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|  | Procedure Name | Investigational Drug Services Shipping and Packaging |
| | SOP # | IDS SOP-07 |
| | Date this Version Effective | 17 Mar 2021 |
| | Responsible for Content | IDS System Manager |

I. Description

This SOP describes the process and documentation of shipping and packaging of investigational product (IP) to satellite locations of the Central IDS and any required return of IP from satellites to Central IDS.

For more information on the transfer of IP between pharmacy sites and associated documentation, see UNC IDS SOP-06

II. Rationale

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

III. Procedures

A. Transfer of IP

1. Prior to any packaging and shipping activities, bulk IP transfers must be appropriately transferred to the receiving location via processes outlined in UNC IDS SOP-06.

B. Packing of IP

1. IP will be packed according to validated and standardized methods tested by IDS to maintain appropriate temperatures during the expected transit time.
2. All packages will be prepared and documented according to current IDS policy and standard work.

C. Shipping and Transport of IP

1. For transport to IDS satellites, shipment may be transported via pharmacy staff performing other routine deliveries to the satellite location, via courier, or via traditional shipping methods.
2. Courier deliveries will be sent either with the Central IDS staff courier or through a third party courier partner with an official business relationship and contract with UNC Health Care.
3. Shipments sent via traditional shipping partners (FedEx, UPS, etc.) will be sent same day or overnight. Traditional shipping will be used only when other avenues are unavailable.

D. Temperature Monitoring and Receipt of Product

1. Temperature during shipment will be monitored.
2. The receiving site will receive the shipment according to IDS policy and standard work.
3. If the transfer experienced a temperature excursion, product will be quarantined. Appropriate action will be taken to resolve the excursion.

IV. Original Procedure Date and Revisions

08 July 2019 – DRAFT

17 Mar 2021 – SOP Live