INVESTIGATIONAL DRUG SERVICES (IDS)

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UNC HEALTH℠

“If we knew what we were doing, it would not be called research, would it?”

-Albert Einstein

Agenda

- IDS Overview
- IDS Startup
- Epic Ordering/Dispensing
- Monitoring Visits
- Pharmacy Close Out

IDS Overview

IDS OPERATIONAL OVERVIEW

IDS TEAM

- General IDS
- Cancer IDS
- 10 Full-Time Pharmacists
- 3 Per Diem Pharmacists
- 8 Technicians
- 1 Reimbursement analyst

STUDIES

- ~600 studies
- Inpatient and Outpatient
- Pediatric and Adult
- Compassionate/ Emergency Use
- On-site at UNC Hospitals
- Off-site at satellite clinics

HOURS

- General IDS: 0730 to 1600, M – F
- Cancer IDS: 0800 to 1630, M – F
- 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

Services

Drug Accountability	Inventory Management	Temperature monitoring	Dispensing	Protocol Amendment Updates	Monitoring Visits
• Shipment Receipt • Storage • Chain of Custody • Returns • Destruction	• Storage under appropriate conditions • Expiration monitoring and handling • Destruction	• Dual continuous temp monitoring (within IDS) • Temp monitoring at all satellites • NIST certification calibration • Management of temperature logs • Temp monitoring in transit	• Verification of Epic orders • Randomization • Preparation and dispensing per protocol • Blinding • Preparing for transit to satellites	• Update to dispensing procedures • Retraining • Update to Vestigo build • Update to Epic – communication with analyst	• On-site and Remote • Monitoring support during visit • Follow-up on pending items

What Regulations and Guidelines Does IDS Follow?

- **Federal**
  - CFR - Code of Federal Regulations
  - FDA
  - NIH
  - NCI
- **State**
  - NCBOP
- **Hospital/Health System**
  - Institutional Policies
  - IDS Policies
  - The Joint Commission
- **United States Pharmacopeia (USP)**
  - 797 – Sterile Compounding
  - 800 – Hazardous Drug Handling
  - 795 – Non-sterile compounding
- **International**
  - ICH - International Conference on Harmonisation
  - GCP – Good Clinical Practice
  - HSP – Human Subjects Protection

Highlight on TJC

Medication Management Standards: MM.06.01.05

Standard: The hospital safely manages investigational medications.

Element of Performance: The hospital's written process for the use of investigational medications specifies that the pharmacy controls the storage, dispensing, labeling, and distribution of investigational medications.

IDS Startup

Requesting IDS Services

Initial Notification & Pharmacist Assignment

- Upon entry of study into CRMS, indicate that you will need IDS services.
- At least 6-8 weeks before study will start, request a pharmacist via CRMS.
- Enter a MySupport Ticket for an Epic Investigational Drug build.
- Pharmacist will be assigned within about a week.

Documents IDS Needs

- Protocol
- Pharmacy Manual
- IB
- SDS
- FDA1572 or list of authorized prescribers from IRB approval

Billing/Budget

- CRMS Complexity Worksheet – Startup and maintenance fees
- IDS SOP exemptions
- Dispensing fees
- Monitoring fees
- Drug fees if applicable

SDS=Safety Data Sheet, IB=Investigator Brochure

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
- Participate in SIV
- Create information sheet for every protocol
- Train IDS staff (and ancillary pharmacy staff as needed) on new protocols
- Development of dispensing processes as required by protocol, hospital policy, needs of study team
- Revise processes when needed for amendments, policy updates, regulation updates
- Communicate continuously with study teams, CROs, sponsors, ancillary pharmacy personnel, vendors

What Does the Lead Pharmacist Do at Startup?

Determining study-specific procedures

Dispensing

- Sterile compounding procedures
- Hazardous/Biohazardous/Gene Therapy preps
- Repackaging
- Blinding
- Dose calculation
- Communication between IDS and study team

Coordination with external departments

- After-hours support
  - Approval from outside department
  - Logistics
  - Training – initial and ongoing

Inventory management

- Vestigo study build
- IRT access communication
- Shipment receipt
- Storage location
- Returns/Destruction procedures
- Temperature monitoring and excursion procedures
- Security (controlled substances)

Regulatory

- IRB information/status
- Authorized prescriber list (e.g. FDA 1572)
- DEA processes (controlled substances)

