
Welcome to today’s postprandial presentation

IDS Pharmacy:

Supporting HSC Researchers in the Conduct of Drug Studies

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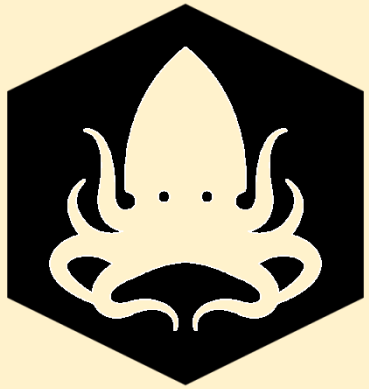
IDS Pharmacy and Other Mythical Beasts





IDS Pharmacy:

Supporting HSC Researchers in the Conduct of Drug Studies

The goal of this presentation is to familiarize audience members with the IDS Pharmacy and some its services

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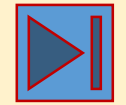

Definitions and Acronyms

Term	Definition
DOPS	Department of Pharmacy Services at UNMH
HSC	University of New Mexico Health Sciences Center
IDS	Investigational Drug Service at UNMH
IMP	Investigational Medicinal Product (study drug)
IP Pharmacy	Inpatient Pharmacy at UNMH
IWRS (IRT)	Interactive Web Response System (Interactive Response Technology)
ODS	Oncology IDS at UNMCCC
PharmD	Doctor of Pharmacy (professional degree needed to become a pharmacist)
RPh	Registered Pharmacist (individual is licensed to practice pharmacy)
SRMC	Sandoval Regional Medical Center (part of UNM but a separate facility from UNMH)
UNMCCC	UNM Comprehensive Cancer Center
UNMH	University of New Mexico Hospitals

IDS Overview

Who	What	When
Where	Why	How

Who we are (1)

- IDS is the Investigational Drug Services pharmacy (sometimes also referred to as Investigational Drug Studies).

- IDS is under the administrative control of the University of New Mexico Hospital (UNMH) Department of Pharmacy Services (DOPS).

Who we are (2)

- IDS operates as part of the UNMH Inpatient (IP) Pharmacy
  - All IDS staff are IP Pharmacy employees licensed to practice pharmacy.
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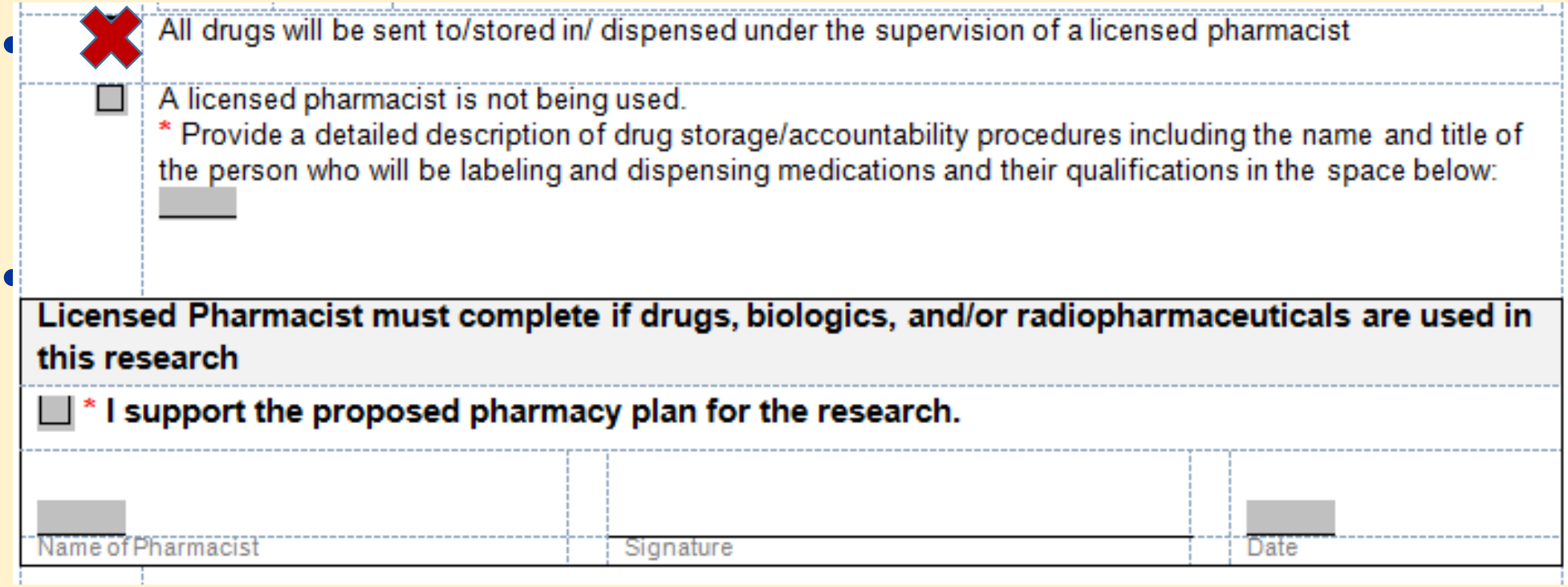


