UPDATES FROM INVESTIGATIONAL DRUG SERVICES (IDS)

Andy Thorne, PharmD, MS
System Clinical Manager, Investigational Drug Services | UNC Health
Assistant Professor of Clinical Education | UNC Eshelman School of Pharmacy
Phone (984) 974-0040
Andrew.Thorne@unchealth.unc.edu
AGENDA

WORKING WITH IDS

IDS WEBSITE

UPDATES
INVESTIGATOR RESPONSIBILITY FOR DRUG PRODUCT

ICH E6 GCP (Section 4.6)
- The investigator is responsible for product accountability at the study site

Investigators can delegate duties
- At UNC, the IDS Pharmacist is delegated this responsibility

Joint Commission Medication Management Standards
- MM.06.01.05
  - “… written process for the use of investigational medications specifies that the pharmacy controls the storage, dispensing, labeling, and distribution of investigational medications.”
### IDS OPERATIONAL OVERVIEW

#### IDS STAFF
- 9.6 Pharmacist FTEs
- 9.0 Technician FTEs
- 1.0 Reimbursement analyst FTE

#### DISPENSING
- ~600 studies
- 11,000 + dispenses for FY20

#### HOURS
- 0730 to 1600, M – F → General IDS
- 0800 to 1630, M – F → Cancer IDS
- Closed on major hospital and university holidays
IDS OPERATIONAL OVERVIEW

Memorial Hospital, 3rd Floor
- Phone: 984-974-0469
- Fax: 984-974-6359
- Sterile compounding, general disease states

Neurosciences Hospital, Ground Floor
- Phone: 984-974-3777
- Fax: 984-974-3471
- No sterile compounding, general disease states

Cancer Hospital, 3rd Floor
- Phone: 984-974-8236
- Fax: 984-974-8560
- Cancer therapeutics, all formulations
IDS SHIPPING ADDRESSES

Do not include investigator’s name

Do not raise shipments without first notifying IDS

UNC Healthcare
Investigational Drug Services
3rd Floor, Room N3122
101 Manning Drive
Chapel Hill, NC 27514

UNC Healthcare
Cancer Investigational Drug Services
NC Cancer Hospital Infusion Pharmacy, RM C3247-5
101 Manning Drive
Chapel Hill, NC 27514
WHAT DOES IDS DO? ALL IDS STAFF

Dispenses investigational product (IP)

Manages inventory

Monitors storage conditions (temperature)

Maintains accountability/data/records (Vestigo web-based IDS system)

Receives monitor visits (and audits)

Responds to questions from study teams/sponsors
WHAT DOES IDS DO? LEAD PHARMACISTS

Each protocol is assigned a lead pharmacist to be the primary driver of the protocol in IDS

- Work up new protocols to distill pharmacy process
- Create information sheet for every protocol
- Train IDS staff (and ancillary pharmacy staff as needed) on new protocols
- Revise protocols as required by amendments or study updates
- Communicate with study teams regarding their protocols
AFTER HOURS EXPECTATIONS

ON – CALL AFTER HOURS

In an emergency, an IDS clinical pharmacist can be paged at 919-216-9727 or through WebExchange.

They will provide assistance with:
- Individual drug or research questions
- The breaking of a treatment blind
- Provide support for inpatient or IV room pharmacy staff who may be unfamiliar with a particular research protocol

AFTER HOURS DISPENSING

If a research protocol will require after hours dispensing, this must be arranged from the start.

