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Investigational Drug Service (IDS) Rotation Tool
APPE Student Rotation

Rotation Description

The goal of an IDS rotation is introduce students to the role the Investigation Drug Service (IDS) pharmacist plays in the conduct of clinical trials. While the scope and breadth of this role varies from institution to institution, there are many common themes, responsibilities and operational activities that define the work of the IDS pharmacist. In addition, a general overview of clinical research is provided framed by the role a pharmacist and/or IDS pharmacist plays in the research framework of an organization. This rotational tool provides a list of suggested goals and objectives to strive to accomplish by the end of the rotation. This tool also provides a list of potential activities to complete to achieve the stated and agreed upon goals and objectives. Additionally, the tool outlines a lists of projects and activities to explore during the rotation. Useful references are provided. And finally, a method for student evaluation is included to use to review rotation performance.

As background, the IDS ensures that investigational drug studies are conducted in a safe and efficient manner. The IDS assists investigators in complying with the requirements of the FDA, study sponsors, State Boards of Pharmacy Regulations, Joint Commission, and hospital and pharmacy policies. Study protocols evaluated by the IDS encompass all phases of drug development, range from investigator-initiated to industry sponsored, and include vaccines, viruses, herbal medications, chemotherapy, as well as traditional drug products.

The IDS pharmacists are responsible for developing and implementing procedures for the proper control and drugs in a wide variety of practice environments (e.g., emergency department, operating rooms, intensive care units, inpatient units, ambulatory care clinics for adults and pediatrics) and disciplines (e.g., hematology/oncology, cardiology, transplant, infectious diseases). These procedures include receipt, storage, medication labeling and dispensing, drug inventory management, destruction and other distribution and control functions. The IDS rotation provides the student with practical experience in the activities described either directly or through shadowing the preceptor.

Some highlights of the rotation include the opportunity to become familiar with the Institutional Review Board (IRB). This may entail the completion of a mock IRB application and the opportunity to attend an IRB meeting in a shadowing/observational function. The opportunity to meet with study investigators and pharmaceutical industry sponsors. Other unique activities include adherence monitoring, participation in blinding dosage forms, and playing an important role in the cutting edge of drug development.

Goals and Objectives

The preceptor and student should agree on which goals and objectives are appropriate for the rotation based on rotation site, rotation objectives delineated by pharmacy school, rotation length and student interests. The following are a list of potential goals and objectives:

1. To gain an understanding of the FDA regulations related to clinical trials, including:
   a. Protection of human subjects
   b. Guidance for Industry: good clinical practice: consolidated guidance
   c. Steps involved in the drug research and approval process from initial drug development through postmarketing surveillance.
2. Develop a working knowledge of the FDA (Federal) regulations related to investigational drugs, including but not limited to:
   a. Informed consent
   b. Investigational and/or unapproved new drug labeling
   c. Unused investigational drug disposition
   d. General responsibilityof investigator
   e. Control of investigational drugs/ Drug accountability
   f. Investigator recordkeeping during the study and after study termination
   g. Inspection of records and reports
   h. Emergency use of the investigational drug
3. Develop an understanding of proper investigational drug documentation including: Investigator recordkeeping, drug disposition records, inventory logs, patient dispensing logs, preparation/compounding instructions, door-to-door chain-of-custody, retention procedure, state board of pharmacy requirements, institutional regulations, Continuous Quality Improvement (CQI) procedures.
4. Develop and demonstrate an understanding of proper investigational drug dispensing including but not limited to: Investigational drug control, investigational drug labeling, disposition of unused supply of investigational drug, monitoring of equipment (refrigerator, freezer, super-cold freezer temperatures), cold chain management, response and recovery plan..
5. Become familiar with the daily operations of a pharmacy-based investigational drug service.
6. Demonstrate the ability to respond to requests for investigational drug information.
7. Demonstrate the ability to critically review investigational drug protocols.
8. Describe investigational drug distribution systems, and identify the advantages and disadvantages of the various systems available
9. List the sources of funding available for investigational drug studies.
10. Communicate effectively and professionally with other clinical IDS staff, both written and verbal
11. Display independent self-learning in the field of pharmacy IDS.
12. Review and discuss the different methods of invoicing for IDS activities and the collection of fees. Discuss the financial viability of an IDS including cost avoidance.

Activities

During the course of the rotation, the student will participate in some of the following activities as assigned by preceptor:

1. Complete orientation to organization's pharmacy operations and clinical activities.
2. Become familiar with the areas of the Distribution Center and the roles the independent services provide.
3. Review, summarize and interprete study protocol and the Investigational Brochure (if applicable) and develop dispensing instructions and associated pharmacy records.

