Pre-Site / Site Initiation Visit Packet
Investigational Drug Services Pharmacy

Updated 25 February 2021

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Introduction

The Investigational Drug Services Pharmacy at UNC Health Care (IDS) is located on the ground floor of Neurosciences, near the elevators, and on third floor of the main hospital (Memorial Hospital).

Business Hours are **Monday through Friday, 7:30am – 4:00pm.**
IDS has a weekly meeting on **Thursdays, 2:30pm – 3:15pm**. We ask that, as possible, coordinators and research staff avoid contacting or visiting IDS during these hours.
We are closed all major holidays.
A pharmacist is on call 24 hours a day, 7 days a week, and 365 days a year.

Controlled access to IDS is granted by approved ID badge only. In case of an emergency, hospital police have access to the pharmacies.

All studies involving products that require sterile compounding and are not chemotherapy are prepared on the 3rd floor of Memorial Hospital, in the 3-West (3W) location or in the UNC Hospitals Central Inpatient Pharmacy. All chemotherapy, both oral and IV preparations, are prepared on the 3rd floor of the North Carolina Cancer Hospital (NCCH). Studies that do not require sterile compounding and are not chemotherapy are dispensed out of the ground floor Neurosciences Hospital location (NS IDS).

IDS requires all documentation from the sponsor to be supplied only in electronic format.

IDS has an onsite destruction policy for both hazardous and non-hazardous drugs.

IDS receives and processes all investigational products in either 3W IDS or NCCH.

Shipping Address:

Investigational Drug Services
University of North Carolina Hospitals
Room N3122 3rd floor Connector Link
101 Manning Drive
Chapel Hill, NC 27514

***** Please address shipments to the lead pharmacist or IDS manager *****
***** Do not address shipments to the Investigator *****

The phone and fax numbers for our two locations are as follows:

NS IDS	3W IDS
Phone: 984-974-3777	Phone: 984-974-0469
Fax: 984-974-3471	Fax: 984-974-6359

If information is required for cancer or chemotherapy studies, please contact IDS to request specific information.

Staff Information

Pharmacist Names, E-mail Addresses:

- William Yun Zhao, PharmD, PhD — Yun.Zhao@unchealth.unc.edu
- Maria Bullis, PharmD — Maria.Bullis@unchealth.unc.edu
- Jennifer Thompson, PharmD — Jennifer.Thompson3@unchealth.unc.edu
- Holly Milner, PharmD, BCPS, BCCCP — Holly.Milner@unchealth.unc.edu
- Sarah Law, PharmD — Sarah.Law@unchealth.unc.edu
- Kristen Gray, PharmD — Kristen.Gray2@unchealth.unc.edu
- Jola Mehmeti, PharmD, MBA — Jola.Mehmeti@unchealth.unc.edu
- Ashley Khan, PharmD — Ashely.Khan@unchealth.unc.edu
- Andrew Thorne, PharmD, MS (Manager) — Andrew.Thorne@unchealth.unc.edu

Technician Names, E-mail addresses:

- Pam Jones, CPhT — Pamela.Jones@unchealth.unc.edu
- Frederick Asamoah, CPhT — Frederick.Asamoah@unchealth.unc.edu
- Marcia Gibson, CPhT — Marcia.Gibson@unchealth.unc.edu
- Caressa Goss, CPhT — Caressa.Goss@unchealth.unc.edu
- Daniel Galeana, CPhT — Daniel.Galeana@unchealth.unc.edu
- Josh Lee, CPhT — Joshua.Lee@unchelath.unc.edu

Equipment Information

IDS locations have room temperature drug storage, refrigerator storage, a -20° C freezer and -80° C freezer. All storage conditions are continuously monitored for temperature. Measurements are permanently documented every 15 minutes.

If any storage condition experiences an out of range temperature, the IDS on call pharmacist will be paged and will respond appropriately. The hospital engineering department will also respond to the alarm. All refrigerators and freezers are supplied with backup electricity via generators in the event of a power failure.

