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

Updated 17 July 2020

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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: 984-074-3471	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:

- Andrew Thorne, PharmD, MS — Andrew.Thorne@unchealth.unc.edu
- 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
- Kristen Gray, PharmD — Kristen.Gray2@unchealth.unc.edu
- Sarah Law, PharmD — Sarah.Law@unchealth.unc.edu
- Holly Milner, PharmD — Holly.Milner@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:** *4667820*

Origination:	*07/2017*
Effective:	*07/2017*
Last Approved:	*07/2017*
Last Revised:	*07/2017*
Next Review:	*06/2020*
Owner:	*Gregory Heindel: Pharmacist*
Policy Area:	*Compliance - Research*
Policy Tag Groups:	
Applicability:	*UNCHCS - All except Rockingham*

Investigational Drug Services

APPLICABILITY:

This policy applies to the following entities (collectively referred to as "UNC Health Care System" or "UNCHCS" 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 Care. As used in this policy, the term "UNC Health Care" encompasses UNCHCS and all UNCHCS Network Entities, 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. Joint Commission) regulatory requirements, and in alignment with sponsoring agencies.

III. Definitions

A. ***Accountability Records:*** Required documentation for material accountability, quantity control, and date of disposal or return of clinical trial material.

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 or products, and/or to identify any adverse reactions to an investigational product or products, and/or to study absorption, distribution, metabolism, and excretion of an investigation product or products with the object of ascertaining its safety and/or efficacy.

D. ***Clinical Trial Material (CTM):*** A drug, biological, or medical supply item which may be approved or unapproved by the FDA for use under protocol for human research

E. ***Electronic Documentation System:*** Computer based software system for the management of investigational drugs

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

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

H. ***Investigational Drug:*** Any drug which has not received FDA approval for use in humans

I. ***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

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

K. ***NCI:*** National Cancer Institute

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

M. ***Protocol:*** Plan for scientific experiment

N. ***Protocol 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 UNCHCS or affiliates that are participating in a clinical trial and are not considered the primary site

P. ***Satellite:*** A pharmacy area other than the Investigational Drug Services Pharmacy responsible for the preparation and dispensing of clinical trial material

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

S. ***Study Team:*** A group of individuals including 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 Care System Investigational Drug Services provide mechanisms for the acquisition,

storage, preparation, distribution, disposal and control of clinical trials materials (CTM) for clinical trials with human subjects conducted at the University of North Carolina Healthcare System. These mechanisms are in accordance with the policies and procedures established for all UNCHCS entities.

2. All investigational drugs and protocols must be approved for use by the UNCHCS IRB, or other approved IRB, unless meeting the criteria for emergency use below.
3. Per The Joint Commission Medication Management Standard MM.06.01.05, the pharmacy must control the storage, dispensing, labeling and distribution of all investigational medications
4. Investigational agents may be received by Investigational Drug Services pharmacies and redistributed to other pharmacy satellite areas for preparation and dispensing.
    a. The IDS pharmacy will be responsible for supplying the pharmacy satellite areas with information required to prepare and dispense the agents appropriately.
    b. Inventories of agents may or may not be split between the Investigational Drug Services Pharmacy and the satellite area. This will be dependent upon the protocol and/or patient location within UNCHCS.
    c. The Investigational Drug Service is responsible for all investigational agents received.
    d. Satellite dispensing areas must follow all protocol specific drug accountability, preparation and dispensing procedures as outlined in the Protocol Summary Sheet found in the study record.

B. **Emergency Use of Investigational Drugs**

1. Emergency use of investigational drugs must utilize IDS pharmacies at UNCHCS
2. Emergency use of an investigational drug must have an approved IND through the FDA.
3. Emergency use of an investigational drug or biologic product may be exempt from FDA requirements for IRB review provided that such emergency use is reported to the IRB within 5 working days.
4. The attending physician documents in the patient's medical record the emergency nature of the situation.
5. Study medications are dispensed by UNCHCS IDS to patients upon the request of an authorized prescriber who has previously obtained informed consent from involved patients or patient representative.
6. In emergency situations, dispensing of CTM 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.
7. Subsequent use of the investigational drug (i.e., in another patient) should not occur unless the process as outlined in this policy has been followed and the protocol and informed consent form have been approved by the IRB. However, subsequent emergency use in another patient should not be withheld pending IRB approval.
8. 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 Drug Studies**

1. Pharmacists, upon request, will release to providers responsible for the care of study protocol patients, information relating to investigational drugs and clinical trials as required to safeguard the health and welfare of patients. Requests from others for information relating to clinical trials deemed

confidential will be referred to the principal investigator or co-investigator.

