UNC HEALTH	Procedure Name	**Investigational Drug Services Centralized Oversight and Auditing**
	SOP #	**IDS SOP-02**
	Date this Version Effective	**01 Jul 2020**
	Responsible for Content	**IDS Manager**

I. Description

This SOP describes the control processes undertaken by Central IDS to ensure that IDS satellite locations perform IDS operations according to established workflows and SOPs. Also included are processes for initial evaluation of a satellite location, periodic oversight, auditing processes by Central IDS, and ongoing training requirements of IDS satellite staff.

II. Rationale

Central IDS has to ensure standardized practice and a high level of service from satellite locations.

III. Procedure

A. Satellite Workflow and SOP Alignment

1. All satellite locations of Central IDS will follow workflows and UNC IDS SOPs as established unless exceptions are approved at the discretion of the IDS manager.

B. Evaluation of Potential Satellites

1. Potential satellites will be visited by a representative of the Central IDS team. At the visit, the representative will evaluate the site using the Evaluation Form for New Investigational Drug Services Satellite Locations. Please see attachment A (Section V.A) to see an example of the form.
2. Based on the findings of this assessment, a determination will be made by the representative and/or the IDS manager to approve the site or to recommend any necessary changes before the site can be a satellite of the Central IDS.
3. If the site is approved as a future satellite of Central IDS, then a pharmacist at the site will be identified by the local manager as the IDS primary pharmacist.

C. Training of Satellite Staff before Go-Live of Satellite

1. The IDS primary pharmacist will complete human subjects protection and good clinical practice trainings through the Collaborative Institutional Training Initiative website (citiprogram.org).
2. Ancillary staff at each satellite location will be trained by Central IDS staff or the IDS primary pharmacist at the applicable satellite. Ancillary staff will be trained on processes applicable to the protocols active at their practice site under the direction of Central IDS staff.
3. For further details on IDS training practices, see UNC IDS SOP-04.

D. Periodic Central IDS Oversight and Auditing

1. Each satellite will be assigned a pharmacist from Central IDS to be the liaison pharmacist to the satellite. This liaison will be the primary point of contact from the satellite to Central IDS. The research pharmacy activity at the satellite is performed under the oversight of the Central IDS liaison for the given satellite.

2. After the satellite has been in operation for a period of time, a representative of Central IDS will audit the practices of the satellite to determine if any changes or re-education are required.
3. The time between audits will vary depending on the complexity of the site and the volume of IDS operations. Audits may happen every three, six, 12 months, or any other frequency to be determined by the IDS manager.
4. As part of the audit, the representative will assess the need for any re-training or emphasis of policy and procedure with ancillary staff and the IDS primary pharmacist.

E. Ongoing Training of Satellite Staff

1. The IDS primary pharmacist at the satellite will maintain human subjects protection and good clinical practice trainings through CITI by re-certifying as dictated by IDS policy or local institutional policy, whichever requires more frequent recertification.
2. Ancillary staff and the IDS primary pharmacist will have just-in-time training at the point of dispense by reviewing the protocol information sheet and/or dispensing summary prior to any dispensing of investigational product. The act of checking and initialing a completed dispense will serve as an attestation of just-in-time training and that the product checked matches the specifications outlined in the information sheet and/or dispensing summary.
3. The liaison pharmacist (or other Central IDS staff) will assess the need for training of ancillary personnel or IDS primary pharmacists when new studies are to begin at the satellite. Needed trainings will be performed either by Central IDS staff or the IDS primary pharmacist for the satellite.

F. Monitor or Sponsor Representative Visits

1. All in-person monitors/visitors should expect to visit IDS at the Central IDS location except in cases where study drug is stored at the satellite. In those cases, the monitors/visitors should visit the satellite only for drug accountability activities and such visits will be time limited.
2. Because all documents for studies (outside of some legacy studies) are maintained electronically, there should be no need for an in-person visit to review only documents. These documents will be made available electronically. For more information on document maintenance and handling, see UNC IDS SOP-10.

IV. Original Procedure Date and Revisions

18 Feb 2019, 06 Mar 2019, 04 Sept 2019, 26 May 2020 – DRAFTS

01 Jul 2020 - Live

V. Attachments

A. Evaluation Form for New Investigational Drug Services Satellite Locations

Questions	Check appropriate column		If answered "No": • Explain discrepancy & action take to correct discrepancy • Use back of this form for additional comments
A. Storage/Facility:	**Yes**	**No**	
1. Investigational product (IP) must be separated from regular inventory. Satellite leadership has a plan for segregation of IP in both room temperature and refrigerated storage.			
2. Temperature monitoring of IP is required for all storage locations and conditions. Satellite leadership and the identified IDS primary pharmacist have access to temperature data and have a plan for continual monitoring of storage conditions. Temperature logs are maintained and retrievable.			
3. Segregated storage will be required for all patient returns. Satellite leadership has a plan for segregation of patient returns of IP until the returns may be sent to Central IDS for processing.			
4. Documentation is paramount in IDS. Any and all documentation related to IDS activity must be retained. Satellite leadership have a plan for the retention and storage of documentation prior to transmission of documentation to Central IDS according to applicable SOPs and standard work documents.			
5. Satellite facility has acceptable label printers for the purpose of producing patient labels for dispensing.			
B. Training of Staff:			
1. An IDS primary pharmacist on staff at the satellite pharmacy has been identified and they have consented to fill this role.			
2. The IDS primary pharmacist has documented their role on the site signature log and will maintain the site signature log.			
3. The IDS primary pharmacist has completed or has plans to complete Human Subjects Research and Good Clinical Practice trainings through the Collaborative Institutional Training Initiative (CITI) at citiprogram.org.			
4. The IDS primary pharmacist has completed the OnCore access request form or has plans to complete this form to request OnCore access. (If OnCore access is required)			

Questions	Check appropriate column		If answered "No": • Explain discrepancy & action take to correct discrepancy • Use back of this form for additional comments
B. Training of Staff (con't):	**Yes**	**No**	
5. The identified IDS primary pharmacist has or will be granted access to Vestigo.			
6. IDS primary pharmacist has been provided IDS SOPs and has plans to review them and ask for any needed clarifications.			
7. Satellite leadership, in cooperation with the IDS system clinical manager, has a plan to train satellite staff to follow all applicable SOPs including but not limited to, receipt of IP, transfer of IP, returns, documentation retention practices, receipt of patient returns, and sending these returns to Central IDS for processing and destruction. Training will be documented according to applicable IDS SOPs.			
C. Study Teams and Coordination:			
1. Study coordinators will be present to facilitate the research activity and progression of patients through their care on applicable research protocols			
2. Research and study teams have committed to work with satellite staff to replicate best practices established by other research groups already serviced by Central IDS and to follow all applicable IDS SOPs.			

Evaluator Name: _____ **Evaluation Date:** _____ **Clinic/Site:** _____

Evaluator Signature: _____ **Date:** _____