Department of Pharmacy Services, Investigational Drugs

STANDARD OPERATING PROCEDURES (SOPs): Investigational Product Shipment to Subject

Policy: The Cancer Center Investigational Drug Services Pharmacy (CCIDS) provides service for drug-related research protocols and is responsible for overseeing the dispensing, labeling, shipment, management of inventory, and accounting for study products associated with research protocols onsite and at participating sites. The CCIDS pharmacy staff is to utilize a standard operating procedure for shipment of investigational product to clinical trial subjects.

Procedure:

A. Dispensing Investigational Drug Products

1. CCIDS will use guidance from the National Cancer Institute Cancer Therapy Evaluation Program (NCI CTEP) and the Food and Drug Administration (FDA) to provide shipment of oral study agents to designated clinical trial subjects. Investigational product (IP) being studied under an IND is eligible for interstate shipment without restriction. Drugs not being studied under an IND application cannot be shipped out of state per the Virginia Board of Pharmacy.

2. Shipment of oral agents to enrolled study subjects on clinical trials will be performed as deemed necessary by the study Investigator and in the best interest of continuity of patient care. Shipment shall be performed only when circumstances prevent the study subject from returning to the clinical trial site and is not a replacement for protocol-defined in-person study visits and assessments.

3. For those clinical trial patients whom the Principal Investigator deems fit to continue oral study treatment, written sponsor approval is required to ship study medication to the subject. NCI CTEP allowed shipment of oral investigational agents directly to subjects effective January 1, 2022, thus, written sponsor approval is not necessary for NCI trials.

4. The quantity of investigational agent supplied will not exceed what is required for the patient prior to the next in-person visit, per the study protocol.

5. Oral IP will be shipped according to temperature requirements outlined in each trial's protocol in a validated shipping container to maintain temperature control and to ensure product quality, safety, and integrity during transit until receipt by subject.

6. A validated shipping container is defined as a shipping container that has been tested and evaluated to maintain the required storage temperature range that encompasses the time from product packaging to receipt by the subject.

7. Oral IP will be shipped following the procedure outlined in Appendix A and will be packaged in a manner which ensures that the IP arrives undamaged to the subject.

B. Shipping Process and Fees for Service

1. Study participants desiring the shipment of oral IP will be charged a flat fee of $35 to cover packing materials and overnight shipping fees.

2. Clinical study coordinators (CRCs) responsibilities are as follows:
   a. Document the need for shipment in the subject's medical record
   b. Complete a CCIDS Shipping Packet which includes the following:
      i. A complete Investigational Drug Shipping Request Form (ATTACHMENT A)
      ii. Written permissions from sponsor and Principal Investigator (email communication is sufficient)
      iii. Patient phone number, address (PO Boxes *will not* be permitted) and availability to receive shipment with adult signature
      iv. Provide the subject with a pill diary, or include the pill diary in the packet if to be shipped with study IP
   c. Inform subject when the agent is shipped, confirm oral IP receipt and record recipient.

3. CCIDS pharmacy staff responsibilities are as follows:
   a. Dispense study IP using prescription provided upon receipt of CCIDS Shipping Packet
   b. Properly label the drug product for patient use and document any patient counseling that is provided
   c. Ship oral IP directly to study participants overnight Monday through Friday and require tracking and signature confirmation for receipt.
      i. CCIDS will only ship to street addresses – PO Boxes *will not* be permitted.
      ii. CCIDS will ship oral IP in validated shipping containers
      iii. CCIDS will include the Investigational Drug Shipping Receipt in shipment (ATTACHMENT B)

d. Apply associated shipping fees to the clinical trial worktag number on file in Vestigo
e. Provide the tracking number for shipment to the CRC
f. Ensure the following documentation is filed in Vestigo:
    i. Date and time of shipment
    ii. Full tracking history including courier name
    iii. Date and time of receipt
    iv. Name of recipient of shipment
    v. Type of shipping container used
g. Input DARF note utilizing standard language template
    i. *IP was shipped to the patient in a SMALL/LARGE validated Veritiv shipping container with consideration of the package size and ambient weather conditions, per SOP. CRC to confirm with patient that IP was received within 36 hours of leaving the pharmacy and document in the patient's chart.*

C. Special Considerations

1. The shipment of agents that are considered Dangerous Goods (DGs) per CTEP is not permitted. Shipment of agents considered hazardous or those that could pose a health and safety hazard to IDS staff or recipients may also be prohibited, unless performed in accordance with applicable regulations and appropriately trained and certified individuals. Adherence to Department of Transportation and International Air Transportation Association regulation methods for shipment is required.

2. Agents must be dispensed in accordance with any REMS dispensing requirements, where applicable.

D. Handling of Returned Study IP

1. Subjects should be instructed to not use study IP that arrives outside of the qualified shipping container's 36 hour baseline timeframe and to hold any leftover study IP until the next onsite visit. CCIDS will not accept patient returns through the mail. A replacement shipment must be provided to the subject, if applicable.
    a. The validated shipping container may provide more than 36 hours of suitable temperature coverage in certain instances, however, inquiries into suitability extensions beyond 36 hours must be verified against the data on file.

2. Any returned study IP must be documented on the NCI Investigational Agent Accountability Record for Oral Agents (Oral DARF) as a patient return.

