UNC HEALTH	Procedure Name	**Investigational Drug Services Roles and Responsibilities**
	SOP #1	**UNC IDS SOP-01**
	Date this Version Effective	**01 Jul 2020**
	Responsible for Content	**IDS Manager**

I. Description

This SOP describes the roles and responsibilities of Central IDS and IDS Satellite pharmacy staffs.

II. Rationale

Clear lines of process and workflow delineation will produce the most efficient practice and foster patient safety.

The goal of this SOP is to define what is in-scope and out-of-scope for UNC Investigational Drug Services (IDS).

III. Procedures

A. IDS Responsibilities

1. IDS will ensure that for all investigational product (IP) the receipt, accountability, disposition, and all record keeping complies with FDA and institutional guidelines and regulations. Please see UNC IDS SOP-05 and UNC IDS SOP-10 for additional details.
2. Record keeping may be either in paper or electronic form at the discretion of IDS.
3. IDS cannot be responsible for IP (including tracking lot numbers or temperature conditions) not under the control of IDS.

B. Temperature Monitoring

1. All locations where IP is stored will be monitored continuously for temperature.
2. Temperature data will be made available to monitors during monitor visits and can also be requested if needed. IDS will not, however, send temperature data to sponsors, monitors, or study teams on a routine frequency.
3. Please see UNC IDS SOP-05 for additional details.

C. Storage of IP

1. All IP will be stored in a secured manner with controlled access. IP will be separated from general stock and clearly labeled as IP with associated protocol numbers and/or IDS numbers.
2. Only staff who may need access to investigational medications will have sufficient permissions to access IP.
3. IDS will have established procedures to ensure proper storage conditions and security of IP is maintained in an emergency such as a power outage.
4. IDS will not accept storage devices or long-term temperature monitoring equipment from sponsors.
5. Please see UNC IDS SOP-05 for additional details, particularly IP accountability processes.

D. Dispensing of IP

1. Per Joint Commission Medication Management standard MM.06.01.05, the pharmacy "controls the storage, dispensing, labeling, and distribution of investigational medications." Per UNC Health policy, IDS is the pharmacy entity responsible for investigational medications.
2. Order entry is not considered to be part of the dispensing workflow and will not be performed by IDS.
    a. For studies that require medication administration in healthcare settings, Epic (the EMR utilized by UNC Health) orders are required and orders must be signed by an authorized prescriber on the study. For more detail on authorized prescribers, please see UNC IDS SOP-14.
    b. Epic orders must be entered by the study team.
    c. Verbal orders will not be considered valid orders.
    d. Paper orders may not be filled out by IDS on behalf of the study team.
    e. Partially completed orders will not be considered valid orders.
    f. Orders with inaccurate information will not be considered valid orders.
    g. IDS will not prepare dispenses in advance of receiving a valid order.
3. IP may not be dispensed to study teams in advance of the date of patient visit unless arranged for in protocol startup and the study team must demonstrate to the satisfaction of IDS that they are able to store, secure, and monitor medications to the same standards as IDS.
4. For further details on the expectations of sponsors and study teams, please see UNC IDS SOP-13.

E. Labeling of IP for Dispensation

1. All IP will be properly labeled according to institutional policy, guidance from the North Carolina Board of Pharmacy, code of federal regulations, and pharmacy best practice standards.

F. Interactive Response Technology (IRT)

1. IDS staff will perform those trainings in IRT systems deemed relevant by the lead pharmacist for the given protocol and for pharmacy activity and roles. Additional trainings beyond what is relevant for pharmacy practice may be performed by IDS staff if approved at the discretion of the IDS manager and for an additional fee.
2. For further details on IRT training, please see UNC IDS SOP-04.
3. IDS staff will confirm the receipt of shipments in IRT systems as applicable and if agreed upon during study startup.
4. IDS staff will notify sponsors immediately if shipments have experienced temperature excursions. If notification, data upload, or email of temperature data is requested for shipments that do not experience temperature excursions, IDS must be notified of this request prior to the receipt of any shipment.
5. IDS will not document data in IRT beyond what is described here or what is agreed upon during study startup at the discretion of the IDS manager (see also section J below regarding EDC).

G. Online Study Management Systems

1. IDS will not perform trainings for online study management systems.

2. IDS staff will not enter data or upload documents into online study management systems.

H. Delegation of Authority (DOA) Logs

1. All IDS staff will be sufficiently trained to perform their delegated and designated functions. For more detail on staff training, please see UNC IDS SOP-04.
2. IDS will maintain a master DOA for every location where research dispensing is performed. All full-time IDS staff and all primary pharmacists at IDS satellites will be listed on the DOA. Ancillary staff will not be listed on the DOA as they are considered to be practicing under the supervision and authority of the lead and/or primary pharmacist.

   NOTE: Ancillary staff can include pharmacists, pharmacy technicians, pharmacy residents, and pharmacy interns.

3. On study-specific DOAs, the IDS manager will sign on behalf of the group. 'UNC IDS' or 'IDS' will be listed on the DOA, followed by the IDS manager's signature. The IDS manager may also designate other IDS staff members to have the authority to sign study-specific DOAs on his/her behalf.
4. Satellites of IDS will maintain staff signature logs listing the name, signature, initials, start date, and end date of all staff. Signature logs will be created annually.

I. Sponsor-Provided Forms or Data Capture Systems

1. IDS will not document data on sponsor-provided forms or data capture systems unless the sponsor form/system includes data that IDS forms/systems do not and this data is critical for the protocol. In these cases, IDS may use the sponsor-provided form/system or may modify existing IDS forms/systems to incorporate the extra data.

J. Electronic Data Capture (EDC)

1. IDS will not document data in EDC systems when these data are already captured by IDS. IDS will provide data to the research teams, monitors, or sponsors in a reasonable form and timeframe as determined by IDS.
2. If IDS is not capturing data in normal IDS workflows and these data are critical for the protocol, IDS may document the data in EDC or may modify existing IDS data capture to incorporate the capture of the data in normal IDS workflows.

K. Exemption Requests for UNC IDS SOPs

1. The study sponsor will be provided all live UNC IDS SOPs only once at the time of study initiation or if an update to the UNC IDS SOPs occurs.
2. Sponsors are expected to document and acknowledge receipt of UNC IDS SOPs, including a list of the UNC IDS SOPs they received. IDS will provide a form for this purpose. For additional details regarding sponsor expectations reference UNC IDS SOP-13.
3. If select UNC IDS SOPs or portions of UNC IDS SOPs are deemed unacceptable by the sponsor there will be a process for the sponsor to request an exemption. IDS will provide a form for exemption requests. Please refer to UNC IDS SOP-13 for details of this process.

IV. Original Procedure Date and Revisions

03 Dec 2018, 15 May 2019, 04 Sept 2019, 29 Jan 2020, 25 Mar 2020, 26 May 2020, 05 Jun 2020 – DRAFTS

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