UNC HEALTH	Procedure Name	**Sponsor and Study Team Expectations**
	SOP #13	**IDS SOP-13**
	Date this Version Effective	**01 Jul 2020**
	Responsible for Content	**IDS Manager**

I. Description

This SOP describes the expectations IDS has for the study team and sponsors.

II. Rationale

To clearly outline roles and expectations for collaboration and communication between study sponsors, study teams, and IDS staff.

III. Procedure

A. Documentation

1. The electronic accountability system will be utilized for documentation storage and maintenance. Study sponsors and monitors may view study-related documents electronically after requesting system access from IDS. IDS staff can be contacted to provide extended access to protocol information/documents.
2. All records will be kept patient-specific, though IDS may keep aggregate records in certain circumstances at the discretion of IDS.
3. For more information on the electronic accountability system and document handling and storage practices, please see UNC IDS SOP-10.
4. The monitor or study team shall ensure IDS has the most updated version of all study documents, particularly the pharmacy manual.

B. Supply of Investigational Product (IP)

1. IDS expects to receive study IP prior to trial opening. If IP supply cannot be shipped prior to trial opening, the study team must coordinate with IDS prior to proceeding with trial opening. If the sponsor is controlling IP re-supply, it is the sponsor's responsibility to ensure IDS has adequate supply on hand.
2. IDS will not accept IP that is improperly labeled.
    a. Proper labeling will include at least the following:
        i. IP name
        ii. IP amount/strength
        iii. Protocol number or identifier
        iv. Expiration or retest date
        v. Kit number (if applicable)
        vi. Lot number
    b. If blinded, 'IP name' may be 'active OR placebo'

c. Expiration or retest date is preferred to be on the label affixed directly to the IP, but if not included on the IP label, it is acceptable for this data to be on the shipping documentation or other documentation supplied with the IP.

d. If improperly labeled IP or containers are delivered to IDS it will be the responsibility of the sponsor/monitor to appropriately re-label IP prior to use or to send replacement IP to IDS.

e. If re-labeling of IP is required after it's been received by IDS, monitors or other sponsor representative will be expected come to UNC and re-label product, rather than IDS re-labeling IP. If this is not possible for the monitor or sponsor representative, please contact the IDS manager and IDS may perform this activity for a fee.

3. Study sponsor will send updated expiration dates or re-test dates to IDS in a timely manner. If not received in a timely manner, IP may be quarantined and may not be available to patients. For more detail on inventory management, including processes for expiring medications, please see UNC IDS SOP-05.
4. IDS will be provided all relevant study documents and supplies.
5. IP assignments from IRT that are provided to IDS will be provided in original documentation and be sent to IDS through a secure fax or email system or be delivered in person. If IP is assigned through IRT, please note that preparation of IP will not begin until this documentation has been provided.

C. Sponsor Attestation to Follow 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 receipt of UNC IDS SOPs, including a list of the UNC IDS SOPs they received. Sponsors are also expected to attest that they will adhere to UNC IDS SOPs. IDS will provide a form for this purpose.
3. If IDS receives no requests for exemptions (see below) of UNC IDS SOPs or portions of UNC IDS SOPs, the sponsor will be noted as having approved, accepted, and will abide by UNC IDS SOPs.
4. If the study has no study sponsor, then the study team will be held to the same expectations as a study sponsor outlined in this section.

D. Exemption Requests for UNC IDS SOPs

1. 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.
2. Requests for exemptions should only be made when patient safety, research integrity, or IP integrity will be compromised by adhering to UNC IDS SOPs.
3. Communication regarding UNC IDS SOP exemptions will occur directly with the appropriate sponsor contact and not only with third parties (CROs, external monitors, etc.). IDS can request supporting documentation including but not limited to assay data, stability tests, sponsor SOPs, or ICH/GCP guidance as justification for the exemption request.
4. Exemption requests must be made as soon as possible and at least two months prior to patient enrollment.

5. Requesting an exemption does not guarantee approval.
    a. Exemptions may be reviewed and approved or denied by pharmacy and/or hospital leadership. This process may take up to 12 weeks.
    b. IDS will review all requests and will work with sponsor personnel to reach a mutually agreeable resolution. The PI or study team may be consulted to aid in determining a resolution.
6. Exemption requests may incur additional fees not included in the initial budget. All exemption-related budget adjustments must be addressed and completed prior to study opening.

E. Study Opening

1. IDS expects local study teams to appropriately use the Clinical Research Management System (CRMS) for appropriate communication and notification of research to IDS
    a. A request for IDS services should be submitted to IDS well in advance of study opening. We recommend doing so *at least* two months before you wish to open a study.
    b. Once submitted, IDS will acknowledge the request for services and will confirm that we are willing to work with the study team to carry out the research at UNC. This document can be used for the IRB application.
    c. Once a study team knows that a study will move forward and wishes IDS to assign a pharmacist to the protocol to begin the work of setting up the study in IDS, they should request a pharmacist assignment through CRMS. This is the trigger to IDS that we should begin the work of setting up the protocol. After a pharmacist is requested, IDS takes 4 – 6 weeks (longer for particularly complex protocols) to complete the process and be ready for patient enrollment.
2. At the time of qualification visit or site initiation visit, IDS expects sponsor representatives or monitors to be available for answering IDS questions.
3. If the monitor cannot address a question or issue, they are expected to acquire needed information and respond to IDS in a timely manner. Failure to respond may result in IDS escalating the question or issue further and/or delays in opening the study.
4. Contact information for an alternate responsible person and immediate supervisor for the study monitor shall be available to IDS prior to study initiation.
5. IDS will be notified in a timely manner regarding changes to study personnel.
6. Local study teams are expected to assist in communication with the sponsor and any monitors that will evaluate UNC IDS.

