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 general IDS and protocol-specific training prior to preparing or dispensing investigational products.

B. New Pharmacist Training for Investigational Drug Studies:

1. All inpatient 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 via a confirmatory CBL that will be assigned by the Coordinator for training.

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 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 study information to inpatient pharmacy staff
    i. Information may include pharmacist information sheet, drug fact sheet, dispensing checklist, or other documents as applicable
4. For adult oncology studies, an IDS pharmacist will attend the oncology pharmacist meeting and provide protocol-specific information necessary to prepare and dispense the study drug(s) in addition to email notification.
    i. For studies in other disciplines, an IDS pharmacist may attend a service-based pharmacy meeting or schedule individual training upon request.

5. 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.

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 but will sign training logs, as necessary.

Applicable Regulations & Guidelines:

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

Implemented: 11/2015
Revised: 7/2022

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