



POLICY AND PROCEDURE

Title: Delegation of Authority/Training	
Policy Number: 3.2	Version Date: 2/01/2023

PURPOSE

To ensure that IDS personnel are appropriately trained in all aspects of investigational drug management which includes receipt, inventory control, dispensing, dose compounding, returned inventory and drug destruction.

IDS PHARMACISTS

IDS pharmacists are responsible for dispensing investigational drugs and correctly dosing study participants enrolled in clinical trials. Pharmacists also oversee technicians' work in drug receipt, inventory maintenance, subject returns processing, IV dose preparation and processing drugs for destruction. Pharmacists are trained on each study initiated in IDS. Training involves a review of the protocol and drug dosing, pharmacy manual, IV drug preparation guidelines, study inventory and storage requirements.

At the beginning of each study, pharmacist training is documented on the Pharmacist Training Log via Docusign. The log is maintained in Vestigo. In addition, IDS pharmacists document retraining on protocol amendments when changes in drug dosing, administration or dose preparation occur. Pharmacists do not document retraining on protocol amendments if the amendment involves administrative changes that do not affect drug dosing or preparation. Pharmacists do retrain and document retraining if a pharmacy-related protocol deviation should occur.

IDS TECHNICIANS

It is the responsibility of the IDS Director to ensure that IDS technicians are appropriately trained in the drug receipt, inventory maintenance, patient returns processing, IV dose preparation and processing drugs for destruction.

DELEGATION OF AUTHORITY

The Director's signature serves as the representative signature for the Investigational Drug Service (IDS) on the delegation of authority log for each study. The Director is responsible for ensuring that IDS staff are trained in the conduct of all IDS studies.

References: 21 CFR 312.53 & .60; FDA Form 1572; Georgia Board of Pharmacy Rules 480-33-03.

Prior Versions: 2/24/2014, 3/24/2017, 1/30/2020, 3/02/2020, 2/01/2022
--