All drugs will be sent to/stored in/ dispensed under the supervision of a licensed pharmacist

A licensed pharmacist is not being used.
* Provide a detailed description of drug storage/accountability procedures including the name and title of the person who will be labeling and dispensing medications and their qualifications in the space below:

Licensed Pharmacist must complete if drugs, biologics, and/or radiopharmaceuticals are used in this research

* **I support the proposed pharmacy plan for the research.**

Name of Pharmacist | Signature | Date

IDS Training and Credentials

- In addition to the usual qualifications required for pharmacy practice (e.g., Pharm.D., RPh, CPhT), all IDS staff maintain current training in research-related coursework, including:
  - CITI Group 1 Biomedical Research Investigator
  - CITI Good Clinical Practice (GCP)
  - HSC Financial Conflict of Interest training
- Protocol-specific training as required by sponsor

IDS Staffing

- Staffing: Most days, IDS is staffed by one pharmacist and one pharmacy technician.
  - Regular IDS staff: Lead IDS pharmacist and IDS pharmacy technician.
  - Backup IDS staff: A small number of pharmacists trained and delegated to cover IDS when the lead pharmacist is absent. These individuals have a wealth of experience in other pharmacy-practice areas in addition to IDS.

Whom we serve

- IDS' services are primarily intended to support UNMH and HSC (north campus) investigators in their clinical research.
  - Excludes SRMC (a separate facility from UNMH)
  - Excludes oncology research
    - Contact ODS, located at UNMCCC, for most oncology studies.
    - Email address: ods@salud.unm.edu
    - Pediatric oncology studies may fall under a different group within UNMH DOPS.
  - *May* include UNM main-campus investigators in some cases for human research that involves a medication component.

Who, in layperson's terms

IDS is part of the UNMH Inpatient Pharmacy and consists of qualified pharmacy staff who are trained and available to help UNM north-campus researchers conduct approved drug-related research in humans.

What we do

Per UNMH policy, IDS follows a standardized procedure for the custody and distribution of IMP within its scope of practice that complies with all applicable regulations and is consistent with the principles of good clinical practice. A qualified individual designated as the lead IDS pharmacist will oversee the management, distribution, and disposition of IMP upon delegation of this authority to IDS by the PI.

What we do, in layperson's terms

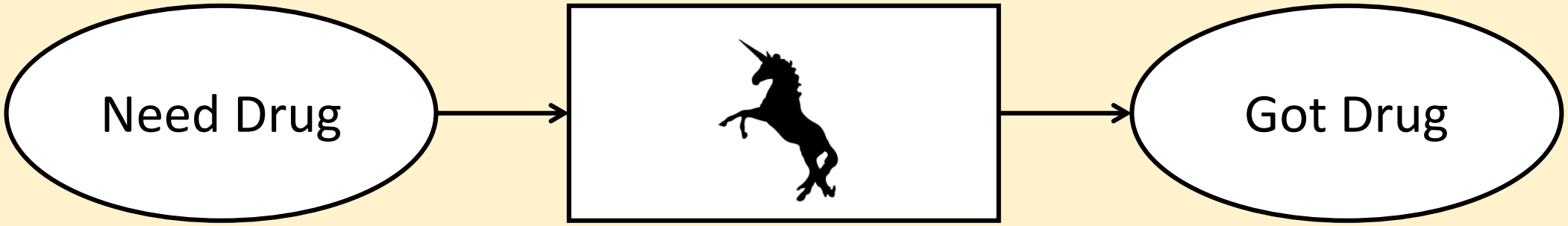
IDS manages IMP so you don't have to.