After hours dispensing or 24 hour dispensing increases the complexity score and can lead to higher fees.
## COMMUNICATION WITH IDS

<table>
<thead>
<tr>
<th>Quick Answer</th>
<th>• Call us</th>
</tr>
</thead>
</table>
| Send Documents | • Email Lead Pharmacist  
• Email shared inbox: [uncids@unchealth.unc.edu](mailto:uncids@unchealth.unc.edu) or [NConcologyIDS@unchealth.unc.edu](mailto:NConcologyIDS@unchealth.unc.edu) |
| Monitor Visit Schedule | • Reach out to request a visit  
• Visits currently restricted due to pandemic |
| Remote Monitor Visits | • For most studies, IDS documentation is stored electronically → prefer that monitors review documents remotely  
• Vestigo remote access can be extended at any time, just ask |
DO I NEED TO USE IDS FOR MY MED-RELATED PROTOCOL

<table>
<thead>
<tr>
<th>Joint Commission requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>At UNC Medical Center, the clinical and distributional services of IDS are required</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any agent/drug (potentially including supplements) could be considered investigational</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sometimes decided on a case by case basis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you’re unsure, just ask!</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>If IND required → investigational</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>If IND not required → could still be considered investigational</td>
</tr>
</tbody>
</table>
HOW AND WHEN DO I INITIATE A REQUEST FOR IDS SERVICES

Use Clinical Research Management System (CRMS)

- Submit request for IDS services
- Embedded worksheet will estimate complexity score and estimate billing
- IDS will review and send confirmation memo
- Coordinator requests a pharmacist assignment through CRMS
- Lead pharmacist assigned by IDS manager
- Study ready for dispensing 6 to 8 weeks after lead pharmacist assigned

Request for IDS services in CRMS should be submitted simultaneously with contract negotiation and request for IRB approval
IDS WEBSITE: https://uncids.web.unc.edu/
Welcome to UNC Health's Investigational Drug Services (IDS) webpage. Here you will find contact information, standard operating procedures, and frequently asked questions. Our goal is to ensure our study sponsors have answers to questions and access to pertinent information.
Meet the Team

Technicians, General IDS

Frederick Asamoah, CPhT

Frederick (Freddie) worked with the Sterile Products Area at UNC Medical Center for 9 years from 2006 - 2015 and the OR Pharmacy for 2 years before he joined the IDS team on August 14, 2017. He is a soccer fan and his favorite team is CHELSEA FC in England.
Standard Operating Procedures

Study Initiation Visit Documents

- General IDS SIV
- Cancer IDS SIV
- REX General SIV

Standard Operating Procedures

- UNC IDS SOP-1 IDS Responsibilities
- UNC IDS SOP-2 Centralized Oversight and Auditing
FAQs

General Information

Do I need to use IDS for my med-related protocol

Any agent or drug (potentially including supplements) used on the study could be considered investigational, and will therefore require IDS services. If the drug is the primary intervention and its efficacy or safety is being studied, it will be considered investigational. If an IND is required, it is classified as investigational. If an IND is not required, it could still be considered investigational and will be decided on a case by case basis. If you are unsure if your med-related protocol is investigational, please reach out to us at uncids@unchealth.unc.edu.

How do I initiate a request for IDS services?

Utilizing the Clinical Research Management System (CRMS), submit a request for IDS services. The embedded worksheet will estimate the complexity of the protocol and estimate the billing. The IDS team will review and send a confirmation memo.
IDS BILLING UPDATED

- Go-live date: October 1, 2020
- New model will only be applied to new studies with pharmacist assignment after October 1, 2020
- Two tiers for billing
  - One for industry studies / One for IITs and network trials
  - Each still has 4 levels (as before), but dollar amounts vary by tier
  - Level determined by points assigned to items that make a study more complex for IDS
  - Calculation of billing level has also been updated
- Introduction of ad hoc fees
  - Charged for individual activities (see fee schedule)
- Individual items defined and explained in definitions document

4 levels of complexity - the level determines fees
IDS MOVING AWAY FROM PAPER ORDERS

Administration setting determined ordering method

Outpatient
- Paper
- Epic Orders

Inpatient or Clinic

Epic outpatient orders will be used in place of paper orders

Outpatient
- Epic OP Order

Inpatient or Clinic
- Epic Inpt Orders

Paper orders phased out
IDS SOPs: Summary

• Three updated SOPs:
  • UNC IDS SOP-04 Training
  • UNC IDS SOP-08 Returns and Destruction
  • UNC IDS SOP-14 Authorized Prescribers

