WVU Medicine	Procedure Name	Reporting Pharmacy Investigational Product Errors
	SOP #05	WVU IDS Pharmacy SOP-05
	Date this Version is Effective	01 January 2026
	Responsible for Content	IDS Pharmacy Manager

I. Description

This SOP describes the process of reporting dispensing errors involving investigational product (IP) being utilized within clinical trials.

II. Rationale

Standard procedures for reporting errors involving IP will produce the most efficient process and ensure all stakeholders are identified and alerted in an appropriate manner.

The goal of this SOP is to define the procedure for reporting ~~of~~ study drug errors at the WVUH and associated WVUH clinics.

III. Procedures

1. IP dispensing errors that are identified will immediately be brought to the attention of the study coordinator, principal investigator, and the Investigational Drug Services (IDS) pharmacy team.
2. The dispensing error will also be reported through Origami Risk and the sponsor may be notified.
    a. The IDS Pharmacy Manager and Medication Safety team will review all EMS reports submitted regarding IP dispensing errors.
3. If appropriate, a Note to File (NTF) describing the incident will be prepared and uploaded to Vestigo under the associated clinical trial.
4. Any other study-specific reporting protocols will be followed, and appropriate documentation will be uploaded to Vestigo.
5. The IDS pharmacist will assist in evaluating the impact on the study.

IV. Original Procedure Date and Revisions

16 March 2022, 01 January 2024, 01 January 2025, 01 January 2026