Investigational medicinal product (IMP) consists of medicinal agents identified in a protocol for research use in human subjects, sometimes referred to as study drug. This may include drugs awaiting approval, prescription drugs already on the market, and drugs approved for non-prescription use.

A Pharmacy within a Pharmacy

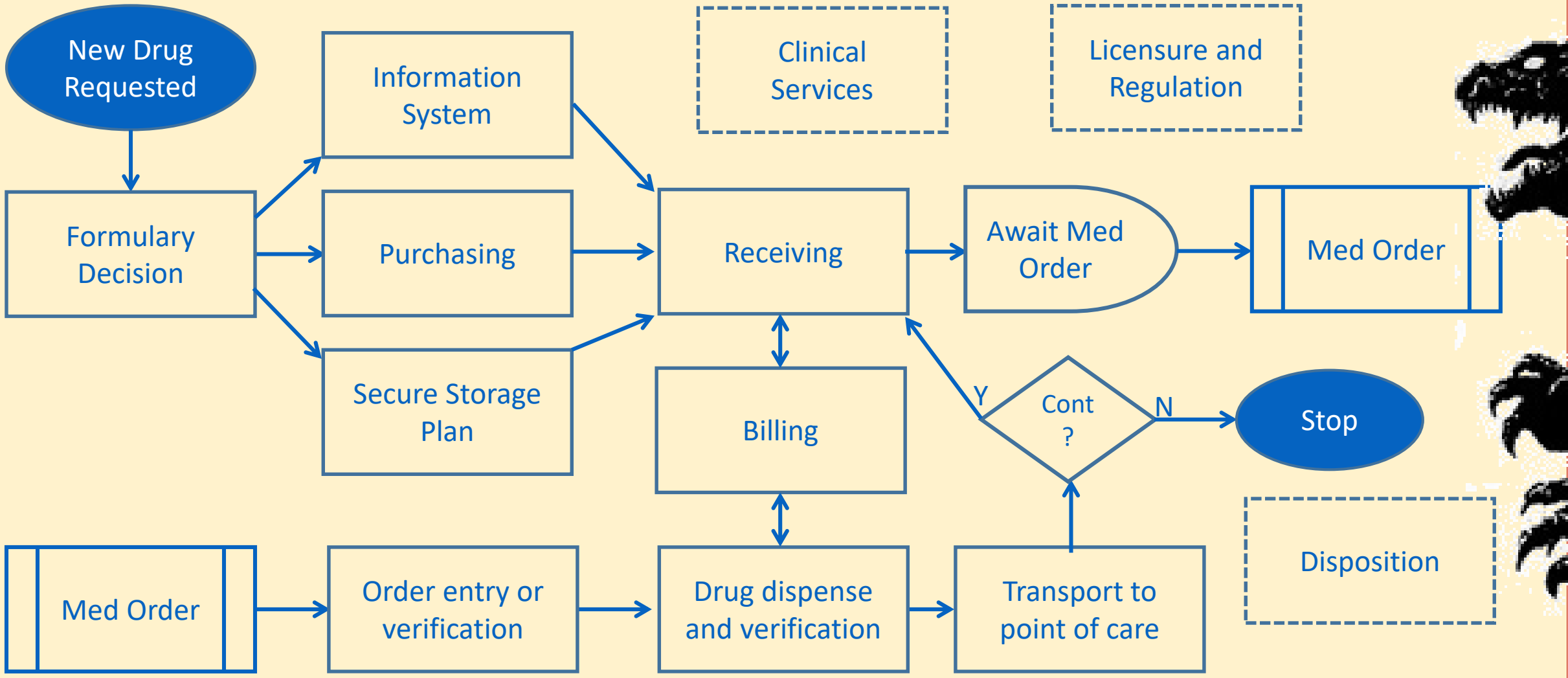
- IDS performs nearly all the tasks of a non-research pharmacy but on a smaller scale and with an even higher level of detail.
  - Compared to IP Pharmacy, IDS is much smaller (staff, square footage, volume of medication orders processed)
  - More steps are required to process a medication order in research, there are additional regulations, and recordkeeping requires a greater level of detail.

