

	Procedure Name	<b>Investigational Drug Services Satellite Locations</b>
	SOP #	<b>UNC IDS SOP-03</b>
	Date this Version Effective	<b>01 Jul 2020</b>
	Responsible for Content	<b>IDS Manager</b>

## I. Description

This SOP describes the process and expectations of coordination and communication of IDS practice by satellite locations under the oversight of Central IDS. Also described are expectations of ancillary staff as well as research staffs at locations with a satellite of IDS.

## II. Rationale

The successful extension of high quality IDS practice from Central IDS to satellite locations will take careful coordination and communication.

## III. Procedures

### A. Establishing a Satellite IDS

1. The establishment of a satellite of Central IDS will be coordinated under the supervision and discretion of the IDS manager.
2. Requests for research activity involving the dispensing or holding for pickup of investigational medication at a UNC Health Care pharmacy location will trigger the evaluation of that site by Central IDS for potential status as a satellite location.
3. Timing for site visits and the initiation of IDS activity at the satellite will be coordinated between the pharmacy leadership at the site, the IDS manager, and any applicable research staff requesting to perform medication-related research. If the potential satellite location does not have embedded pharmacy staff and leadership, the IDS manager will work in coordination with the local and system level pharmacy leadership to determine the appropriateness of Central IDS support and create a plan for providing the appropriate level of oversight and services.
4. Satellite IDS locations must be able to satisfy all regulatory, process, storage, and service demands required of IDS practice. For further details on the establishment of satellites and ongoing oversight by Central IDS, see UNC IDS SOP-02.

### B. Satellite Master Records

1. Each satellite will be required to maintain a master signature log with printed name, signature, start date, end date, and initials.
  - a. All staff at the satellite who may perform activities for the dispensation of investigational medications must be included on the log.
  - b. Initials used for checking finished product should be the initials recorded on the signature log.
  - c. Date should be listed as the start date for the individual signing the log or the date of satellite IDS location establishment, whichever is later.
  - d. End date should be the date of termination of the employment of the ancillary staff member.

## Satellite Locations

2. The site master signature log will serve as the master delegation of authority log for that satellite.
3. All site-specific master records will be maintained by the IDS primary pharmacist under the guidance of Central IDS.

### **C. Expectations of Research Staff Working with Satellites of IDS**

1. Research staff (PIs, coordinators, research nurses, etc.) are expected to follow the same policies and procedures when interacting with satellite IDS locations as they would be when interacting with the Central IDS.
2. For more detail on these expected activities, please refer to UNC IDS SOP-13.

## **IV. Original Procedure Date and Revisions**

26 May 2020 – DRAFT

01 Jul 2020 - Live