WVU Medicine	Procedure Name	**IDS Notification Process**
	SOP #03	**WVU IDS Pharmacy SOP-03**
	Date this Version is Effective	**16 March 2022**
	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 WVU Clinical and Translational Science Institute (WVU CTSI), WVU Cancer Institute Clinical Research Unit (CRU), or study coordinator will notify the 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 initiation.
    a) Pharmacy 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 study initiation, the study coordinator is to contact the IDS 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 WVU Medicine.
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 the study coordinator of potential study initiation once WVU Medicine is being considered as a site for an investigational drug study.
2. If WVU Medicine is selected as a site, and approval is obtained from the IRB, the IDS team will be contacted by the study coordinator.
    a) Notification of the pharmacy team is documented within the IRB protocol submission questionnaire.
3. The study coordinator 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 ensure 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 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.

IV. Original Procedure Date and Revisions

16 March 2022