Ochsner Health

Operational Standard

SUBJECT:	Disaster Plan for Pharmacy Investigational Drug Services OCHSNER HEALTH Emergency Preparation
ISSUE DATE:	October 2019
EFFECTIVE DATE:	August 27, 2025
RESPONSIBLE DEPARTMENT:	Pharmacy
OPERATIONAL STANDARD NUMBER:	OHS.PHARM.OS.046

I. Purpose

This operational standard addresses investigational (INV) pharmacy staffing and the management of investigational medications during natural disasters such as hurricanes and other events which lead to evacuation periods.

II. Scope

The scope of this operational standard is for all pharmacy-based areas in the Ochsner Health system that maintain investigational medications for clinical trials. This includes designated investigational pharmacies as well as inpatient or infusion pharmacies which store and dispense these products.

III. Definitions

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.

IV. Standard

[This space intentionally left blank]

V. Procedure

A. Within 3-5 calendar days prior to a storm or event becoming an imminent threat to the region:

i. The Director of Pharmacy Investigational Drug Services or designee will meet with investigational pharmacy employees to evaluate staffing needs for upcoming weather event.
ii. The Ochsner clinical trial leadership team or designees will be contacted by investigational pharmacy staff to review and confirm status of anticipated research visits requiring dispensation of investigational drugs for the periods leading up to and following the threat.
iii. Staff cell phone numbers will be reviewed for accuracy.

B. Within 36 hours of the onset of the storm or event, staffing schedules will be confirmed. Hurricane Essential Personnel Assignments will be followed as appropriate, if ordered into effect by Ochsner Leaders.

C. The Director of Pharmacy Investigational Drug Services in conjunction with investigational pharmacy staff and/or a local Pharmacy Leader or designee is responsible for determining a location for investigational drug storage dependent on severity of the threat. More specifically:

i. Within 48-24 hours of a storm or event becoming an imminent threat, investigational pharmacies located on the first floor will move low lying documents such as pharmacy binders as well as supplies and research medications to higher shelving, counter-tops, or other secure area depending on anticipated threat of flooding.
ii. For areas with full back-up generator power (including ambient air and availability of red plugs or equivalent for powering refrigerators and freezers), investigational medications will be kept in their respective pharmacy areas unless otherwise instructed based on severity of the threat. Investigational pharmacy leadership must confirm with local pharmacy leadership that investigational medication storage areas have generator backup or else prepare accordingly.
iii. For areas without any or all back-up generator power, medications may be moved to an alternative, secure, temperature-controlled location such as another pharmacy department. Medications that require transport to another area or to another facility either prior to or following a disaster may be packaged and transferred as outlined in OHS.PHARM.OS.011 Disaster Plan for Medication Inventory Management Ochsner Health Emergency Preparation and/or OHS.PHARM.OS.053 Transport of Investigational Medications.

D. A plan for emergency access to all Investigational Pharmacy areas (such as storage of an extra key in another secure pharmacy-based area) will be coordinated between the Director of Pharmacy Investigational Drug Services and local Pharmacy Leader or designee at all sites where research is conducted. This will be verbally reviewed by May 1 of each year to ensure continued compliance.

E. Should a research subject require medication during or immediately following the weather emergency timeframe, the study sponsor or sponsor representative will be contacted by Ochsner clinical trial leadership team or designee to discuss

either providing additional medication in advance of the event or identifying means for procuring additional research medication(s) not already available on site. Additionally, provisions may be made to have medications shipped to a different location (such as to another medical facility or a patient's home) and will be managed on a case-by-case basis. Decisions will be relayed to the investigational pharmacy staff by the clinical trial leadership team or designee.

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

[This space intentionally left blank]

VIII. References

1. OHS.PHARM.OS.011 Disaster Plan for Medication Inventory Management
2. OHS.PHARM.OS.053 Transport of Investigational Medications
3. Weather Emergency Contingency Plan (Division of Research) July 2025
4. Ochsner Research HRPP Guidance Document Disaster Plan

IX. History

Original Version Effective Date 25 November 2019

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 of Last Review	Notes
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*