below and documents the temperature when the dose is placed in the carrier. The courier transports the carrier, and upon receiving it, the recipient documents the temperature at receipt on the Chain of Custody and faxes the form to IDS.

Shipments to Patients

On certain occasions, a study medication may need to be shipped to a patient's home. IDS will ship study medication at the request of the Principal Investigator or Research Coordinator, and if approved by the Sponsor. The request should be submitted in writing with the study participant's prescription and a Fedex or UPS airbill. IDS will package and ship the medication, and the study team will be responsible for tracking the package to ensure delivery.

There may be occasions in which a participant receives an investigational IV infusion at home, under the care of a home infusion nurse who is working under contract with the study sponsor. When this occurs, it is the sponsor's responsibility to make arrangements for the home infusions and to contract a commercial courier to pick up inventory or prepared doses from IDS. The Emory study team sends the signed order and appropriate paperwork to IDS to prepare and dispense the dose.

Chain of Custody

IDS personnel use the IDS Chain of Custody (COC) form when study drug is transported locally via commercial courier. The form is used to document the protocol#, delivery location, date and time of pickup and delivery, and name and # of the driver. The recipient of the shipment signs the form and faxes it to IDS to verify that the shipment was received. IDS personnel upload the signed COC form to Vestigo with the drug order.

References:

Georgia Board of Pharmacy Rules 480-33-.06, 480-33-.09; 21 CFR 1301.74(e)

Prior Versions: 2/24/2014, 3/24/2017, 1/30/2020, 3/2/2020, 9/30/2021, 2/1/2022