MUSC Health
PHARMACY SERVICES

MUSC Medical Center
Investigational Drug Services (IDS) Pharmacy

Title:	**Guidance for Shipping Investigational Drugs to Patients during the COVID-19 Pandemic**		
Owner:	**IDS Pharmacy**		
Location/File:	**U:\IDS Shared Documents\IDS Policies and Procedures**		
Date Originated: **03/2020**	**Reviewed:** **4/1/2020**	**Revised:**	**Effective Date:** **4/1/2020**

Table of Contents

I. PURPOSE

To describe the temporary process for shipping investigational medicinal products (IMP) to patients' homes during the COVID-19 pandemic. This document may be revised during the pandemic, as it has proven to be a very dynamic situation requiring frequent modifications to operations.

II. DEFINITIONS

N/A

III. SCOPE

This procedural manual was developed in response to the COVID-19 pandemic. To safely provide investigational medications to clinical trial participants, many regulatory agencies have temporarily allowed sites to ship medications directly to patients' homes. This document provides guidance on procedures for shipping investigational drugs from MUSC to patients' homes.

IV. PROCEDURES

A. Sponsor Approval

1. Industry Trials

a. Study teams must receive approval from study sponsors prior to shipping IMP from the study site to study participants' homes.

b. Various sponsors have preemptively distributed guidance via email for shipping IMP to patients. Study teams should determine if any guidance information has been released specific to their trials.
c. Some sponsors may require the pharmacy of record to manage drug shipments to patients.

2. NCI (CTEP) Trials

a. The NCI Cancer Therapy Evaluation Program (CTEP) released a COVID-19 guidance update on March 23, 2020. For studies under an IND, the Pharmaceutical Management Branch (PMB) standard operating procedures will be altered for 90 days from March 16, 2020 to June 14, 2020 to allow the Dispensing Pharmacy to ship oral investigational agents directly to patients. Requests for authorization do not need to be submitted to the PMB, CTEP for review. "Since this is an alteration to the standard operating procedures of the CTEP PMB (not part of the protocol), this is a not a protocol deviation and it does not need to be reported to the IRB of record for the trial. Sites will not be asked to submit Corrective Action Plans for shipments to subjects under these circumstances."
b. The MUSC IRB is applying requirements for amendments to all trials, regardless of the sponsor type.
c. Per the CTEP PMB, the pharmacy of record must manage drug shipments to patients.

3. DAIDS Trials

a. The DAIDS Pharmaceutical Affairs Branch (PAB) released COVID-19 guidance for pharmacists on March 18, 2020. Per the PAB guidance document, "for emergency cases, the Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks permits shipment or courier of study product from the site directly to participants. This method should only be used on a short-term, protocol-specific basis and only if permissible by the local institution and/or IRB/EC."
b. Per the DAIDS PAB, the pharmacy of record must manage drug shipments to patients.

B. Protocol Amendments

1. IRB Approval

a. The FDA and NIH have released guidance documents allowing for alterations in clinical trial procedures to maintain patient safety.
b. The MUSC IRB has released guidance for submitting protocol amendments for changes in procedures, such as virtual study visits and shipping drug to patients. The IRB recognizes that some procedures may need to be completed prior to amendment approval to prevent patient harm.

c. It is the responsibility of the PI to consider the above guidelines, and to decide whether drug should be shipped to a patient prior to an approved protocol amendment.

C. Interstate Transport of IMP

1. IMP under an IND

a. An IND allows for the interstate transport of IMP as part of the clinical trial.

2. IMP NOT under an IND

a. Medications without an IND are subject to state pharmacy board regulations and may require a non-resident pharmacy permit in the destination state.
b. Some state boards of pharmacy are allowing temporary non-resident permitting to allow patients who cannot return home to receive their medication. This would be considered a last-resort option and study teams would be responsible for any associated costs.

D. Packaging and Handling

1. Temperature Control

a. Qualified shipping containers should be used to maintain temperature control and the integrity of IMP. Temperature monitors may or may not be required by various sponsors.
b. Industry sponsors may provide shippers and/or temperature monitors as part of their COVID-19 response plan. Sponsors with more complex plans requiring extra coordination and/or paperwork are subject to higher fees, even if they provide a shipper.
c. IDS is working to procure validated shippers for shipping IMP at 15-25°C and 2-8°C over a period not to exceed 36 hours. The shippers have been validated to maintain the specified temperature ranges based on the number and arrangement of gel packs inside the shippers. The packing varies according to outside temperatures when shipping.
d. Using validated shippers removes the need for temperature monitors, unless specifically required by a sponsor. In such cases, the sponsor must provide the temperature monitors to be used. Shipments using temperature monitors will be subject to higher fees to accommodate for the extra time required to manage the monitors and data reports.
e. IDS will assist study teams with shipping as resources allow, but the responsibility ultimately lies with the PI/study teams. Trials using life-saving IMP, such as chemotherapy for cancer, may be prioritized over other trials if necessary.

2. Chain of Custody / Tracking

a. Shipments should be sent via FedEx or UPS for overnight delivery with options for shipment tracking and delivery confirmation. Shipments should require a signature upon receipt.
b. It is the responsibility of the study teams to coordinate delivery dates/times with their patients and to ensure the patients have received their medications after being shipped.
c. IDS will include an itemized packing slip from Vestigo in each shipment.
d. Study teams/sponsors may request for additional documents to be included in shipments (e.g. patient diaries). If IDS must complete extra documentation (e.g. sponsor forms) or follow-up, a higher charge will be incurred.