4. Discuss study design (s), treatment arms and study drug blinding and unblinding procedures with study staff and protocol sponsor.
5. Reviewing a protocol from an IRB perspective for discussion. Preparing a mock IRB proposal to experience the IRB application process.
6. Preparing a series of study drug monograghs to educate staff in the organization
7. Create spreadsheets and drug accountability logs for tracking the use of investigational agents and document study drug dispensing.
8. Participate in the procedure of dispensing of study investigational drugs (including exposure to IVRS/IWRS systems for randomizations and subsequent dispensing) following locally established IDS study-specific procedures, protocol specific requirements and standardized IDS procedures.
9. Review the institutional guidelines regarding storage, dispensing, labeling and record keeping for investigational drug studies and/or prepare and set-up IRB-approved studies to be ready for the acquisition, accountability, storage, security, packaging, labeling and distribution of study drugs.
10. Create drug description of study number, drug name, strength, how supplied, storage, route of administration, dose, dilution instructions if intravenous, administration instructions and any special instructions for the IDS information sheet and for pharmacy information systems to use to create pharmacy labels and Medication Administration Records.
11. Review physician's orders by verifying accuracy and appropriateness using patient-specific information, the protocol, the Medical Center's Policy on Medication Orders for inpatient and clinic orders and state law on outpatient prescriptions.
12. Assess and evaluate applicable laboratory reports to determine course of treatment and changes in dose or drug regimen.
13. Demonstrate an understanding of the evolving need for the protection of human subjects, privacy issues, the barriers,and the resulting handicaps and apply this knowledge to IDS and the specified hospital.
14. Assure departmental compliance with institutional policies, accreditation, legal, regulatory, and safety requirements.
15. Evaluate/Discuss the process for providing pricing guidelines and negotiating and developing estimates for starting new studies (budgeting and billing).
16. Counsel a patient enrolled in the study if applicable.
17. Conduct at least on IDS drug audit of drug accountability records for a research study.
18. Present the assigned protocol and dispensing instructions as an in-service to the IDS pharmacists with discussion of the backgroung and rational of the study.
19. Provide in-service education to IDS staff, inpatient pharmacy staff, nursing and research staff.
20. Provide concise, applicable and timely responses to requests for drug information from your preceptor, IDS staff, study coordinators, monitors and other study-related staff.
21. Review IDS resources:
    a. American Society of Health System Pharmacists (ASHP)
    b. Center for Drug Evaluation and Research (CDER)
    c. Food and Drug Administration (FDA)
    d. National Cancer Institute
    e. National Institutes of Health (NIH)
22. Participate in day to day dispensing for IDS-based studies.

23. Attend all assigned pharmacy and interdisciplinary meetings relative to IDS, such as:
    a. Site IDS team
    b. Site-specific sponsor initiation visits
    c. Site-specific study monitoring visits
    d. Site-specific in protocol pre-site visits, when possible
    e. Pharmacy and Therapuetics committee meetings
    f. Clinical Services/Tech Meetings
    g. Specific Clinical Trials Group meetings
    h. IRB meeting
    i. Pharmacy Medication Management meeting
    j. Pharmacy Practice Meeting
    k. Various other meetings as directed
24. Read necessary/assigned materials and be prepared to discuss with the preceptor during topic discussions. Prepare and lead at least one topic discussion on a relevant pharmacy IDS related topic.
25. Completing Human Subjects Protection training
26. Participate in training sessions with other department staff.
27. Complete other activities as assigned by preceptor.

Topic Discussions

As time permits, preceptors should schedule time when they can discuss various topics with the student. Background readings should be provided when available (some suggested readings listed with topics in this section). The student should be expected to lead at least one topic discussion towards the end of the rotation.

Potential Topics	***(Select topics as they apply to national/regional/state/local regulations and practices.)***
The Belmont Report	✓ www.hhs.gov/ohrp/humansubjects/guidance/belmont.html ✓ What is contained in the report. ✓ Principles discussed.
The Tuskegee Syphilis Study	✓ www.cdc.gov/tuskegee/timeline.htm ✓ Lessons learned. ✓ Other examples where lessons in ethics played a role in the development of regulations
International Investigational Drug Studies	✓ What regulations apply. ✓ Differences between studies conducted in the U.S. ✓ Economic benefits of investigational drug services at an academic institution
AIDS Clinical Trials Group and IMPACT Studies	✓ www.aactg.org ✓ https://actgnetwork.org/about-actg/network-coordinating-center ✓ Definition and scope of practice.
Adult Oncology Studies	✓ bethesdatrials.cancer.gov ✓ Specific institutional dispensing practices. ✓ Industry vs. federally funded studies.
Pediatric Oncology Studies	✓ www.ncbi.nlm.nih.gov/pmc/articles/PMC2435316/ ✓ www.ncbi.nlm.nih.gov/pubmed/9849753 ✓ Specific institutional dispensing practices. ✓ Industry vs federally funded studies.

