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 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 medicants are received, inventoried, stored, and dispensed for a clinical trial.

IDS - Investigational Drug Service

Investigational Medications - Drugs specifically designated for use in a clinical trial. Also referred to as study medications.

Satellite Dispensing Area - Also known as a satellite pharmacy or a satellite site, where research medications are received directly from the controlled dispensing area for the purposes of dispensing medications to research subjects at that facility or location. Typically, satellites are not physically adjoined or connected to the controlled dispensing area.
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 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.

D. An established courier service must be utilized to transport medications (whether compounded or bulk) between OHS 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. Example of Chain of Custody Form is attached as Attachment 1.

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 possible 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, an institutional 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 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.

In order to maintain version control, printed copies of operational standards are for reference only. Please refer to OchWeb for the latest version.
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
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X. Approved [REQUIRED]

Deborah Simonson, VP Pharmacy

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

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System P&T Committee Approved
Wednesday, August 19, 2020
OHS.PHARM.OS.053 – Transport of Investigational Medications
Attachment A: Example Chain of Custody Form

IP TRANSPORT
CHAIN OF CUSTODY

Study Protocol Name and Number: XXXXXXXX
Medication Name and Strength and Size/Volume: XXXXXXXXXXXXXXX

Patient Name: ___________________________ MRN: ___________________________

Transported from XXXXXXXXXXXXXXXXXX (Facility and Address) and sent via XXXX Courier Service to XXXXXXXXXXXXX (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
If YES, please explain: ___________________________________________________________________

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

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