2. Information will only be released to providers directly responsible for the patient and all applicable HIPAA rules and regulations will be observed.
3. Unblinding of treatment assignments will occur with authorization of the principal investigator, or medical monitor, unless otherwise stated in the study protocol.
4. Any questionable release of information will be 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 and Fee Schedule**

1. The UNCHCS IDS provides services related to the procurement of clinical trial materials, managing the randomization, inventory and dispensing of clinical trial materials for investigators conducting clinical trials.
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 is responsible for coordinating the provision of services for clinical trials.
4. IDS fees will be determined as follows:
   a. A principal investigator or designee will submit a request for Investigational Drug Services with a copy of the protocol, and a completed "Protocol Intensity Worksheet" (see attachments) which has been scored using the study protocol.
   b. IDS charges are assigned according to the total points calculated from the Intensity Worksheet which will be used to create a budget for the pharmacy services related to the trial. Budgets are forwarded to the principal investigator.
   c. The IDS will receive both a one-time start-up fee and an ongoing monthly fee are for each protocol. The cost of drugs required by the study, and not provided by the sponsor, are calculated into the total cost of the pharmacy fees for the study budget.
   d. A signed copy of the budget must be received by the IDS before initiating any protocol activities; if the signed copy of the IDS budget is not returned to IDS, IDS is authorized to bill for its services based on the submitted Protocol Intensity Worksheet as-is.
   e. The IDS Pharmacy Manager or designee is responsible for maintaining billing information and generating a protocol specific statement of charges on a monthly basis.
   f. Upon receipt of an invoice, the investigator must submit payment within 90 days, after which a past due letter requesting payment is sent to the principal investigator. The business administrator is copied if appropriate.
   g. Ongoing lack of payment will result in the discontinuation of services.Services will be billed in accordance with the system policy, "Research Billing Compliance – Investigational Products."

E. **Investigational Drug Service Study Records**

1. The IDS will prepare and maintain study records for each IRB approved clinical trial requiring pharmacy services, which contain detailed instructions on how to dispense clinical trial material (CTM).
2. Electronic documentation of IDS activities initiated within UNC Health Care 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 will have a unique username and password. The use of shared or common accounts is not allowed.

c. Original copies of paper records are maintained in addition to electronic files.

3. Study Sponsor created documents that are otherwise available as templates in the electronic documentation system will not be used unless approved by an IDS Pharmacy Manager or designee.

4. A study record contains the following items which are described in detail in the IDS SOP Manual (see attachments):

a. A Protocol Information Sheet

b. Patient List

c. Randomization Tables or List (if needed)

d. An inventory and dispensing record for each CTM to be dispensed in the protocol

e. Individual Patient Dispensing Records (if needed)

f. Pharmacy Personnel Signature and Training List

g. A copy of any templated orders or prescriptions that have been created for the protocol

h. A Monitoring Visit Record

i. A copy of the most up to date version of the study protocol

j. A list of authorized prescribers or copy of FDA 1572 form

k. Other records as required by the sponsor of the study

5. At the close of a study, protocol records will be 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.

6. All paper documents will be placed in an expandable folder, labeled, and archived with long term records at off-site storage facilities. Material will be retrievable upon request within a reasonable amount of time and no later than 10 business days.

7. Electronic records for closed studies will be stored in the electronic documentation system as a closed protocol.

F. **Procurement and Storage of Clinical Trial Material**

1. Once the Institutional Review Board (IRB) has approved a protocol, and all legal requirements are fulfilled, the Investigational Drug Service (IDS) will be responsible for procuring and storing Clinical Trial Materials (CTM) for specific protocols as outlined in the protocol itself or by special arrangement with the principal investigator.