Investigational Drug Services System Policy

Current Status: *Active* **PolicyStat ID:** *8345022*

Origination:	*07/2017*
Effective:	*07/2020*
Last Approved:	*07/2020*
Last Revised:	*07/2020*
Next Review:	*07/2023*
Owner:	*Gregory Heindel: Pharmacist, Coordinator*
Policy Area:	*Compliance - Research*
Policy Tag Groups:	
Applicability:	*UNC Health Care System (all owned and managed entities)*

Investigational Drug Services

APPLICABILITY:

This policy applies to the following entities (collectively referred to as "UNC Health" in this policy):

✓	UNC Health Care System/UNC Medical Center*	✓	Johnston Health
✓	UNC Physicians Network	✓	Lenoir Memorial Hospital
✓	UNC Physicians Network Group Practices	✓	Margaret R. Pardee Memorial Hospital
✓	Rex Healthcare / Rex Hospital	✓	Nash Healthcare System / Nash Hospitals
✓	Chatham Hospital	✓	Wayne Memorial Hospital
✓	Caldwell Memorial Hospital		
✓	UNC Rockingham Health Care / UNC Rockingham Hospital		

***UNC Medical Center includes all UNC Hospitals' facilities and the clinical patient care programs of the School of Medicine of UNC-Chapel Hill (including UNC Faculty Physicians).**

I. Description

Describes the manner in which Investigational Drug Services are conducted at UNC Health. As used in this policy, the term "UNC Health" encompasses UNC Health and Network Entities designated above, including hospitals and physician groups.

II. Rationale

The purpose of this Investigational Drug Services policy is to ensure investigational drug research is conducted in accordance with applicable federal, state, accrediting agencies (e.g., The Joint Commission) regulatory requirements, and in alignment with sponsoring agencies.

III. Definitions

A. **Accountability Records**: Documentation for material accountability, quantity control, and date of

disposal or return of investigational product

B. **ACTG**: AIDS Clinical Trial Group

C. **Clinical Trial**: Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamics effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy

D. **Electronic Accountability System**: Computer-based software system for the management of investigational drugs

E. **FDA**: Food and Drug Administration

F. **Good Clinical Practice (GCP)**: A standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials or studies

G. **Institution of Origin**: Institution dispensing or transferring IP

H. **Investigational Medication**: Any investigational product which is a drug/medication/supplement and which is being studied for safety or efficacy, whether or not it has previously received FDA-approval for use in humans

I. **Investigational Product (IP)**: For the purposes of this policy, IP is equivalent to 'investigational medication'

J. **IRB (Institutional Review Board)**: An independent group of professionals designated to review and approve research protocols, informed consent documents, study advertisements, and patient brochures, to ensure that the research is safe, effective, and ethical for human participation; It is also the responsibility of the IRB to ensure that the research adheres to all applicable regulations

K. **Medical Monitor**: A physician or group of physicians who are responsible for medical and safety oversight of a clinical trial

L. **Principal Investigator**: Person ultimately responsible for the conduct of a clinical trial

M. **Protocol**: Plan for clinical trial, which can be supported by supplemental documents with a more specific area of focus

N. **Protocol Monitor (Monitor)**: Person acting as an agent of sponsor who oversees the progress of a clinical trial, and ensures that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), GCP, and the applicable regulatory requirements

O. **Offsite Location**: Sites within UNC Health or affiliates that are participating in a clinical trial and are not considered the primary site

P. **IDS Satellite (Satellite)**: A pharmacy area other than the Investigational Drug Services Pharmacy responsible for the preparation and dispensing of investigational product

Q. **Study Coordinator (Coordinator)**: Individual(s) acting as a liaison between investigators, primary care providers, the Institutional Review Board (IRB), and the sponsor of a clinical trial

R. **Study Sponsor (Sponsor)**: Individual, company, institution or organization responsible for the initiation, management and/or financing of research

S. **Study Subject**: A participant in a study

T. **Study Team**: A group of individuals including, but not limited to, the Principal Investigator, Sub-

Investigator(s), Research Manager, Research Nurse(s)/Study Coordinator(s), Study Pharmacist(s), Data Manager(s), and support staff responsible for conducting a clinical trial