Don’t Forget! We Need to Know…

- Where are the study visits taking place?
- Who will perform the randomization?
- Are courier services needed?
- Whether the IDS SOPs been provided to the sponsor?
- Study monitor and/or Sponsor contact information.
- Who is your backup coordinator?
- Do you need IDS to dispense auxiliary supplies?
  - Examples: IV sets, Fluids for flush, Supplies for home use by patient

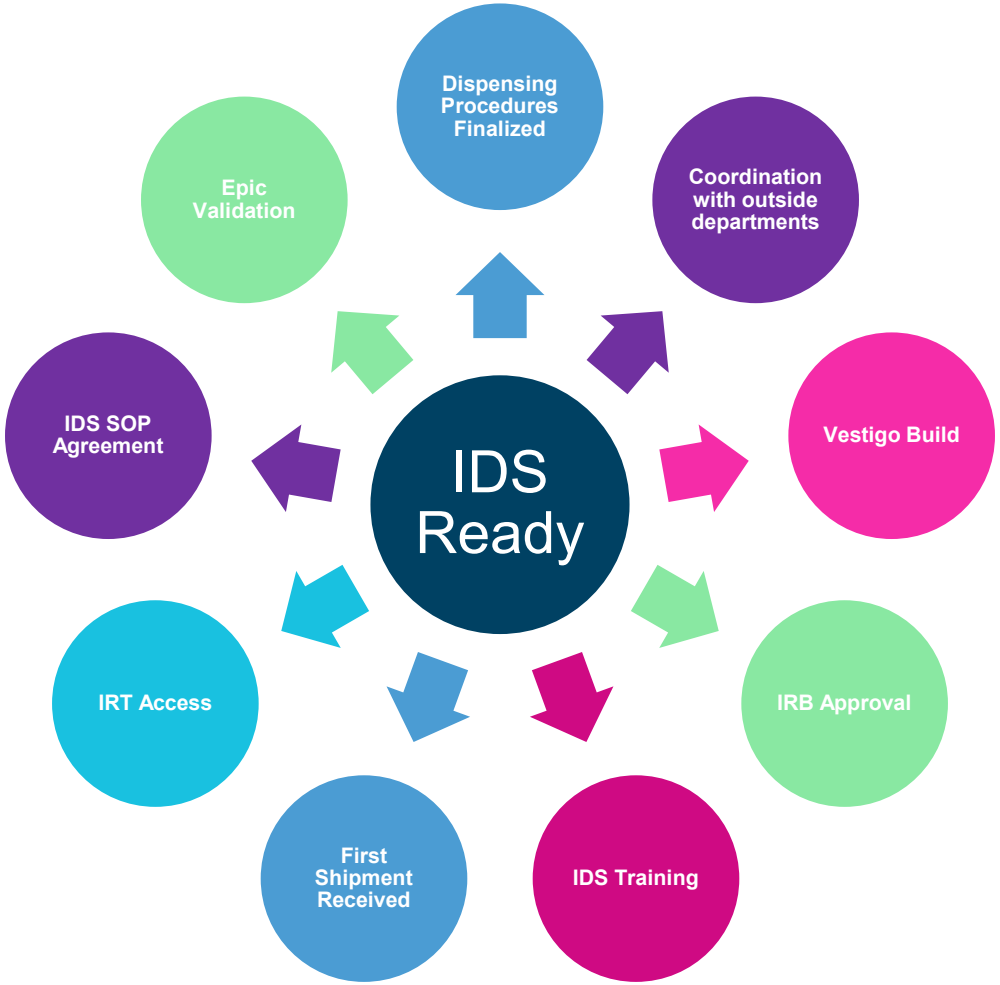
IDS SOPs

- **Due to the volume of studies managed in IDS, having streamlined processes is essential.**
  - Staff become familiar and experienced with operations
  - Decreases likelihood of errors in procedure
  - Decreases time it takes to complete processes
- **Certain IDS SOPs also benefit the health and safety of IDS staff and the patients we serve (e.g. IP Returns).**
- **Exemptions (operations that violate our standard process) indirectly affect operations for other studies by removing the benefits listed above.**

Examples – Focus on IP Returns

- **Returns processed for 25 studies in one day performed in 25 different ways**
  - Unfamiliarity of process by the IDS technician (increased chance of an error)
  - Longer time to process prescription returns (affecting day-to-day operations/efficiency)
- **Returns kept on site while awaiting monitor review**
  - Unsanitary products kept on shelves within the same pharmacy (and proximal storage areas) as available inventory that is dispensed to patients
  - Decreases available storage space for study inventories
  - Increases time spent on-site for monitor visits
    - Increased fees associated with monitor visits

IDS Readiness



Ordering/Dispensing

What Does IDS Need to Fill a Prescription?