Pharmacy Workflow, Simplified

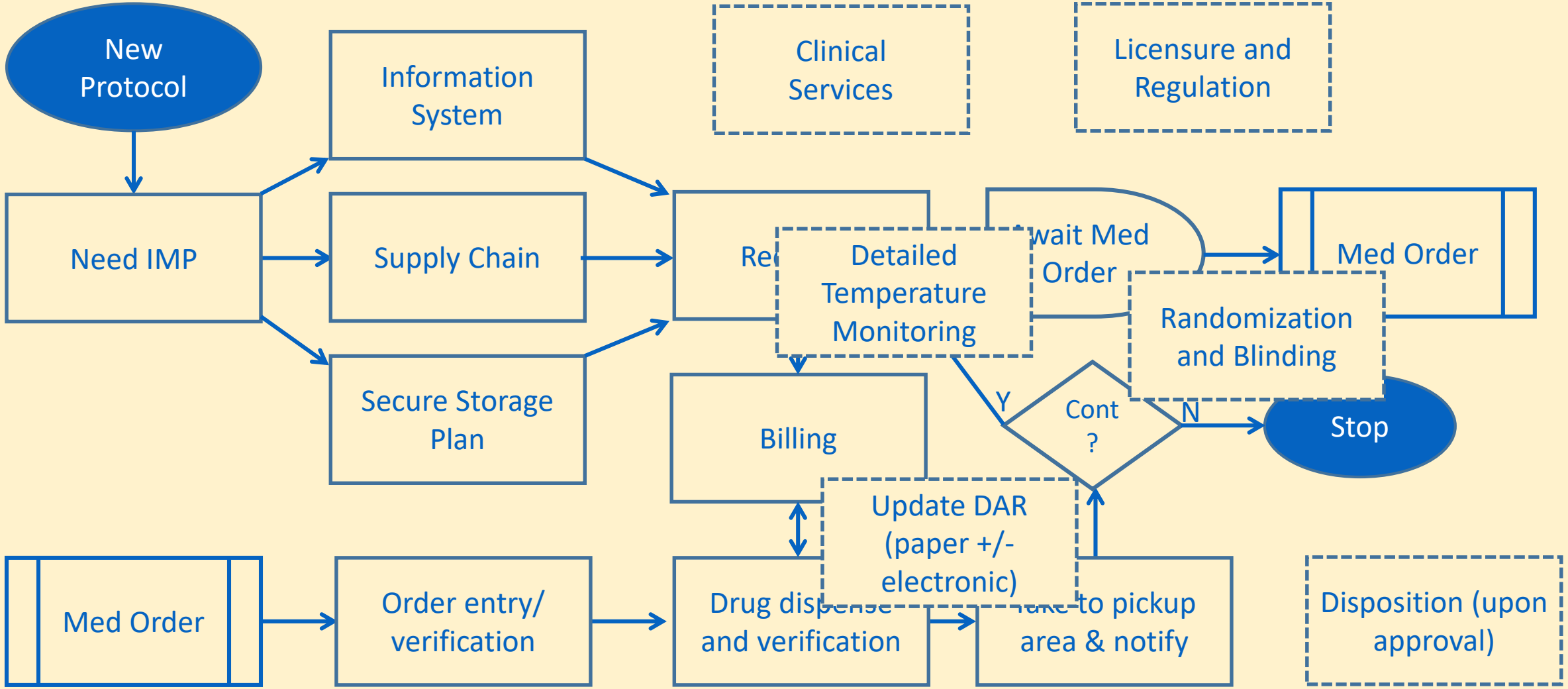


Simplified view of Inpatient Pharmacy's operations	**IDS operations for comparison**
Formulary management (e.g. P&T committee)	Based on the needs of current approved protocols
Information system (e.g. Cerner®)	Vestigo® for all subjects, hospital information system (e.g. Cerner®) for inpatients, protocol-specific systems…
Purchasing (Contractual agreements with suppliers)	Most IMP is sponsor supplied. Some is procured through IP Pharmacy and billed to study.
Receiving (Loading dock to IP Pharmacy)	Receiving (Loading dock through IP Pharmacy to IDS)
Inventory Control (secure storage in pharmacy or at patient-care locations, e.g. Pyxis®)	Inventory Control (Secure storage in IDS or very rarely in other locations)
Medication-order processing	Medication-order processing
Order transmission (Usually via PowerChart)	Order transmission (IWRS, email, FAX)
Order entry or verification (Cerner®)	Order entry or verification (Vestigo®+/- Cerner®)
Drug preparation and verification	Drug preparation and verification
Distribution (delivered by techs or tube system)	Distribution (pickup area in IP Pharmacy)