IV. Policy

A. **General Use of Investigational Drugs**

1. UNC Health Investigational Drug Services (IDS) provides mechanisms for the acquisition, storage, preparation, distribution, disposal and control of investigational product (IP) for clinical trials with human subjects conducted at the UNC Health. These mechanisms are in accordance with the policies and procedures established for all UNC Health entities.
2. All investigational drugs and protocols must be approved for use by the UNC Health IRB, or other approved IRB, unless meeting the criteria for emergency use below.
3. IDS oversees pharmacy research activities and controls the storage, dispensing, labeling and distribution of all investigational medications.
4. IDS may receive investigational medications redistribute them to other satellite pharmacy locations for preparation and dispensing.
    a. IDS is responsible for all investigational medications received.
    b. IDS supplies the IDS satellites with information required to appropriately prepare and dispense the agents.
    c. Inventories of IP may or may not be split between IDS and the satellite. This will be dependent upon the protocol and/or patient location within UNC Health.
    d. IDS satellites follow all protocols specific to drug accountability, preparation and dispensing procedures as outlined this policy and any current UNC IDS SOPs.
5. IDS maintains a standard operating procedure (SOP) manual that supports this policy and expands upon the specifics addressed here.
6. UNC investigators and their study teams, as well as the sponsors they work with, follow procedures outlined in these SOPs. IDS may grant exceptions, within reason, if required.

B. **Emergency Use of Investigational Drugs**

1. Emergency use of investigational medications must utilize IDS
2. Emergency use of an investigational medication must have an approved IND through the FDA.
3. Emergency use of an investigational medication may be exempt from FDA requirements for IRB review provided that such emergency use is reported to the IRB within 5 working days.
4. Investigational medications are dispensed by IDS or satellites to patients upon the order of an authorized prescriber who has previously obtained informed consent from involved patients or patient representative.
5. In emergency situations, dispensing of IP may not be dependent on obtaining informed consent. However, a "Waiver of Consent" procedure must be followed in accordance with guidelines from the FDA and the IRB.
6. The IRB is responsible for monitoring compliance by the physicians with these established procedures and for initiating any appropriate action related to noncompliance.

C. **Confidentiality of Information Related To Clinical Trials**

1. Pharmacists, upon request, release information relating to IP and clinical trials to providers responsible for the care of study patients, as required to safeguard the health and welfare of patients.
    a. Pharmacists refer requests for information from others to the principal investigator or co-investigator.
2. Information is only released in compliance with applicable HIPPA rules and regulations to providers directly responsible for the patient.
3. Unblinding of treatment assignments only occurs with authorization of the principal investigator, or medical monitor, unless otherwise stated in the study protocol.
4. Any questionable release of information is reviewed with the principal investigator to determine the appropriateness of the release of information and reported to the appropriate Compliance Officer.

D. **Scope of Investigational Drug Services**

1. IDS provides services related to the procurement of investigational product, managing the randomization, inventory and dispensing of investigational products for investigators conducting clinical trials. For more detail regarding the activities of IDS, refer to the UNC IDS SOP manual.
2. The provision of these services for clinical trials is integrated with established pharmacy services to the extent that it is possible.
3. An IDS pharmacist coordinates the provision of services for clinical trials and IDS maintains oversight of all research-related dispensing of IP.

E. **Fee Schedule**

1. All activities of IDS are billed for directly and study teams engaged with IDS for the management of clinical trials are expected to pay invoices within 45 days of issuance.
    a. IDS follows up with the designated billing contact if the invoice is unpaid at 60 days.
    b. IDS issues a past due letter requesting payment to the principle investigator and any applicable business administrator if the invoice is unpaid at 90 days.
    c. IDS discontinues services after an ongoing lack of payment.
2. IDS fees are determined according to the most up-to-date fee schedule at the time of assignment of an IDS pharmacist to the clinical trial
3. IDS maintains a fee schedule and fee estimation tool that is made available to all study teams.
4. Upon assignment to a pharmacist, that pharmacist reviews the clinical trial in depth and finalizes the billing amounts.
    a. If these amounts do not match with what was estimated at the time of clinical trial submission to IDS, then IDS notifies the study team of the change in billing amount.

F. **Investigational Drug Services Records**

1. IDS prepares and maintains study records for each clinical trial requiring pharmacy services,
2. Electronic documentation of IDS activities initiated within UNC Health may be used for, but not limited to, inventory management, dispensing, and monitor visit support, provided that:
    a. The electronic documentation system meets compliance standards for HIPAA and the Code of Federal Regulations 21 Part 11.

b. All users have a unique username and password, which are not shared or used as group accounts.

c. Original copies of paper records are maintained in addition to electronic files, unless the electronic files are certified copies, as defined in CFR.

3. Sponsor-provided documents that are otherwise available as templates in the electronic documentation system are not used unless approved by an IDS manager or designee.

4. At the close of a study, protocol records are stored by the Department of Pharmacy for each institution and maintained for a minimum of 15 years or longer as mandated by Federal and/or International Regulations.

