

	Procedure Name	IDS Centralized Operating Model – Centralized Oversight and Monitoring of Satellite Locations
	SOP #01	WVU IDS Pharmacy SOP-01
	Date this Version is Effective	16 March 2022
	Responsible for Content	IDS Pharmacy Manager

I. Description

This SOP describes the WVU Medicine Investigational Drug Services (IDS) model and expectations of centralized services and satellite locations.

II. Rationale

The goal of this SOP is to outline expectations for onboarding, communication, and collaboration between IDS satellite locations and WVU Hospitals.

This SOP also outlines procedures related to satellite site visits by the WVU Hospitals IDS pharmacy team.

III. Procedures

1. Central IDS Definition

- a) IDS Pharmacy team located at WVU Hospitals in Morgantown, West Virginia.

2. Central IDS Procedures

- a) All investigational product (IP) shall be stored and dispensed by the IDS pharmacy team that is centrally located at WVU Hospitals in Morgantown, West Virginia.
- b) The IDS pharmacy team will be responsible for the dispensation of IP to patients enrolled in clinical drug trials.
- c) The IDS pharmacy team will be responsible for packaging, labeling, order review, profile maintenance, and delivery of all IP to satellite locations. The following special requirements exist:
 - i. The IP is dispensed only upon receipt of an order entered into EPIC by an authorized investigator.
 - ii. The prescription label is distinguishable from other labels by the legend, “investigational drug”.
 - iii. The prescription drug label contains the study protocol and subject ID.
 - iv. In circumstances where the IP is required to be compounded and/or manipulated by the satellite, the WVU Hospitals IDS pharmacy team will

provide specific instructions pertaining to how to appropriately prepare the IP prior to administration.

3. Satellite Location Definition

- a) Any clinic or hospital outside of WVU Hospitals.

4. Satellite Opening and Maintenance

- a) Initiation of clinical trials that utilize IP at satellite locations must be approved by the WVU Hospitals IDS Manager.
- b) Satellite locations will follow all WVU Hospitals IDS Policies and Standard Operating Procedures (SOP).
- c) Satellites will be subject to monitoring visits completed by the WVU Hospitals IDS pharmacy staff at least annually.
 - i. Ad hoc visits may be conducted at the discretion of the IDS pharmacy team.
- d) A minimum of one pharmacist at each satellite location will complete the required IDS training detailed in WVU IDS Pharmacy SOP-02.
 - i. A record containing a list of pharmacy employees trained, the trainer, and date of training will be kept at each satellite location (Appendix A) and virtually by the WVU Hospitals IDS pharmacy team.

5. Expectations for Satellite Documentation

- a) Satellite locations will ensure that all accountability logs are up to date in Vestigo for all studies currently in progress at their site. This may be done in collaboration with the WVU Hospitals IDS pharmacy team.
- b) Satellite staff will follow all applicable IDS SOPs.

6. Role in Distributing IP

- a) The satellite location will alert the centralized IDS pharmacy staff of all patients scheduled for the following week no later than 1200 each Thursday.
- b) The satellite location will be responsible for any necessary compounding, dispensing, and administering of the IP following delivery from the WVU Hospitals IDS pharmacy team.
 - i. The satellite location is required to comply with standards set by USP when compounding or manipulating IP.
 - ii. If IP requires compounding or manipulation, and the satellite location does not have an appropriate pharmacy space to perform these tasks, the centralized

location will be responsible for the compounding or manipulation of IP should the study protocol and beyond use dating support this practice.

- c) If the patient cancels or the IP is not administered, the site will return the product to the centralized IDS pharmacy team immediately.

7. Chain of Custody

- a) If the IP final label is placed on the product by WVU Hospitals IDS pharmacy staff and the IP will be sent to another location only for holding and/or administration, a standard chain of custody form will be used to document delivery and receipt of IP.
- b) If the IP is being sent by the WVU Hospitals IDS pharmacy staff and the satellite will prepare and/or label the IP onsite, there will be an additional form sent with the chain of custody document for the satellite location to fill out and return to the centralized team. Documentation in Vestigo will be performed by the WVU Hospitals IDS pharmacy staff.
- c) Satellite staff will retain all completed chain of custody forms for return to the WVU Hospitals IDS pharmacy staff to be uploaded to Vestigo under the corresponding trial.
- d) WVU Hospitals IDS pharmacy staff will close out the transfer and will retain documentation of the transfer.

