WVU Medicine	Procedure Name	**IDS Notification Process**
	SOP #03	**WVU IDS Pharmacy SOP-03**
	Date this Version is Effective	**02 February 2024**
	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. Oncology Studies

1. The Protocol Review and Monitoring Committee (PRMC) will notify the IDS team of potential study consideration.
    a) The IDS pharmacy team will review the study protocol prior to the next month's PRMC meeting or will complete an administrative review for fast tracked studies.
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. 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 treatment/therapy plan build process.

D. 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.

E. 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 and bill the study sponsor for acquisition.

F. **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