Billing (purchasing agreements, patients' insurance)	Billing (movement of funds from study to IDS)
Clinical services	Clinical services
Pharmaceutical/hazardous waste management	Pharmaceutical/hazardous waste management
	Blinding, randomization, temperature monitoring, DAR…

New-Drug Scenario – "Standard" Pharmacy



New-Drug Scenario – IDS Pharmacy



What we do not do

- IDS does not process medication orders for non-research purposes (IRB-approved protocol is required).
- As prohibited by regulation, licensure and/or hospital policy, IDS does not participate research involving:
  - Blood products
  - Food products
  - Drugs for use in animal studies
  - Medical devices not associated with a drug component (e.g., certain implants) or containing human tissue
  - Controlled substances on schedule 1

When (Hours of Operation)

- IDS is generally staffed Monday through Friday, excluding UNMH holidays.
- Hours may vary according to the day's requirements.
  - "Core" hours of operation are 08:30 to 16:00.
  - The IDS pharmacy technician is available most days from 07:00 to 15:30.
  - The IDS pharmacist is available most days from 08:00 to 17:30.

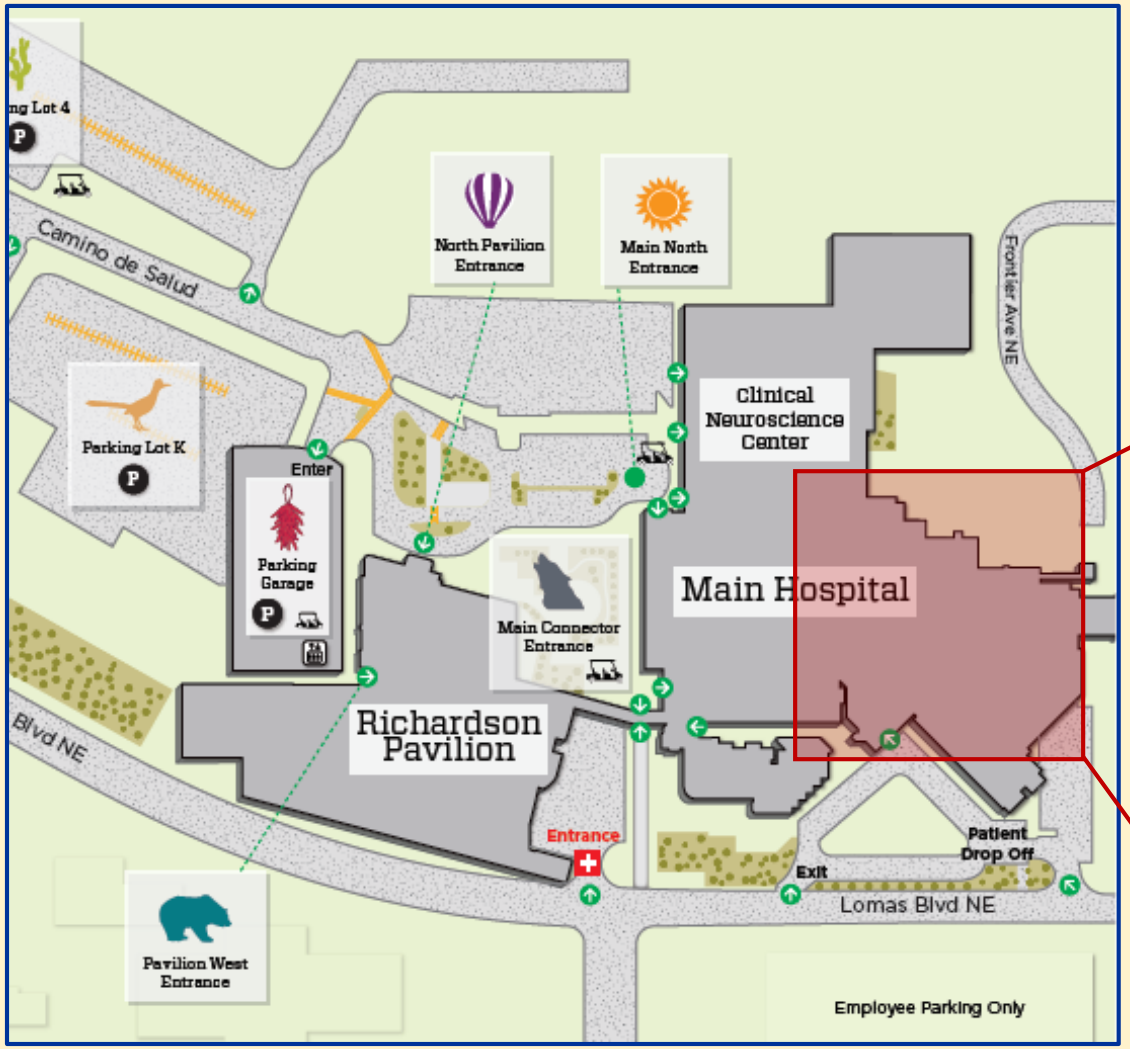
What about after-hours coverage?

