WVU Medicine	Procedure Name	IDS Notification Process
	SOP #02	WVU IDS Pharmacy SOP-02
	Date this Version is Effective	01 January 2026
	Responsible for Content	IDS Pharmacy Manager

I. Description

The Investigational Drug Services (IDS) team is notified in various ways of the initiation of new studies. This SOP describes the expectations for communication to the IDS team for study initiation.

II. Rationale

This SOP clearly outlines the expectations for notification to the IDS team of study initiation.

III. Procedures

A. Notification

The WV Clinical and Translational Science Institute (WV CTSI), WVU Cancer Institute Clinical Research Unit (CRU), or a WVUH research team member will notify an IDS Pharmacy team of the intent to initiate an investigational drug study or clinical trial.

B. Adult Oncology Studies

1. The Disease Team will notify the Investigational Drug Services (IDS) pharmacy team of new study considerations in advance of their scheduled Disease Team meetings.
    a. The Disease Team will provide the IDS pharmacy team with all necessary study documents, including the protocol, pharmacy manual, and Investigational Brochure (IB).
    b. Upon receipt, the IDS pharmacy team will review the protocol and related documents prior to the Disease Team meeting in which the study will be discussed. If the Disease Team approves the study for further consideration, the protocol will then be submitted to the Protocol Review and Monitoring Committee (PRMC) for formal review.

2. In the event the PRMC committee approves said study, the study coordinator is to contact the IDS pharmacy team and provide protocol documents along with the pharmacy manual.

3. Following PRMC approval, the study will submit for Institutional Review Board (IRB) approval to conduct the study at WVUH.

4. Following PRMC and IRB approval, an IDS pharmacist is assigned to be the lead pharmacist on the study and takes over treatment/therapy plan build procedures.

C. Pediatric Oncology Studies

1. IDS will receive notification from CRU representative or WVUMedicine Children's Hospital (CH) Oncology Pharmacist when a pediatric oncology study is approved for subject enrollment at CH.

2. IDS will receive pertinent study documents (Protocol, Investigator Brochure mandatory) from the Pediatric Oncology study coordinator or CRU representative.

3. After document review, IDS pharmacist will submit Epic Request for ERX build via IT Ticket.

4. IDS Pharmacist will share completed ERX details with CH Oncology Pharmacist

5. CH Oncology Pharmacist utilizes ERX to complete treatment/therapy plan build.

D. Non-Oncology Studies

1. The IDS team will be notified by a member of the WVUH research team of potential study initiation once WVUH is being considered as a site for an investigational drug study.

2. If WVUH is selected as a site, and approval is obtained from the IRB, the IDS pharmacy team will be contacted by the study coordinator.

    a Notification of the pharmacy team is documented within the IRB protocol submission questionnaire.

3. A WVUH research team member will provide protocol documents along with the pharmacy manual to the IDS pharmacy team.

4. An IDS pharmacist is assigned as the lead pharmacist on the study and takes over the treatment/therapy plan build process.

E. Supply of Investigational Product (IP)

1. The IDS team must receive IP prior to the scheduling for treatment of patients who are enrolled in clinical trials.

2. It is the responsibility of the study coordinator to make certain the IDS pharmacy team has adequate IP supply on hand prior to subject enrollment.
    a. No trial will begin without an adequate supply of IP at WVU.

3. IP will be stored in accordance with WVU IDS Pharmacy SOP-07.

F. Supply of Standard of Care Medications

1. If non-investigational, FDA approved medications are required per protocol for a study, the IDS pharmacy team will:
    a. Request the study sponsor to supply the required agents, OR

b. Refer to standard of care workflows followed by the health-system to procure, administer, and bill for therapy, OR
c. Collaborate with pharmacy supply chain to obtain medication supply, then submit for reimbursement through the study sponsor.

2. If the sponsor does not supply SOC or commercially available medications, these medications will be managed through the institution's routine pharmacy processes.
    a. IDS will not track lot numbers, expiration dates, or maintain drug accountability records.
    b. The product will not be labeled "For Investigational Use."
    c. Dosing calculations and changes will follow standard pharmacy procedures.

3. If the sponsor reimburses for SOC or commercially available medications but does not require a study-specific supply or additional handling, IDS may determine that these medications will also be managed through routine pharmacy procedures.
    a. IDS will not track lot numbers, expiration dates, or maintain drug accountability records.
    b. The product will not be labeled "For Investigational Use."
    c. Dosing calculations and changes will follow standard pharmacy procedures.

G. Patient Enrollment

1. For any study that requires 24/7 pharmacy coverage, the first subject will be enrolled during the business hours of 0700-1700 Monday through Friday.

IV. Original Procedure Date and Revisions

16 March 2022, 01 January 2024, 02 February 2024, 01 January 2025, 01 January 2026