2. Procurement:

a. IDS will be responsible for the procurement of CTM for all protocols following procedures set forth in the specific protocols. The only exception is a Compassionate Use protocol (see 2.d. below).

b. The principal investigator or his/her designee will supply the pharmacy with all documents necessary for ordering initial and subsequent shipments of CTM. All CTM will be shipped to the

most appropriate location within the pharmacy department.

c. Special formulation supplies, non-formulary and formulary commercially available drugs (not considered standard of care) for specific studies will be obtained and billed to the study and invoiced through normal billing procedures.

d. For Compassionate Use Protocols (Expanded Access), it is the responsibility of the physician to contact the sponsor and arrange for shipment of CTM. Treatment of patients on these protocols is on a patient-specific basis with the initial shipment of CTM for each patient always being initiated by the physician.

e. A trained IDS pharmacy staff member may accept the delivery of CTM. CTM accepted by a non-IDS pharmacy staff member will be placed in the designated storage areas (refrigerated and non-refrigerated) for subsequent receipt by an IDS staff member.

f. If any deviations exist between shipping records and CTM received, they will be reconciled with the study team and/or study sponsor

3. Storage

a. The Department of Pharmacy Investigational Drug Service shall maintain control of the storage, dispensing, labeling and distribution of all CTM at UNC Health Care.

b. CTM will be stored in a secure location separate from regular medication inventory and with limited access to authorized personnel.

c. If the CTM is a controlled substance, the investigator shall take adequate precautions, including storage of the CTM in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited to authorized personnel, to prevent theft or diversion of the substance into illegal channels of distribution.

d. The IDS Pharmacy will maintain a perpetual inventory of all CTM stored in the Pharmacy.

e. CTM should be stored in a secure area according to local regulations. It is the responsibility of the investigator to ensure that CTM is only dispensed to study subjects. CTM must be dispensed only from official study sites by authorized personnel according to local regulations.

f. The IDS will ensure that CTM is stored in accordance with the environmental conditions (temperature, light, and humidity) as determined by the sponsor. Additional detail regarding cold chain integrity and temperature deviations is outlined in the IDS SOP Manual.

g. The IDS pharmacy staff will reconcile the CTM logs to the physical inventory. The pharmacist will attempt to reconcile any differences. If the discrepancy is not readily resolved, the pharmacist will document findings and provide the principal investigator and study sponsor with a report describing the details of the discrepancy and an action plan per the IDS SOP Manual.

h. Any freezers, refrigerators, and rooms utilized to store CTM will be monitored for temperature and humidity (when applicable). Monitoring will occur continuously 24 hours a day, 7 days a week.

G. **Medication Orders and Dispensing of Clinical Trial Material**

1. Medication orders for CTM entered into the Electronic Health Record (EHR) will be ordered using pre built templates designed in collaboration with IDS staff and the EHR build team prior to activation of the study.

2. If paper orders are used they will be designed as pre built templates by IDS staff and approved by

the Principal Investigator.

3. If a paper order is used, an original order must be presented to the IDS staff at each dispensing. Authorized prescribers must be listed on the FDA 1572 form for both paper and electronic orders.
4. A new order must be received with any dosage or therapy changes.
5. Once a medication order is received either electronically or on paper, the dispensing pharmacist will review the "Protocol Information Sheet" for the specific protocol they are dispensing.
6. The pharmacist will screen the medication order for completeness as detailed in the IDS SOP Manual.
7. Protocol specific inventory and dispensing records are completed each time a dose is dispensed or wasted to account for the distribution of each unit of a CTM dispensed by the pharmacy. These records may be either paper logs or electronic.
8. Subject order records will be maintained in protocol specific records such as folders, or notebooks, or electronic file.
9. CTM is clearly labeled "For Investigational Use", with the identity of the protocol being followed, the patient ID number or code, and customary labeling instructions for distribution to patients according to the institution.