F. Ordering Dispensation of Investigational Medication

1. IDS requests advance notice of upcoming patient visits requiring dispensation of investigational medication. Method of advance notification will vary by site and circumstances, but all stated processes and turnaround times assume that advance notice of at least two business days (preferably three business days) is given.
2. All orders must be signed by an authorized prescriber on the study. Please see UNC IDS SOP-14 for more detail on authorized prescribers.

3. Provision of a paper original prescription may be accepted if electronic orders are not possible or used for the applicable protocol. If electronic order entry is available, paper orders will not be accepted.
4. For protocols requiring clearance for treatment orders, these must be released prior to dispensing. Patients must be cleared for treatment by a member of the study team who is documented to have performed the appropriate training for the study.

G. Monitor Site Visit

1. To schedule a monitor visit, please call IDS. For monitor visits in the North Carolina Cancer Hospital, please email nconcologyids@unchealth.unc.edu
2. Monitors should bring copies of, or have readily accessible, all communication from Vestigo or IDS to facilitate efficient access.
3. Monitor site visits should be scheduled at least two weeks in advance. Pharmacy monitoring visits are scheduled separately from appointment the monitor has with the study team. If the study requires an immediate visit after the initial patient is enrolled this two week notice may be waived. The monitor is expected to let IDS know as early in advance as possible for these visits.
4. Cancelling or rescheduling a visit should be done with at least 48-hours' notice and is done at the discretion of the IDS staff.
5. Monitor visits are time limited and monitors may not stay beyond the scheduled end time for their visit.
6. Monitors shall respect the schedule of other study monitors and IDS staff and arrive on time for their visit. If a monitor is running late for a scheduled appointment then the monitor shall inform IDS of this via phone or email. The visit time will be limited to the time slot that was scheduled. If more time is needed, then another visit will need to be scheduled.
7. Space will be provided by IDS for the monitor to work during their visit. This space is limited. The monitor is expected to bring their own laptop to the visit. It is also recommended that monitors test their access to Vestigo prior to the visit. IDS will not be responsible for time lost working through access issues.
8. Paper copies of electronic records will not be provided.
9. Monitors will be assisted by technicians during the visit, a pharmacist may or may not be available for any questions or issues. If a significant issue arises during a monitor visit, a pharmacist must be notified prior to the monitor leaving the pharmacy.
10. If the monitor needs to view IP, they will be accompanied by the IDS personnel or satellite pharmacy staff.
11. When entering sterile or hazardous areas (IV rooms) the monitor will be required to don appropriate personal protective equipment. IDS personnel will be available to assist with this as needed. Entry to sterile or hazardous areas will only be permitted based upon demonstrated need.
12. The monitor may be exposed to hazardous drug during the monitor visit, the monitor will be expected to comply with institutional policies around hazardous drug handling.
13. The monitor may not remove documents from the study binder or study folder other than to make a photocopy.

14. The monitor assumes the responsibility for de-identifying patient information as necessary.
15. Monitor noncompliance may be reported to the monitor's manager or study personnel. Continued failure to comply with requirements may result in the monitor not being allowed to visit IDS in the future.
16. IDS will not store or maintain copies of regulatory items maintained in the study team's regulatory binders.
17. Prior to departure from IDS, the monitor is expected to provide notice of any findings or concerns to IDS staff. Every effort should be made to rectify issues prior to the end of the visit.
18. The monitor is expected to review relevant items in the electronic accountability system and mark any drug, patient returns, or any other relevant item as reviewed, attested to, and/or authorized for further processing.
19. After the site visit, the monitor is expected to provide IDS with a monitoring report that includes a summary of items reviewed and the monitor's statements concerning significant findings/facts, deviations and deficiencies, conclusions, actions to be taken, and actions recommended to secure compliance. IDS will address findings, deviations, and deficiencies presented by the monitor.
20. Corrective action plans will be documented and filed appropriately.
21. IDS shall be notified in a timely manner by the sponsor, the outgoing monitor, or the study team when a change in monitor occurs.
22. Current monitors will file documents so that they will be available to future monitors. All documents provided to the previous monitor will be passed to the new monitor. IDS expects that sufficient handoff occurs between the outgoing monitor and the incoming monitor such that all agreed upon procedures will continue and will not require review or revision. IDS expects the new monitor to be up to date on the protocol and past events on the protocol with IDS such that IDS will not be required to re-educate new monitors. Requests for records previously provided may incur an extra charge, refer to UNC IDS SOP-17. Requests for documents after the close out visit is complete may incur an extra charge, refer to UNC IDS SOP-17

IV. Original Procedure Date and Revisions

26 May 2020, 05 Jun 2020 – DRAFTS

01 Jul 2020 - Live