WVUMedicine	Procedure Name	**Reporting Pharmacy Investigational Product Errors**
	SOP #06	**WVU IDS Pharmacy SOP-06**
	Date this Version is Effective	**01 January 2024**
	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 the reporting of study drug errors at the WVUH main campus 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. If appropriate, the dispensing error will also be reported through the health-system Electronic Medical System (EMS) pathway and the sponsor may be notified.
    a. The IDS Pharmacy Manager and Medication Safety Pharmacist will review all EMS reports submitted regarding IP dispensing errors.
3. 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 be consulted to assess the impact on the study.

IV. Original Procedure Date and Revisions

16 March 2022, 01 January 2024