Ochsner Health

Operational Standard

SUBJECT:	Transport of Investigational Medications
ISSUE DATE:	August 19, 2020
EFFECTIVE DATE:	August 27, 2025
RESPONSIBLE DEPARTMENT:	Pharmacy
OPERATIONAL STANDARD NUMBER:	OHS.PHARM.OS.053

I. Purpose

This operational standard describes the process of transporting investigational medications used in clinical trials.

II. Scope

This standard applies to any site conducting a therapeutic clinical trial utilizing investigational medications within the Ochsner Health system. Transport refers to the moving of study medication from a primary dispensing area to a satellite dispensing area located at another facility. Transport may also refer to the moving of medication within different areas of a single facility as part of preparation, dispensing, or administration steps.

III. Definitions

Primary Dispensing Area- Also known as the controlled dispensing area or primary site, where research medications are received, inventoried, stored, and dispensed for a clinical trial.

Investigational Medications- Any medication, biological, botanical, or other substance used in a clinical research study or access program as named in an investigational protocol and Institutional Review Board (IRB) submission. Such medications can be either commercially available or not commercially available and used according to, or outside of, the FDA-approved indications.

Satellite Dispensing Area- Also known as a satellite pharmacy or satellite site, where research medications are received directly from the controlled dispensing area for the purposes of dispensing to research subjects at that facility or location. Typically, satellites are not physically adjoined or connected to the controlled dispensing area and are utilized when a study sponsor will not send a unique supply of investigational medications, nor assign a primary shipping designation or unique site number.

IV. Standard

A. To facilitate accessibility, investigational medications may be couriered by a third party to another approved facility within the system for dispensation. This includes medication in stock containers as well as compounded products.
B. Investigational products may be transported within a facility as part of the dispensing process.
C. Appropriate documentation should be maintained by investigational pharmacy staff when transporting study medications to a satellite on both the originating and receiving end.
D. An established courier service must be utilized to transport medications (whether compounded or bulk) between Ochsner Health facilities. Employees may not transport medications in their own vehicles. A courier is not needed to transport medications to different areas within a facility.
E. If a transported medication is dispensed within 24 hours of being received, the receiving site does not need to maintain a separate written accountability record for the dose(s) received.

V. Procedure

A. Transporting medications from one facility to another

i. Unless explicitly stated in a written guidance, approval must first be obtained from a Sponsor of a respective protocol to allow transport of investigational medications previously received and stored from a primary dispensing area to a designated satellite.
ii. Medications should be packaged in appropriate sealable containers (with ice packs or dry ice as appropriate) to ensure security of the product and to maintain allowable storage temperature. Guidance may be obtained from the protocol, investigator brochure, pharmacy manual, written email from Sponsor, or equivalent.
iii. Packaged shipment should contain an original, partially completed Chain of Custody Form as well as a temperature excursion monitor (if required by the Sponsor). An example Chain of Custody Form is attached as Attachment A.
iv. Upon receipt, the satellite will complete the Chain of Custody form including time and date of receipt and indicate whether an excursion occurred. Medication may then be dispensed or moved to appropriate storage conditions based on product stability data. If an excursion was noted, the protocol should be reviewed, with Sponsor notification to assess appropriateness of dispensing the product.
v. The completed Chain of Custody form must be returned to the pharmacy of origin, although not required to be by courier. Fax or scan is allowed.
vi. If medication will be maintained for greater than 24 hours at a satellite, a separate accountability log should be created to document receipt and storage of the product(s).

vii. The satellite must have adequate locked doors and cabinets, and daily monitoring of temperatures for the product storage areas if maintained for greater than 24 hours.
viii. Unused or undispensed stock medications will be transported back to the primary pharmacy for subsequent use in another study, return to Sponsor designee, or local destruction per established Sponsor guidance.

B. Transporting medications within a facility located on one physical campus

i. Medications utilized for clinical trials are sometimes stored in a pharmacy in one area of a facility and prepared for dispensation in another. Medications may be transported from one area to another without need for chain of custody form or temperature excursion sensor if transport is completed within 15 minutes; occurs indoors; and is between same or attached buildings. An indoor crosswalk is included in the definition of attached buildings.
ii. If any of the criteria above are not met, then the product should be packaged and transported as per Section A. However, a third-party courier is still not required.
iii. Medications which have been compounded, prepared, or are in a sealed stock bottle which are ready to be dispensed may be given to a study research coordinator, infusion nurse, or transported to a patient care area without need for chain of custody form or temperature monitor if transport is completed within 15 minutes; occurs indoors; and is between same or attached buildings. An indoor crosswalk is included in the definition of attached buildings.

C. Transporting medications during periods of declared emergency

i. Should medication need to be shipped to alternative facilities, or to a patient's home in the time of a weather disaster, a pandemic, or other declared emergency, guidance and approval should first be obtained by the respective study Sponsor(s) such as pharmaceutical industry or governing regulatory agency such as the National Cancer Institute (NCI) Pharmaceutical Management Branch (PMB).
ii. All attempts should be made to transport medications utilizing a Chain of Custody Form and a temperature excursion sensor (if required). If not feasible, notify the Sponsor and document the shipping process.

VI. Enforcement

Failure to comply with this operational standard may result in progressive discipline for employees or termination of contract or service for third-party personnel, students, or volunteers.

VII. Attachments

Attachment A: Example Chain of Custody Form

VIII. References

-OHS.PHARM.020 Medications Used in Clinical Research

-NCI Cancer Therapy Evaluation Program- Pharmaceutical Management Branch
https://ctep.cancer.gov/branches/pmb/default.htm

-OHS.PHARM.OS.046 Disaster Plan for Pharmacy Investigational Drug Services

IX. History

Last revised and approved: August 20, 2020

X. Approved

Deborah Simonson 9/3/2025

Deborah Simonson, VP- Chief Pharmacy Officer Date

Reviewers

Operational Standards are required to be reviewed, at a minimum, by:

- *A direct report of any Responsible Department Department/Division Leader approver; and*
- *Any subject matter experts*

Reviewer	Date	Comments, Decision
PL Policy Committee	*5/8/25*	*Approved*
System Pharmacy Operations Subcommittee	*5/27/25*	*Approved*
Pharmacy Leadership Team	*6/30/25*	*Approved*
System P&T	*8/27/25*	*Approved*

IP TRANSPORT
CHAIN OF CUSTODY

Study Protocol Name and Number: XXXXXXXX

Medication Name and Strength and Size/Volume: XXXXXXXXXXXXX

Patient Name:_____ MRN: _____

Transported from XXXXXXXXXXXXXXXXXX (Facility and Address) and sent via XXXXX Courier Service to XXXXXXXXXXX (Facility and Address)

Packed by: _____

Signature: _____

Picked up by Courier: Date: _____ Time: _____

Quantity of Product Sent: _____

Received by: _____

Signature: _____

Received from Courier: Date _____ Time: _____

Quantity of Product Received: _____

Was there a temp excursion identified? Circle One: YES NO_____N/A

If YES, please explain: _____

PLEASE RETURN THIS COMPLETED FORM TO XXXXX PHARMACY.
Questions call XXXX at XXXXXXX