5. Archived paper documents can be recalled from long-term storage.

   a. Requests for archived paper documentation must be received at least 10 business days in advance of the expected delivery date.

6. For more detail regarding documentation and the retention of study records, see UNC IDS SOP manual.

G. **Procurement and Storage of Investigational product**

1. IDS may procure and/or store IP for specific protocols as outlined in the protocol itself or via special arrangements with the principal investigator.

2. IP may not be stored outside of IDS or an approved IDS satellite location without IDS evaluating and approving the proposed storage outside of IDS.

3. Procurement:

   a. IDS is capable of procuring medications and supplies through the UNC Health supply chain.

      i. If this is required for a clinical trial, IDS is notified at the time of study start-up and the procurement is determined at the discretion of IDS.

   b. IDS is not responsible for procuring supplies that are specially required for a clinical trial and are not part of the typical supplies used in pharmacy settings at UNC Health.

   c. For Compassionate Use Protocols (Expanded Access), the physician or primary investigator contacts the sponsor and arranges for shipment of IP. Treatment of patients on these protocols is on a patient-specific basis with the initial shipment of IP for each patient always being initiated by the physician.

   d. IDS staff or ancillary staff at an IDS satellite may receive IP.

   e. If any deviations exist between shipping records and IP received, they are reconciled with the study team and/or study sponsor at the time of receipt or within a reasonable time frame.

4. Storage

   a. IDS maintains control of the storage, dispensing, labeling, and distribution of all IP at UNC Health in compliance with The Joint Commission standards.

   b. IP is stored in a secure manner, separate from regular inventory.

   c. If the IP is a controlled substance, IDS stores the IP in a manner consistent with applicable laws and regulations pertaining to controlled substances.

   d. IDS maintains a perpetual inventory of all IP stored in the Pharmacy.

e. IDS only dispenses IP pursuant to a valid and complete order from an authorized prescriber on the clinical trial.

f. IDS continuously monitors the temperature and storage conditions of IP and maintains all temperature data indefinitely.

g. Further information regarding the storage and dispensing of IP can be found in the UNC IDS SOP manual.

H. **Medication Orders and Dispensing of Investigational product**

1. All medication order forms or electronic heath record order builds are validated by the primary investigator prior to enrollment of any patient.
2. Changes to therapies, including dose changes, require new orders.
3. Refills are not allowed for investigational medications.
4. Orders and dispensing activities are recorded and documented in either paper or electronic logs.
5. IP is clearly labeled "For Investigational Use". All other labeling is compliant with applicable guidance and requirements from the NC Board of Pharmacy.
6. IDS does not dispense via procedures that are not in compliance with pharmacy best practices and applicable guidance and requirements from the NC Board of Pharmacy.

I. **Transportation of Investigational product**

1. Transportation of IP
   a. IP are transported in accordance with state and federal laws as well as the most up-to-date procedures found in the UNC IDS SOP Manual.
   b. Couriers utilized for IP transport between the institution of origin and off site location engage with IDS through a contractual business relationship and provide proof, upon request, of compliance with all applicable laws and regulations regarding the handling of medications.
   c. IP are labeled as investigational medication.
   d. IP classified as "hazardous" are transported according to institutional hazardous handling policies.
   e. Upon arrival of IP at the receiving location, staff immediately open and move IP to a secure, temperature monitored area.
2. Documentation of Transportation
   a. If at any time the integrity of the IP cannot be assured, it is immediately quarantined and the study sponsor or investigator is contacted for further action.
   b. Documentation of transport is completed according to the procedures outlined in the most up-to-date UNC IDS SOP Manual.

J. **Study Closure, Investigational Product Returns, and Disposal**

1. Study teams must request IDS services be terminated.
2. IP inventories, including patient returns, must be zero at the close of a study.
3. Study records are dispositioned as described above and in accordance with the UNC IDS SOP Manual.
4. Upon completion or termination of a study protocol, both used and unused, IP and associated

supplies are returned or destroyed as described in the UNC IDS SOP Manual.

5. Controlled substances are be returned to the sponsor or destroyed according regulatory requirements.
6. All records of returns and destruction are maintained by IDS in accordance with applicable state and federal regulations.
    a. Requests for archived documentation must be received at least 10 business days in advance of the expected delivery date.