H. **Transportation of Clinical Trial Material**

1. Transportation of CTM
   a. Transportation will be in accordance with state and federal laws, as well as any requirements of the study sponsor regarding storage.
   b. The transportation of CTM between locations must remain within the immediate control of the institution of origin (see definitions above).
   c. CTM ready to be transported from the institution of origin to an off-site location will remain in a secure area within designated storage conditions until the time of delivery or pick-up.
   d. Couriers utilized for CTM transport between the institution of origin and off site location will provide proof of documented training annually on the appropriate policies and procedures for CTM transport, handling of hazardous materials, and oncologic/cytotoxic exposure.
   e. Shipping carriers (e.g. UPS, FedEx and US Postal Service) cannot be utilized for transport of CTM unless authorized by the sponsor and evaluated on a case by case basis to ensure all applicable federal, state and local regulations are followed.
   f. CTM will be packed and secured in a rigid container to prevent damage to the product. The package will be labeled as containing investigational clinical trial materials.
      i. Room temperature drugs will be transported in an insulated container.
      ii. Refrigerated drugs will be transported in an insulted container labeled "Refrigerate" with the appropriate cool packs to ensure product stability consistent with study protocol.
      iii. Drugs will be transported with a temperature monitoring device as specified by the sponsor.
      iv. Temperature monitoring is not required for subject returns to the originating IDS pharmacy.
   g. CTM classified as "hazardous" will be transported according to institutional hazardous handling policies.

h. Upon arrival of CTM at the receiving location, staff will immediately open and move CTM to a secure, temperature monitored area, consistent with the study protocol.

2. Documentation of Transportation
   a. Written approval for transporting CTM will be obtained from the sponsor prior to dispensing.
   b. If at any time the integrity of the CTM cannot be assured, it should be immediately quarantined and returned to the institution of origin and the study sponsor or investigator should be contacted for further action.
   c. The "Investigational Drug Transport Log" (see attachment) must be completed immediately upon receipt of CTM at the offsite location.
   d. Investigational Drug Transport Log records will be study specific and maintained with study records per the IDS SOP Manual.

I. **Study Closure, Clinical Trial Material Returns and Disposal**

1. IDS services are terminated when the study coordinator provides the IDS notification of study closure.
2. The IDS will account for final CTM inventories with the protocol monitor. All CTM inventories must be zero at the close of a study.
3. All study records are dispositioned as described above in Section E. Investigational Drug Service Study Records.
4. Upon completion or termination of a study protocol, both used and unused, CTM and associated supplies shall be returned to the sponsor, if not authorized by the sponsor to be disposed of by the pharmacy department, per institutional policy and in accordance with regulatory agencies.
5. Controlled drugs must be returned to the sponsor or destroyed according regulatory requirements and study protocol.
6. The protocol monitor shall be responsible for coordinating the return of any CTM within 30 calendar days upon request by pharmacy, and complete removal within 90 days of initial contact. For any studies not utilizing a protocol monitor, returns and requests for disposal of CTM will be the responsibility of the pharmacy department.
7. All used and/or partially used CTM, including subject returns, returned to the pharmacy department shall be securely stored in a manner that segregates them from drugs to be dispensed, until disposal authorization is obtained.
8. All used, partially used, or unused CTM (including associated supplies) identified as hazardous will be disposed of safely by the pharmacy department at the site per institutional policy to assure compliance with regulatory agencies within the timeframes below:

Expired CTM	Immediately
Subject Returns	Immediately
Partial Vials remaining after dose preparation	Immediately
CTM remaining upon study closure	Within 90 days

9. All returns or disposal of CTM will be documented at the time of such disposition in accordance with study protocol, sponsor instructions and regulatory agencies. Records will be maintained with study protocol documentation.

J. **Quality Assurance Monitoring of Investigational Drug Service**

1. The IDS will regularly review adherence to established policies and procedures to assure compliance with practice standards, sponsor requirements, and regulatory agencies.
2. Areas reviewed will include but not be limited to:
   a. Documentation of accountability for CTM inventory and transport records.
   b. Documentation of completed staff training.
   c. Reconciliation of required temperature monitoring of CTM.
   d. Proper disposition of study records.

V. References

21CFR Part 50 – Protection of Human Subjects

21CFR Part 56 – Institutional Review Boards

21CFR Part 201 – Drug Labeling

21CFR Part 312 – Investigational New Drug Applications

21 NCAC 46 Section 1412 – Physical Requirements

21 USC Title 21 Chapter 13 – Drug Abuse Prevention and Control

ICH GCP Consolidated Guideline—Part 4.6 Investigational Product(s)

Research Billing Compliance – Investigational Products Policy

The Joint Commission Standards for Medication Management

Related Policies

Research Billing Compliance – Investigational Products

Attachments

IDS SOP Manual

Investigational Drug Transport Log

Protocol Intensity Worksheet

Attachments:

IDS Fee Calculation Worksheet
Investigational Drug Transport Log
UNC IDS Protocol Intensity Worksheet

Applicability

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

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.