Epic Order *Required*

- Enter under correct encounter – orders do not work under 'Research Support' visits
- Fill in study visit # - this is helpful for all studies and **crucial** for some
- Outpatient prescriptions
  - Pick-up date/time
  - If multiple visit locations used for study, indicate **location of visit**

Informed Consent *Required*

- Attestation in Epic order – confirm patient has signed
  - No need to provide the signed ICF
- We are unable to process any prescriptions for patients that have not signed the informed consent

IRT *If Applicable*

- Send IRT emails to UNCIDS@unchealth.unc.edu
  - Randomization confirmations
  - IRT kit assignment emails

Other *If Applicable*

- Send any necessary communication as previously planned with your lead pharmacist during the startup phase
  - For emails, always include IDS shared inbox: UNCIDS@unchealth.unc.edu
  - If a phone call is needed, be sure you know which pharmacy to call (3W or NSH)

Monitoring Visits

Scheduling Monitor Visits*

*For General IDS only, not for Cancer IDS.

Email **UNCIDS@unchealth.unc.edu** to request a monitor appointment with the appropriate appointment information:

- Protocol name / IDS # (preferred) / IRB #
- Monitor name and email address
- Date(s) and type of visit needed

Type of Visit	Days	Time Slots
Virtual *(WebEx with IDS Technician)*	Mon – Thu	11:00-11:30
On-site	Mon/Wed/Thu	08:30 – 11:00
Remote *(Vestigo Access Only)*	As requested	As requested

Virtual or Remote visits preferred.

Times are subject to change.

What Can the Monitor Get From a Remote Visit (Vestigo only)?

- Drug accountability reports
- Dispensing documentation
- Chain of custody documents
- Shipping documentation
- Continuous temperature monitoring reports
- Current and past protocol versions
- Current and past pharmacy manuals
- Current and past investigator brochures
- Official study communications
- Other protocol documents
- FDA 1572 documents

What Benefit Does a Virtual Monitoring Visit Provide?

- **Viewing of current inventory in real time.**
- **Viewing of returns in real time (if exempt from SOP).**

On-Site Visits

- **Vestigo access is provided prior to the on-site visit.**
  - Vestigo review to be completed prior to or after the visit.
- **IDS will have all medications needed for review ready upon monitor's arrival.**
- **Cubicle space provided.**
- **Access to enter the pharmacy for the purpose of checking storage conditions of current inventory.**

Pharmacy Close-Out

What Does Pharmacy Close-Out Entail?

Inventory

- Monitor performs final accountability with assistance from pharmacy technicians.
- Final disposition instructions for all remaining inventory are provided by monitor and followed by technicians.
  - Packaging of remaining IP
  - Labeling for return to sponsor/depot
  - Destruction of remaining IP, auxiliary medications, supplies
  - Documentation of return to sponsor or destruction
  - Final destruction certificates provided to study monitor

Resolution of final inquiries

- Monitor provides verbal or written inquiries to lead pharmacist and pharmacy technicians.
- Lead pharmacist and technicians work together to resolve queries, provide any requested documentation.

What Does Pharmacy Close-Out Entail? (continued)

Vestigo

- Once all inventory, quarantined IP, expired IP, and returns are either destroyed or sent back to sponsor, Vestigo account is closed in the system.

Paper Records

- All original documents are repackaged into long-term storage folders/boxes.
- Closed study folders containing original documentation are queued up for transport to Iron Mountain.
  - Includes preparation of numbered boxes, entry into a database containing the box numbers to be traced back to the specific protocol.
- Iron Mountain is scheduled for pickup of original records.
- Iron Mountain picks up from IDS and transports to long-term storage warehouse.

What is Needed for Pharmacy Close-Out?

Close-Out Visit

- All drug accountability must be completed.
- All inventory must be zeroed out.
  - Includes inventory, quarantined items, and returns.

Written request for pharmacy close-out

- Make request when there will be no further information, documentation, or support needed from IDS for the study.
- *Maintenance billing will continue until pharmacy close-out is completed.*

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