V. References

A. 21CFR Part 50 – Protection of Human Subjects
B. 21CFR Part 56 – Institutional Review Boards
C. 21CFR Part 201 – Drug Labeling
D. 21CFR Part 312 – Investigational New Drug Applications
E. 21 NCAC 46 Section 1412 – Physical Requirements
F. 21 USC Title 21 Chapter 13 – Drug Abuse Prevention and Control
G. ICH GCP Consolidated Guideline—Part 4.6 Investigational Product(s)
H. Research Billing Compliance – Investigational Products Policy
I. The Joint Commission Standards for Medication Management

VI. Related Policies

A. Research Billing Compliance: Investigational Products Policy

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
	Benjamin Daniels: HCS-VP Pharmacy	07/2020
SYSTEM Site Administrator	Emilie Hendee: HCS Attorney Sr	07/2020
	Gregory Heindel: Pharmacist	07/2020

Applicability

Caldwell Memorial Hospital, Chatham Hospital, Johnston Health, Nash UNC Health Care, Pardee Hospital, UNC Health Care System, UNC Lenoir Health Care, UNC Medical Center, UNC Physicians Network, UNC Rex

Healthcare, UNC Rockingham Health Care, Wayne Memorial Hospital

UNC Health Care IDS Electronic Records Memo

January 2, 2018

To Whom It May Concern:

UNC investigational Drug Services (IDS) will institute the use of electronic study records in Vestigo™ for all new trials beginning February 1, 2018. Vestigo™ is a web-based software system designed especially for accountability of investigational drugs, and is able to electronically store all of the documents that are needed for an electronic study record.

IDS requires all study documents in electronic format so they can be uploaded to Vestigo™ and/or the IDS shared drive and stored as electronic study records. All paper documents will be scanned and stored as an electronic document in Vestigo™. Once the scanned document is validated by at least two IDS personnel to have been stored appropriately, the paper document will be discarded.

All study documents provided by the sponsor such as protocols, investigator brochures, pharmacy manuals, and IRT instructions will be saved as electronic documents and the paper copies will be shredded on site. We will not keep paper copies of any sponsor documents that are saved electronically.

Monitors and study staff will be given access to Vestigo™ to view all of the needed documents at monitoring visits.

Please bring any issues or concerns to our attention prior to opening the study.

Thank you very much,
Sue Pope, RPh
Manager of Investigational Drug Services

UNC Health Care Vestigo Expectations for Monitors Memo

Investigational Drug Services
UNC Health Care

Apr 19, 2019

To Whom It May Concern:

UNC Investigational Drug Services exclusively uses Vestigo logs on all trials. Sponsor logs will not be used. Vestigo is a computerized inventory system designed especially for investigational drugs, which is able to electronically capture accountability for the investigational agent and the subject dispensations and returns. Vestigo Verify is a read-only portal for monitor use to view data in the Vestigo database.

All records related to investigational agent accountability, single subject accountability, multiple subject accountability, and return and destruction accountability will be kept in Vestigo and is viewable by monitors through the Vestigo Verify portal. Monitors are required to use Vestigo Verify to authorize destruction or return to sponsor of applicable patient returns, quarantined IP, and direct product returns from inventory to the sponsor in Vestigo at the time of monitor visits. IDS will not accept sponsor-provided forms documenting the above listed items. Additionally, because the authorization by the monitor is user-specific and equivalent to an electronic signature, IDS cannot input the monitor authorization on behalf of the monitor.

If you require information that is not included in the Vestigo logs please bring it to our attention and we may be able to have a Vestigo log customized to obtain the required information.

Please address any concerns with this policy to me in advance of your visit.

Thank you very much,

Andrew Thorne

Andrew Thorne, PharmD, MS
System Clinical Manager, Investigational Drug Services
UNC Health Care
Chapel Hill, NC 27514

UNC IDS Delegation of Authority Memo

Investigational Drug Services
Note to File

Date:	30 Jul 2020
To:	UNC Research Community and Associated Sponsors/Partners
From:	UNC Investigational Drug Services (IDS)
Re:	UNC IDS Delegation of Authority and Master Signature Log

To Whom It May Concern:

UNC Investigational Drug Services (IDS) has updated our approach to delegation of authority (DOA) and signature logs. IDS will maintain a master DOA and signature log and the IDS manager or delegate will sign the study-specific DOA as 'IDS'. This will refer to the master DOA.

Additional details are outlined in UNC IDS SOP-01. Please refer to this SOP for details.