3. Hazardous Medications

a. Hazardous medication containers must display hazardous labeling and must be placed in sealed plastic "chemo" bags before being placed inside the shipping containers.

4. Dangerous Goods

a. The Department of Transportation (DOT) does not include hazardous medications in the list of hazardous materials which require special shipping restrictions. Local pharmacies generally do not treat hazardous medications, such as chemotherapy, as dangerous goods when shipping. If an IMP does require DOT shipping restrictions, IDS will not ship it.
b. CTEP considers the following NCI-provided drugs dangerous goods; therefore, these drugs cannot be shipped by IDS at this time.
   - NSC 732517 Dasatinib
   - NSC 767034 GSK2141795
   - NSC 768435 MLN0128 (TAK-228)
   - NSC 783668 LY3023414
   - NSC 787289 Vistusertib (AZD2014)

5. Patient Returns

a. Patients should NOT return anything to IDS during the COVID-19 pandemic due to safety concerns.
b. Study teams should develop alternate methods to ensure patient compliance during the pandemic and may instruct patients to retain used IMP containers until an on-site visit is possible.

E. Associated Costs

1. Shipping Fees

a. FedEx and/or UPS shipping charges are the responsibility of the sponsors/study teams. The preferred method of payment is for study teams

to provide IDS with shipping labels with the account number AND the patient's address already completed.

b. Alternatively, IDS may ship drugs under a pharmacy UPS account and charge the study UDAK in the same manner as dispensing fees.

c. If IDS is required to complete shipping labels by hand, higher fees may be incurred due to the extra time required. This case would apply to study teams who supply a FedEx or UPS account number without prefilled labels.

2. Packaging and Coordination Fees

a. IDS will charge a packaging fee to help cover the costs of the validated shippers and the staff time required to pack and coordinate the shipments. These fees will be charged to the study UDAK in the same manner as dispensing fees. The estimated fees are listed below but may need to be adjusted depending on the size and type of shipping container/packaging used (i.e. room temp vs. refrigerated) and the time required to coordinate and prepare each shipment, as some trials/drugs may prove to be more demanding. Industry trial shipments tend to be more time consuming due to specific sponsor requirements, and therefore are more costly even when shippers are provided by the sponsor.

   i. Industry Trials: ~ $35-45/shipment
      a. With temperature monitors (Complex): $45
      b. Without temperature monitors: $35
   ii. Non-Industry Trials: ~ $25/shipment
      a. Extra documentation/planning required (Complex): $35

b. Please note that these fees may be lower than fees under normal operations and should not be used for future budgeting purposes post-COVID-19 pandemic.

F. Requesting Shipping Services from IDS

1. Send Patient Info

a. Study teams should send an email to idspharm@musc.edu with:
   - Patient names and addresses
   - Drugs to be shipped
   - Due dates for next doses for each patient/drug (≥ 3 days later)
   - Quantity or days' supply to be shipped to each patient

b. Prescriptions should be submitted per regular practice at least one business day prior to the date of shipping.

2. Provide Shipping Info

a. Study teams should provide a shipping account number, prefilled shipping label (hardcopy or via email), or UDAK to be charged (if different than current study UDAK).

b. Study teams should provide any additional documents requested to be included in shipments (e.g. patient diaries). IDS may print 1-2 pages per patient as needed. If IDS must complete extra documentation (e.g. sponsor forms), a higher charge will be incurred.

3. Agree to Costs

a. Study teams should acknowledge via email agreement to pay the associated costs.

b. The following fees have been added to SPARC, so they can be included in IDS service requests for new trials.

4. Send Approval Info

a. Protocol amendments should be uploaded in SPARC when submitting the IDS amendment service request per normal practice.

b. Sponsor approvals should be emailed to IDS at this time but may be uploaded in SPARC as well.

c. Any ancillary IRB approvals outside of an amendment should be emailed to IDS.

5. IDS Contact Info

a. Phone: (843) 792-9643, Fax: (843) 792-2834

b. Email: idspharm@musc.edu, On-call Pager: 17269

c. Shipping address:
MUSC Investigational Drug Services Pharmacy
169 Ashley Avenue, MH Room 161
Charleston, SC 29425

G. Miscellaneous

1. Prescription Requirements

a. Shipping a drug to a patient does NOT negate the need for a prescription. Prescriptions will be processed in Epic/Vestigo per normal practice.

2. Time Requirements

a. Study teams should notify IDS of the need for shipping at least THREE BUSINESS DAYS prior to the date the drug is needed by the patient and must provide all the aforementioned information at least ONE BUSINESS DAY prior to shipping.

3. Non-IDS Drug Shipping

a. Study teams who normally manage IMP on their own may contact IDS for assistance. IDS may be able to procure qualified shippers for these teams via an IIT if resources allow. Depending on the demand and the involvement required by IDS staff, a small administrative fee may be necessary.

   i. Study teams should email requests to idspharm@musc.edu and should include:

      - Estimated quantity of shippers needed
      - Date(s) needed
      - Temperature required (15-25°C or 2-8°C)
      - Size of shippers (2 L are the smallest and work for most drug shipments, 3 L may be required for larger shipments)

V. REFERENCES

NCI CTEP PMB Memo: Updated Interim Guidance for Patients on Clinical Trials Sponsored by the NCI Cancer Therapy Evaluation Program: Shipment of Oral IND Agents to Clinical Trial Subjects, March 23, 2020.

DAIDS PAB Memo: Coronavirus Disease 2019 (COVID-19) and DAIDS HIV/AIDS Network Clinical Research Studies- Additional Pharmacy Operations Guidance, March 18, 2020.

Approvals:

As Required	**Date**
IDS Management	4/1/2020