8. Transfer and Packing of IP

- a) Prior to delivering IP to satellite facilities, IP must be appropriately packaged and validated for delivery by WVU Hospitals IDS pharmacy staff.
- b) IP will be packed according to validated and standardized methods tested by the WVU IDS pharmacy team, ensuring maintenance of appropriate temperatures during the expected transit time as in accordance with WVU IDS Pharmacy SOP-07.
 - i. Temperature during shipment will be continuously monitored.
 - ii. If there was a temperature excursion during the transfer of IP, the IP will be quarantined, and appropriate action will be taken to resolve the excursion.
 - iii. Temperature monitoring logs (Appendix B) from the delivery of IP will be uploaded to the corresponding trial on the Vestigo platform.
- c) Shipment may be transported to satellite locations via pharmacy staff performing other routine deliveries to the satellite location or via courier.

- i. Courier deliveries will either be sent with a designated courier or through a third-party courier partner with an official business relationship with WVU Medicine.

9. IP Preparation at Satellite Locations

- a) Inventory transfer to a satellite location will be processed in Vestigo. The satellite staff will be made aware of an incoming transfer the day of delivery.
- b) When the IP delivery arrives at the satellite, the individual receiving the IP will sign the chain of custody form, and the IP will be unpacked and processed within 30 minutes upon arrival.
- c) IP prepared and labeled by the central IDS team and sent to a satellite will be held at the satellite location in appropriate storage conditions until the time of administration.

10. IP Administration at Satellite Locations

- a) Upon administration of IP at satellite locations, staff at the satellite will confirm they are administering the correct IP to the correct patient by confirming at least two patient identifiers.
- b) Administration of IP will be recorded in the corresponding patient's electronic medical record.
- c) If records of administration are required by a specific trial, the records will be completed and returned to the WVU Hospitals IDS pharmacy staff.
- d) If a medication error relating to an IP were to occur, the WVU Hospitals IDS pharmacy team will be notified immediately and procedures in WVU IDS SOP-06 will be followed.

11. Expectations Surrounding Site Visits

- a) The WVU Medicine IDS pharmacy team and IDS Pharmacy Manager will schedule an initial visit to the satellite prior to opening of their first trial to ensure that the satellite is adequately prepared to support clinical trials.
- b) The WVU Medicine IDS pharmacy team will schedule monitoring visits at the satellite locations at least annually.
- c) Site visits will be scheduled a minimum of two weeks in advance.

- d) Cancelling/rescheduling a visit must be done a minimum of 48 hours prior to the scheduled visit.
- e) Pharmacy technicians or pharmacists are responsible for assisting WVU Hospitals IDS pharmacy team members during the visit.
 - i. If a significant issue is found during the visit, a satellite location pharmacist or principal investigator must be notified prior to the IDS pharmacy team leaving the site.
- f) Satellite location non-compliance will be reported upon no later than 10 business days following the visit. This information will be provided directly to the IDS pharmacy manager and any other relevant parties.
- g) If areas of non-compliance are identified, the site will have 10 business days after receiving the non-compliance report to respond to the identified deviations and make appropriate changes.
- h) The WVU Medicine IDS pharmacy team may schedule a follow-up visit if they see fit.

IV. Original Procedure Date and Revisions

16 March 2022

Appendix A:

WVU Medicine Department of Pharmaceutical Services
Investigational Drug Services Pharmacy Staff Training Log
Satellite Location: _____

[illegible]

Appendix B:

WVU Medicine Department of Pharmaceutical Services

Investigational Drug Transport Log

Name of Receiving Hospital/Clinic: Hospital/Clinic: Institution Phone/Fax:	Contact at Receiving Hospital/Clinic:
Instructions: 1. Use one line for each item dispensed 2. Copy of original log will be transported with records dispensed, filled out completely then returned to WVU Medicine IDS Staff for appropriate record keeping 3. IDS staff member will upload document to Vestigo platform under corresponding trial	Required Temperature (Circle One): <ul style="list-style-type: none"> • Room Temperature (20 °C-25°C) • Refrigerated (2 °C-8°C) • Frozen (< -20°C)

Protocol #		Date/Time Picked Up	
Subject #		Picked Up By	
Date/Time Prepared		Temp. On Departure (C)	
Item Dispensed		Date/Time Arrival	
Quantity Dispensed		Temp. Upon Arrival (C)	
IDS Team Member Dispensing		Received By	