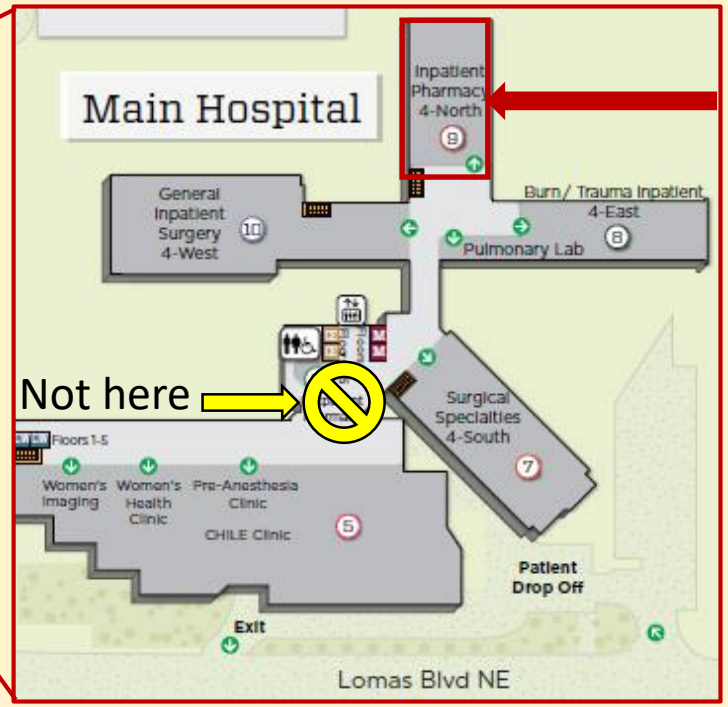
- IDS' schedule is primarily targeted toward the needs of research that takes place during typical clinic hours.
- IDS does not operate around the clock and is not staffed to provide on-call service after hours.
- IP Pharmacy is always open and in many cases IP Pharmacy staff can provide limited IDS services after hours.