• Five new SOPs:
  • UNC IDS SOP-01 IDS Responsibilities
  • UNC IDS SOP-02 Centralized Oversight and Auditing
  • UNC IDS SOP-03 Satellites
  • UNC IDS SOP-05 Inventory Control and Temperature Monitoring
  • UNC IDS SOP-13 Sponsor and Study Team Expectations
IDS SOPs: Updated SOPs

- Explanation of what is updated is at the end of each updated SOP
- Example below is from UNC IDS SOP-08 Returns and Destruction

IV. Original Procedure Date and Revisions

01 Jul 2019 – SOP live

15 Jun 2020 – Updated period of retention of expired medications. Clarified language to be more specific. Expanded criteria for quarantine to include improperly labeled IP. Clarified the reasons why requests for maintenance of patient returns may or may not be approved. Inserted details for destruction process.
UNC IDS SOP-01 IDS Responsibilities

- IDS takes care of research medications, including storage, security, temperature monitoring, labeling, and dispensing
- Clarifies what is required for an order to be considered valid by IDS
- IDS activities in interactive response technology (IRT) systems
  - Includes receiving product, and (occasionally) randomization of patient treatment assignment
  - Excludes electronic data entry (EDC) and any trainings for IRT deemed to be non-applicable to pharmacy roles
- Delegation of Authority (DOA) Logs
  - IDS will maintain a master DOA
  - Study-specific DOAs will list ‘IDS’, be signed by IDS manager or delegate, and refer to the IDS master DOA
- IDS will use IDS forms, not sponsor-provided forms
UNC IDS SOP-02 Centralized Oversight and Auditing

- Describes process for establishing IDS satellites
- IDS will oversee activities at satellites through periodic audit
- A point person from IDS and a point person from the satellite are identified as primary liaisons back and forth between the satellite and IDS
UNC IDS SOP-03 Satellites

- Further details on satellites and establishing satellites
- Record keeping at satellites
  - Master signature log
  - Training for satellite IDS primary pharmacist
- IDS will have the same expectations of process in the most instances at satellites as we do with full-time IDS locations
UNC IDS SOP-05 Inventory Control and Temperature Monitoring

- **Inventory management practices**
  - IDS can manage inventory levels and source product (if available through wholesaler)
  - If managing inventory, will use standard inventory management practices (par and re-order levels)

- **Electronic accountability**
  - Accountability will be electronic, never on paper
  - Accountability kept for study medication, not ancillary or standard of care medication

- **Security**

- **Temperature monitoring**
  - Standard temperature ranges, as defined by United States Pharmacopeia (USP), will be used
  - Recording will be in Celsius and rounded to the nearest whole degree
  - Standard excursion reporting framework
  - No monitoring of ancillary or standard of care medication or after medications have been dispensed
UNC IDS SOP-13 Sponsor and Study Team Expectations

- Investigational medications must be properly labeled to be accepted by IDS
- Sponsors and/or study teams will be asked to read and attest to UNC IDS SOPs
  - This will be done through study startup infrastructure
  - Sponsors can request exemptions to SOPs if they wish
- Study opening
  - CRMS is the method for requesting IDS services and timepoints for work in IDS are related to the timing of CRMS requests
  - IDS expects timely responses from study teams and sponsors for information required to open studies
- Monitor site visits
  - Monitor visits in IDS will be time limited and limited only to review of medications if documents are electronic
  - IDS expects proper handoff from departing monitors such that IDS does not have to revisit process with new monitors
UPDATES FROM INVESTIGATIONAL DRUG SERVICES (IDS)

Andy Thorne, PharmD, MS
System Clinical Manager, Investigational Drug Services | UNC Health
Assistant Professor of Clinical Education | UNC Eshelman School of Pharmacy
Phone (984) 974-0040
Andrew.Thorne@unchealth.unc.edu