Emergency Use of an Investigational Drug	✓ www.fda.gov/RegulatoryInformation/Guidances/ucm126491.htm ✓ Provisions outlined in the Code of Federal Regulations.
Randomization Programs	✓ Specific institutional practices. ✓ Kinds available. ✓ Block stratification.
Vaccine Studies	✓ www.vrc.nih.gov/ ✓ www.niaid.nih.gov/topics/vaccines/ ✓ Industry vs. federally funded.
Second Instition Guidelines	✓ www.fda.gov/RegulatoryInformation/Guidances/ucm126432.htm ✓ Institution specific guidelines.
Filing an IND application	✓ http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/default.htm ✓ Steps involved.
Compassionate Use Drugs	✓ www.fda.gov/.../AccesstoInvestigationalDrugs/ucm176098.htm ✓ Discuss of procedures for obtaining. ✓ Expanded access.
FDA Audits	✓ www.fda.gov/downloads/Training/CDRHLearn/UCM293102.pdf ✓ Preparing for one (previous institutional experience.)
GCP Training	✓ www.nihtraining.com/gcp.html ✓ www.citiprogram.org/ ✓ What is involved/institutional requirements.
Charging Subjects for Investigational Drugs	✓ www.hhs.gov/ohrp/archive/irb/irb_chapter2.htm

Additional Topics

Informatics and the IDS
Medication Safety and the IDS
Role of the IDS technician
Compounding and the IDS (sterile and nonsterile products)
Clinical trial design, advantages and disadvantages

Projects

The student should complete at least one longitudinal investigational drug service project. Preceptor and student should choose a project during the second week of rotation. Students should identify an area of practice interest (i.e. by topic or by patient population) and a new/upcoming IDS study identified for assignment. (Some leeway is required for topic selection, as topics are dependent on Student should present findings / deliverables to the appropriate audience during the rotation.

Evaluation

The preceptor will evaluate the student on achievement of the predefined goals and objectives for the rotation. Students will also be asked for any specific personal goals for the rotation. Students will also be evaluated on their interactions with pharmacists and pharmacy technicians from the Organization's Pharmacy, as well as daily discussions with the preceptor concerning current drug studies in the IDS and discussion topics. The evaluation will include an oral mid-point evaluation to assess progress. The preceptor and student will complete a final written evaluation at the conclusion of the rotation according to school of pharmacy criteria.

Additional Website Resources

Code of Federal Regulations	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?
Clinical Trials	www.clinicaltrials.gov
U.S. Food and Drug Administration	www.fda.gov
Clinical Investigator Inspection List (CIIL)	www.fda.gov/Drugs/InformationOnDrugs/ucm135198.htm
Access to Investigational Drugs – For Patients and Patient Advocacy.	http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/accesstoinvestigationaldrugs/ucm176098.htm
FDA Drugs	www.fda.gov/Drugs/default.htm
FDA Medwatch	www.accessdata.fda.gov/scripts/medwatch/medwatch/medwatch-online.htm
FDA Medwatch Bulletins	www.fda.gov/Safety/MedWatch/default.htm
FDA Patient Safety News	www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/index.cfm

American Society of Health System Pharmacists

Investigational Drug Services Resource Center	www.ashp.org/ids
ASHP Best Practices	www.ashp.org/DocLibrary/BestPractices/ResearchGdlClinical.aspx

Hospital IDS Policies

University of Kentucky IDS Policies	http://www.hosp.uky.edu/pharmacy/ids/default.html

Miscellaneous References

NIH Research and Training Website	www.nih.gov/science/
ASHP IDS Resource Center Helpful Links	www.ashp.org/menu/PracticePolicy/ResourceCenters/IDS/Helpful-Links.aspx
National Cancer Institute Investigator Resources	http://ctep.cancer.gov/investigatorResources/investigators_handbook.htm
National Cancer Institute Access to Investigational Drugs Fact Sheet	http://www.cancer.gov/cancertopics/factsheet/Therapy/investigational-drug-access
FDA Center for Drug Evaluation and Research	www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/default.htm
ASHP Preceptor ToolKit	www.ashp.org/Import/MEMBERCENTER/Sections/SectionofInpatientCarePractitioners/Resources/ASHPPreceptorsToolKit.aspx
NIH ClinicalTrials.gov website	http://clinicaltrials.gov/ct2/about-site/link-to