Where (Our physical location)$_{(1)}$

- IDS is in the UNM Main Hospital at 2211 Lomas Blvd NE
- We are located inside the IP (inpatient) Pharmacy, 4-North
  - Enter through Pharmacy Administration, just north of the Pulmonary Lab
  - Pharmacy is an escort-only area. Please call IDS upon arrival and one of us will come greet you.
  - Pickup area for prepared study drug is at the operations side of IP Pharmacy in the hallway adjacent to the 4-East hospital wing.
- The pharmacy located at 4ACC is an outpatient pharmacy

Where (Our physical location) (2)

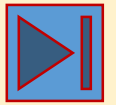




Why?

More on this after “Best Practices” discussion

No. I cannot wait.



How to Contact IDS

Email (shared*)	investigationalpharmacy@salud.unm.edu
Tel	505-272-2515
FAX	505-272-2037
Mailing address	UNMH IDS Pharmacy 4-North, Main Hospital 2211 Lomas NE Albuquerque, NM 87106

*Note: The shared email address should not be used for creating any type of secure user account (e.g., IWRS)

IDS and Best Practices

- IDS as subject-matter experts on pharmacy practices and research regulations, especially during design phase of research plan
  - Procurement, compounding, and storage requirements
  - Forms design (e.g., transportation/custody log, medication order)
  - Blinding and randomization plan
    - IDS is often the only unblinded site staff on a study
    - IDS has no direct subject contact, which helps maintain blinding

IDS and Best Practices

- Additional security and safeguards for IMP
  - Detailed temperature monitoring and accountability records
  - IMP segregated from non-research medications
    - A badge-access controlled area within the badge-access controlled area of IP Pharmacy
    - Minimal opportunity for diversion of research medications to non-research purposes
    - Separate area for subject/inventory returns as quarantine

Boundaries Between Practice and Research (Belmont Report)

Research

Intended to create generalizable knowledge

Practice

Intended to enhance the well-being of an individual

Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy.

Help us Help You$_{(1)}$

- IDS is here to help, and every current or proposed project is important to us. However:
  - As of late June 2019, IDS was responsible for managing 89 active protocols in various stages of activity.
  - A maximum of two staff members is present at any given time.
  - Scheduling and ongoing communication is critical.

Help us Help You$_{(2)}$

- When making a request
  - A specific deadline (date and time) is much more helpful than “ASAP”.
    - Unfortunately, “now” and “today” are not always possible.
  - Please specify your name and contact information and identify the protocol.

Help us Help You – Pre-study(1)

- Pre-study
  - Involve IDS in the planning process as early as possible.
  - Schedule pre-qualification and site-initiation visits with IDS in advance.
  - Involve IDS early in the design of local investigator-led research
    - Example “I’ll just pull the drug from Pyxis and keep it in my desk drawer”
    - Example “How can I prepare blinded active and placebo study medication?”

Help us Help You – Pre-study$_{(2)}$

- Notify IDS as study status changes.
  - Site selected or not
  - IRB approval
  - Initial subject(s) scheduled for screening
- Provide correct contact information to sponsor (e.g., shipping address, IWRS access).

Help us Help You – During Study Conduct$_{(1)}$

- Schedule CRA visits with IDS in advance.
- Notify IDS of *planned* dispensing visits as they are scheduled, cancelled, or re-scheduled.
- Some studies involve unplanned visits—notify IDS as soon as a potential subject is identified.

Help us Help You – During Study Conduct

- Written medication orders (prescriptions) are required as source documents
  - Notification by IWRS is sufficient
  - For complex dispenses with no IWRS, a prescription signed by the investigator is required
  - An email from a study coordinator may be sufficient in some cases by prearrangement
  - Informal “heads-up” email or telephone call ahead of time is appreciated but does not replace the signed medication order

Help us Help You – At Study Closure

- As study end approaches, notify IDS promptly
  - Especially important for studies in which IDS purchases commercially available drug
- Schedule close-out visit with IDS in advance
- Local investigator-led studies may not require closeout, but disposition of IMP must be approved

Conclusion:
Why Might an Investigator Choose to Use IDS?