Andrew Thorne, PharmD, MS

UNC Investigational Drug Services, System Clinical Manager
UNC Health
Andrew.Thorne@unchealth.unc.edu

Monitor Visit Communication

PLEASE NOTE: During the COVID-19 pandemic, monitor visits are being restricted due to the difficulty of distancing in the pharmacy space. Please contact UNC IDS at UNCIDS@unchealth.unc.edu to get updates on the latest monitoring guidelines. The following may or may not be accurate.

PLEASE NOTE: Monitor visits to the pharmacy are available by appointment only. The following document outlines the process for scheduling and flow for the monitor's visit.

Making an appointment:

1. The sponsor monitor should contact their designated UNC Clinical Research Associate (CRA) or Study Coordinator at UNC or Lineberger to let them know they will be scheduling a monitoring appointment with IDS.
2. Then the UNC CRA/Study Coordinator or the sponsor monitor should **call the IDS pharmacy,** to request a Monitor Appointment (see page 9).
3. New sponsor monitors will be emailed a temporary Vestigo™ login/password to access documents prior to site visit (see Day of Visit below).

Table 1. Available Appointments and Locations*

Location	Days	Time Slots
NeuroScience (NS)	Monday – Thursday	8:30 AM – 12:00 PM
		1:00 PM – 3:30 PM
3-West (3W)	Monday – Thursday	8:00 AM – 9:30 AM
		1:00 PM – 3:30 PM

* Variations in allotted time will be accommodated as necessary when notified at point of scheduling for closeouts and audits.

Day of Visit:

1. The monitor will only have access to the IDS pharmacy during their designated appointment time.
2. The monitor is given temporary Vestigo™ access on the day of visit. The monitor needs an appointment with IDS pharmacy to be given temporary access to Vestigo™, even if they are off-site and do not plan to come to the IDS pharmacy.
3. Vestigo™ will send an email to *new* monitors with the details of their access. Otherwise monitors will log into https://unc.vestigo.biz and use their current Vestigo™ password. The monitor will need to view and print relevant documents or records in a location separate from the IDS pharmacy. Alternatively, they can save documents as .pdf files to print later.
4. If the sponsor has issues with Vestigo™, they should contact the company directly. Contact information for Vestigo™ is in the email sent along with their temporary password.
5. In the unlikely event that Vestigo™ is experiencing downtime during the monitor's visit, the pharmacy will send the monitor the Drug Accountability Record Forms (DARFs) and shipping documents when the system is available.

Monitor Visit Request

For a monitoring appointment, please call the Pharmacy where your drug is stored and have information below available:

For oral or prepackaged products call Neuroscience IDS: 984-974-3777
For IV products call 3-West IDS Pharmacy: 984-974-0469

Monitor Contact Information Needed when Scheduling:

Monitor Name:_____
Monitor Email: _____
Monitor Phone #: _____
Company Monitor Associated with:_____
All Studies Monitored:_____
***** It is very helpful if you know UNC's 4-digit IDS number *****

Visit Request:

4-Digit IDS Number:_____
Type of Visit: Monitoring, Close-out, or Audit
Date:_____
Time: _____
***** Please note available times for scheduling on previous page (Table 1) as they are different depending on the location you will be visiting: *****

Training Process

Training

1. IDS personnel are trained on each new study that opens by the pharmacist of record that prepared the study for dispensing.

2. Many protocols request IDS staff to perform online training sessions. Designated pharmacists will be responsible to do these training sessions during their office time as time permits and only if other training avenues are not available.

3. Per UNC IDS SOPs, some online trainings will be performed and others will not be performed by IDS. Please refer to UNC IDS SOP-04 for further guidance. Note: in an effort to keep this packet relatively brief, all SOPs are not included but can be provided upon request. If the Training SOP does not clarify training policies pertinent to a given study, please ask the lead pharmacist or the IDS system manager.

4. All IDS staff will document their training.

5. All IDS personnel are currently trained in Good Clinical Practice (GCP) and Human Subject Protection (HSP) training. These trainings are repeated every 3 years through CITI. Certificates can be produced upon request.

6. Amendments and Investigator Brochures that do not impact the pharmacy will be stored with other study documents, **but no training will be documented.**

7. In the event of a 24 hour study that requires the support of our Sterile Products Area (SPA), the pharmacist that receives the information regarding an after hour subject dispensing will pass on this information to the SPA pharmacist. Study documents, including the information sheet, will be available to the SPA pharmacist.

8. If there are questions after hours, an IDS pharmacist is on call 24 hours a day, 365 days a year at pager number: 919-216-9727.