

	Procedure Name	Investigational Drug Services Inventory Transfers to IDS Satellites
	SOP #	IDS SOP-06
	Date this Version Effective	17 Mar 2021
	Responsible for Content	IDS Manager

I. Description

This SOP describes the process and documentation of transfers of investigational product (IP) between Central Investigational Drug Services (IDS) and its satellite locations.

For a discussion of shipping methods and packing procedures, please refer to UNC IDS SOP-07.

II. Rationale

Central IDS will send IP to satellite locations as either prepared and labeled IP or as stock of IP to be prepared and dispensed.

III. Procedures

A. Central IDS

1. Central IDS will be the hub for all IDS activity across the UNC Health Care System. In most cases, shipments of IP will be shipped to and received by Central IDS before being transferred to satellite locations as necessary. Other workflows may be used at the discretion of IDS.
2. If Central IDS is the location where the final label is placed on the product and it will be sent to another location only for holding and pickup, a standard chain of custody form will be used to document delivery and receipt. If Central IDS is sending IP for the satellite to prepare and/or label on site, a send out form will accompany the IP and will also serve as a chain of custody document.
3. Send out of bulk IP will be processed in Vestigo. IP transfer will be confirmed by the receiving location and all documentation will be returned to Central IDS. Documentation in Vestigo will be performed either by the Central IDS staff or by the local pharmacy staff. Central IDS staff will then close out the transfer and retain documentation of the transfer.

B. Central Preparation/Chain of Custody Form

1. When the delivery arrives at the satellite, it will be unpacked and processed in a timely manner.
2. IP prepared and labeled by Central IDS and sent to a satellite will be held at the satellite location in appropriate storage conditions until the time of pickup. At the time of pickup, ancillary staff at the satellite will confirm they are dispensing the correct product using at least two patient identifiers and the individual picking up will fill in the date and time and sign the pickup log.
3. Satellite staff will retain all completed chain of custody forms and pickup logs for return to Central IDS.
4. TempTales, re-usable packing material, and all documentation will be retained and ultimately returned to Central IDS.

IDS Inventory Transfers to IDS Satellites

C. Satellite Dispensing/Send Out Packing Slip

1. Inventory transfer will be processed in Vestigo and the send out packing slip filled out by Central IDS staff. Satellite staff will be notified of an incoming transfer.
2. Upon receipt at the satellite, IP will be unpacked and processed in a timely manner. Receiving staff will complete the send out form and scan and email the form to Central IDS.
3. Stock IP will be held at the satellite location in appropriate storage conditions until the time of preparation.
4. Satellite staff will retain all completed send out forms for return to Central IDS.
5. Satellite staff will follow all applicable SOPs when preparing and dispensing IP.
6. Satellite staff or the IDS contact person requiring assistance or backup preparing or documenting the preparation of IP may contact the lead pharmacist for the applicable protocol or they may reach out to the IDS on-call pharmacist.

D. Procedure for Misplaced or Damaged IP

1. Central IDS will lead investigations into any IP that has been misplaced or damaged. Satellite staff will respond quickly and professionally to Central IDS staff through the process of investigation.

E. Procedure for Protocol Deviations

1. If it is determined that transfer processes result in a protocol deviation, the IDS manager will lead an investigation of circumstances that led to the deviation and will work to correct the deviation.
2. Central IDS staff and ancillary staff at the relevant satellite location will assist the IDS manager as necessary at the discretion of the IDS manager.

IV. Original Procedure Date and Revisions

18 Feb 2019, 28 Jul 2020, 04 Dec 2020 – DRAFTS

17 Mar 2021 – SOP Live