Applicable Regulations & Guidelines:

FDA Guidance on Conduct of Clinical Trials FDA-2020-D-1106
NCI CTEP Guidance for Shipment of Oral IND Agents 1Jan2021
Food and Drugs, Investigational New Drug Application, 21 C.F.R. § 312.1. 2011

REVISION HISTORY				
Version	Reason	Relevant Reviewers	Approved By	Date of Approval
MAR 2020	New	CCIDS Pharmacists	--	--
MAR 2023	Revision	LeBegue-Polley, Luedtke	Michael Neace	07 MAR 2023

Department of Pharmacy Services, Investigational Drugs

ATTACHMENT A

Cancer Center Investigational Drug Services
Department of Pharmacy Services
1240 Lee Street
4th Floor, Room 4326
Charlottesville, Virginia 22903
Tel: (434) 982-5385
Fax: (434) 243-7394
clpharmacyec4idsservices@hscmail.mcc.virginia.edu

Investigational Drugs Shipping Request Form

To: **Cancer Center IDS** From:

Date: Pages (including coversheet):

CCIDS will charge a flat fee of $35 to cover overnight shipping costs and shipping supplies

Required Items to Ship:

(Please attach Sponsor and PI approvals with prescription – NOTE separate sponsor approval not necessary if NCI CTEP managed drug)

☐ Sponsor Approval ☐ PI Approval ☐ Shipping Address (Must be street address —PO Box NOT permitted) ☐ Patient Diary included to be shipped with study IP

Patient Name:	HSR:
MRN:	Phone number:
Address:	** Shipping is only available **Monday – Friday**. We will only ship to the patient and not to another addressee. Package(s) will require signature at time of delivery. **

Department of Pharmacy Services, Investigational Drugs

ATTACHMENT B

Investigational Drug Shipping Receipt

Patient Name: Date Shipped:

Address:

Medication:

Do not use this drug if received after: _____

If this medication arrives after _____ please contact your study coordinator. Keep the medication in its original container and bring it back with you to your next onsite visit at the Emily Couric Cancer Center.

UVA Health

Department of Pharmacy Services, Investigational Drugs

CCIDS IP Shipping Packout Decision Tree

CRT: Controlled Room Temperature

Note: packages can be expected to hold desired temperature for approximately 36 hours. For specific questions, consult the spreadsheets.

CRC requests IP be shipped directly to patient's home.

Step 1: Confirm you have the following:

1. Sponsor permission to ship IP
2. Rx for IP
3. Completed shipping request form

Step 2: Confirm product storage requirements

- Maintain Controlled Refrigeration
  - **Step 3**: Confirm expected outside temperature
    - **≤ 59°F**
      - **Step 4**: Choose packaging of appropriate size
      - **Small vs Large Winter Packout – Refrigeration**
        S: 8x6x5 Outer Box and Liner
        L: 10.5x8x6.25 Outer Box and Liner
    - **> 59°F**
      - **Step 4**: Choose packaging of appropriate size
      - **Small Vs Large Summer Packout – Refrigeration**
        S: 8x6x5 Outer Box and Liner
        L: 10.5x8x6.25 Outer Box and Liner
- Maintain Controlled Room Temperature
  - **Step 3**: Confirm expected outside temperature
    - **≤ 59°F**
      - **Step 4**: Choose packaging of appropriate size
      - **Small vs Large Winter Packout – CRT**
        S: 8x6x5 Outer Box and Liner
        L: 10.5x8x6.25 Outer Box and
    - **> 59°F**
      - **Step 4**: Choose packaging of appropriate size
      - **Small vs Large Summer Packout – CRT**
        S: 8x6x5 Outer Box and Liner
        L: 10.5x8x6.25 Outer Box and Liner

UVA Health

Department of Pharmacy Services, Investigational Drugs

Small Winter Packout - Refrigeration

Bubble to Fill Void

One Refrigerated 24oz Gel

1 Layer Bubble Wrap

Payload

1 Layer Bubble Wrap

One Frozen 24oz Gel

8x6x5 Outer Box and Liner

Large Winter Packout – Refrigeration

Bubble to Fill Void

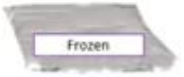
Two Refrigerated 24oz Gel

2 Layers Bubble Wrap

Payload

2 Layers Bubble Wrap

One Frozen 24oz Gel



10.5x8x6.25 Outer Box and Liner

UVA Health

Department of Pharmacy Services, Investigational Drugs

Small Summer Packout – Refrigeration

Bubble to Fill Void

One Frozen 24oz Gel

1 Layer Bubble Wrap

Payload

1 Layer Bubble Wrap

One Frozen 24oz Gel

8x6x5 Outer Box and Liner

Large Summer Packout – Refrigeration

Bubble to Fill Void

Two Frozen 24oz Gel

2 Layers Bubble Wrap

Payload

2 Layers Bubble Wrap

One Frozen 24oz Gel

10.5x8x6.25 Outer Box and Liner

UVA Health

Department of Pharmacy Services, Investigational Drugs

Small Winter Packout – CRT

Bubble to Fill Void

One Ambient 24oz Gel

1 Layer Bubble Wrap

Payload

1 Layer Bubble Wrap

One Ambient 24oz Gel

8x6x5 Outer Box and Liner

Large Winter Packout – CRT

Bubble to Fill Void

Two Ambient 24oz Gel

2 Layers Bubble Wrap

Payload

2 Layers Bubble Wrap

One Ambient 24oz Gel

10.5x8x6.25 Outer Box and Liner

UVA Health

Department of Pharmacy Services, Investigational Drugs

Small Summer Packout – CRT

Bubble to Fill Void

One Refrigerated 24oz Gel

1 Layer Bubble Wrap

Payload

1 Layer Bubble Wrap

One Refrigerated 24oz Gel

8x6x5 Outer Box and Liner

Large Summer Packout - CRT

Bubble to Fill Void

Two Refrigerated 24oz Gel

2 Layers Bubble Wrap

Payload

2 Layers Bubble Wrap

One Refrigerated 24oz Gel

10.5x8x6.25 Outer Box and Liner