- IDS is here to help, and there are many efficiencies associated with delegating the management of IMP to IDS.
- IDS' processes exist to promote best practices in research.
  - For sponsored research, the use of a dedicated research pharmacy for IMP management is often the sponsor's preference.
  - For local investigator-led research, IDS' past experiences can point the way to a better experience

UNMH IDS Pharmacy

Email	investigationalpharmacy@salud.unm.edu
Tel	505-272-2515
FAX	505-272-2037
Mailing address	UNMH IDS Pharmacy 4-North, Main Hospital 2211 Lomas NE Albuquerque, NM 87106

Supplemental Materials

Scenario #1	Scenario #2
Scenario #3	Scenario #4

Scenario 1

- Local investigator's research plan was for a double-blinded comparison of the effectiveness of two active, over-the counter medications in hospitalized subjects.
  - Both medications were commercially available in tablet form.
  - The two tablets did not have a similar appearance.
  - The first dose would need to be given soon after the occurrence of a specific clinical.
- How might IDS meet this researcher's needs?

Scenario 1 – Resolution$_{(1)}$

- Issue a: The two tablet types were not blinded as supplied.
- Resolution: Formulate active ingredients into capsules at the required dose. IDS had recently invested in a capsule-filling machine to facilitate this process. Used opaque capsule shells.
  - Initial batches were prepared with tablet fragments, as the tablets did not crush readily. Resulting capsules were uncomfortably large and irregular in shape. One of the tablet types had a strong odor that was noticeable in the finished capsules.
  - A source of powdered active ingredients was later identified, and the capsules were reformulated to be smaller, uniformly smooth, and odorless. (Protocol mod submitted and approved first.)

Scenario 1 – Resolution$_{(2)}$

- Issue b: IDS is not open 24/7, but the study could need a dispense at any time.
- Resolution: IDS developed a process for abbreviated after-hours dispensed and trained key IP Pharmacy staff.
- Pre-enrollment “kits” were prepared containing vials of pre-counted capsules partially labeled with key information from Vestigo®, including a subject ID number.
- At the time of enrollment into study, IP Pharmacist would enter order in Cerner® and complete the dispense.
- IDS would update DAR on the next business day for after-hours dispenses.

Scenario 2

- Protocol procedure inconsistent with local practice and safety standards
  - The protocol required the use of equipment for time-sensitive sterile drug preparation.
  - Once the drug was prepared, it was to be transported in the machine from pharmacy to the operating room.
  - At UNMH, this would require transport between sterile and non-sterile areas.
- How might IDS meet this researcher's needs while following safe practices?

Scenario 2 - Resolution

Compounded sterile preparations (CSPs): Per USP <797> the following are CSPs "compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

Immediate-use CSP: intended only when there is an emergency or immediate patient administration. The immediate-use CSP is compounded from not more than three (3) sterile, commercially, manufactured, non-hazardous products and not more than two (2) entries into any container.

staff to be signed at the time of the after-hours dispense.

- IDS would update DAR on the next business day for after-hours dispenses.

Scenario 3

- PhD student needed a customized controlled substance for off-site study
  - Special formulation needed as oral sublingual liquid for a controlled substance on Schedule 3
  - Visits to take place at investigator’s lab on main campus
- How should IDS proceed?

Scenario 3 - Resolution

- Main campus research is not IDS' primary focus, but in this case IDS agreed to the project to promote subject safety and proper custody of drug.
  - Confirmed medical oversight (MD on premises) and IRB approval (main).
  - Original formulation requested could not be prepared on-site. Formulated an alternative liquid formulation and matched placebo.
  - Developed forms (med orders, randomization tables, custody log…)
  - Developed process was for preparing small batches in advance.
  - On the day of visit, upon presentation of a signed med order, the required volume was drawn into a subject-labeled oral syringe.
  - The investigator would sign out each dose from IDS and hand carry it to the site of the visit.
  - Used or unused doses would be stored in a locked cabinet in the lab and returned to IDS for accountability and disposition, usually the next day.

Scenario 4

- Open-label IMP for inhalation, required reconstitution, dispensing needed 24/7, drug only good for one hour after preparation
  - Protocol specified that sterile preparation was not required
  - UNMH practices require sterile preparation of compounded medications for inhalation
- Now what?

Scenario 4

- IDS opted for the side of local policy and patient safety and prepared all doses under sterile conditions and coordinated prompt pickup by a study coordinator.