STANDARD OPERATING PROCEDURES (SOPs): CLINICAL PHARMACIST STAFF AND PHARMACY RESIDENT TRAINING FOR INVESTIGATIONAL DRUG STUDIES

Policy:

The Investigational Drug Service is responsible for establishing standard procedures for the appropriate control of investigational drugs and biologics used in human subject research.

Procedure:

A. All pharmacists must complete investigational drug services training prior to preparing or dispensing investigational products.

B. General Training for Investigational Drug Studies:

1. All inpatient and oncology pharmacists will receive in-person training on procedures for management of patients on investigational agents
    i. Clinical and operational aspects will be addressed during the training session
2. Training will be documented as part of pharmacist on-boarding and orientation.
    i. Main IDS: via a confirmatory CBL
    ii. Cancer Center IDS: via docusign

C. Protocol-Specific Pharmacy Staff Training for Investigational Drug Studies:

1. Sponsors and the FDA require all pharmacy staff involved in clinical trials to have protocol-specific training.
2. IDS pharmacists will develop pharmacist information sheets for all trials which allow for pharmacists to self-train on individual protocols.
    i. Pharmacist information sheets will be located in the protocol-specific pharmacy binders (Main IDS only) as well as the pharmacy shared network drive.
    ii. Pharmacist information sheets will reflect the current protocol version.
3. For all new inpatient trials, major amendments (i.e. changes that directly affect pharmacy information), and procedural changes, an IDS pharmacist or designee will send an email with study information to inpatient pharmacy staff
    i. Information may include pharmacist information sheet, drug fact sheet, dispensing checklist, or other documents as applicable
    ii. Upon completion of training (by self-training and/or attending a meeting), each pharmacist or IDS technician must sign the Pharmacy Staff Training Log, which will serve as documentation of staff training.

4. Pharmacists are expected to reference the pharmacist information sheet prior to verifying or checking any investigational agents.
    - Adult Oncology Pharmacists sign a docusign attesting they know to check the pharmacist information sheet prior to performing any study related activities.
    - Main IDS Pharmacists will sign a training log in the protocol binder attesting they have reviewed and understand the pharmacist information sheet and the pharmacist checklist prior to dispensing.
5.

D. Pharmacy Residents

1. PGY1 or PGY2 Pharmacy Residents may complete rotations in IDS
2. Under direct supervision from an IDS pharmacist, residents will perform the same roles as an IDS pharmacist, including drug dispensing and accountability
    i. As their duties are performed under supervision of an IDS pharmacist, residents will not be required to sign a protocol's delegation of authority log/

Applicable Regulations & Guidelines:

Joint Commission Standard MM.06.01.05
ASHP *Guidelines on Clinical Drug Research*

Implemented: 11/2015
Revised: 7/2022
Revised: 10/2024

Attachment A

HSR XXXXX (Sponsor name)
Pharmacy Staff Training Log

Date Log Initiated: _____ **Protocol Version:** _____

Prior to preparing drug or verifying final drug product for this study please sign below to indicate that you have reviewed and understand the preparation procedures as outlined in the compounding instructions of the Pharmacist Information Sheet. Thank you.

Date	Printed Name	Signature