

**Investigational Drug Service  
Emory University School of Medicine  
Standard Operating Procedure**

**Guidance on Shipping Study Medication to Patients during  
Coronavirus Pandemic (COVID-19)**

This document provides guidance to research coordinators and investigators regarding resupply of investigational product (IP) and shipments to patients who are unable to visit the site due to COVID-19. The Investigational Drug Service (IDS) continues to operate during the pandemic at usual business hours, Monday – Friday 7:00AM to 4:30PM and is available by phone at 404 727-0028; 404 712-7485; 404 727-0036. IDS will ship medications to patients' homes following sponsor approval and according to the following guidelines.

**SHIPPING METHODS**

- 1) Fedex box or other packaging – if the sponsor does NOT require that the IP be shipped at controlled temperature and does not require temperature monitoring during shipment, IDS can package the IP in a Fedex box or other container and will ship overnight to the patient's home
- 2) Inmark Sepio shipper – if the sponsor requires that the IP be shipped in a temperature controlled shipper, IDS has validated shippers in stock which can be used to ship IP at controlled room (15 – 25 degrees C) or refrigerated (2 – 8 degrees C) temperatures. The shippers provide controlled temperatures for up to 72 hours when packaged according to the manufacturer's specifications. A copy of the shipper specification sheet is attached. The research coordinator is responsible to obtain approval from the sponsor to use the Inmark shipper.
- 3) Sponsor provided shipment – if the sponsor requires that the temperature be recorded during shipment using a temperature monitoring device, the sponsor will contract with a commercial shipper such as Marken or World Courier. IDS will dispense the IP and will hold it for pickup by the designated commercial courier at the IDS clinic location below.

Investigational Drug Service  
Emory Clinic, Building A, Suite 1200  
1365 Clifton Road, NE  
Atlanta, GA 30322

**PROCEDURE FOR RESEARCH COORDINATOR TO REQUEST SHIPMENT TO  
PATIENT'S HOME**

Research coordinator notifies IDS of the need to ship to patient's home, giving IDS several days lead time. Research coordinator obtains approval from sponsor to ship IP to patient's home by one of the 3 methods defined above.

## 1) Fedex box or other packaging

- Research coordinator obtains prescription for resupply
- Research coordinator obtains the Fedex or other air bill to ship to patient's home. When obtaining the air bill, the weight of most shipments is less than 10 pounds
- Research coordinator sends prescription and air bill via fax (404) 727-0265 or email [idsfax@emory.edu](mailto:idsfax@emory.edu) to IDS with notification from sponsor that IP does NOT need to be shipped at controlled temperature
- IDS ships the IP according to instruction and maintains documentation of the shipment in the patient study records in Vestigo, including the notification to ship and a copy of the air bill

## 2) Inmark shipper

- Research coordinator obtains prescription for resupply
- Research coordinator obtains the Fedex or other air bill to ship to patient's home. When obtaining the air bill, the weight of the Inmark shipper should be included at 25 pounds for a small shipper and 40 pounds for a large shipper.
- Research coordinator sends prescription and air bill via fax (404) 727-0265 or email [idsfax@emory.edu](mailto:idsfax@emory.edu) to IDS with notification from sponsor that IP must be shipped at controlled temperature and with sponsor's approval to use the Inmark shipper
- IDS maintains documentation of the shipment in the patient study records in Vestigo, including the notification to ship and a copy of the air bill
- IDS bills the grant for the cost of the shipper:
  - Small @ \$34.00/shipper
  - Large @ \$49.00/shipper

## 3) Commercial shipper

- Research coordinator works with sponsor to arrange pickup at IDS via commercial courier
- Research coordinator submits prescription for resupply to IDS with instructions on which commercial courier is being used and when the courier will pick up from IDS
- IDS maintains documentation of the shipment in the patient study records in Vestigo, including the notification to ship and a copy of the air bill