Investigational Drug Service
PGY2 - Health-System Pharmacy Administration (87405)

Faculty: MacDonald, Elyse A.

Site:
University of Utah Hospitals and Clinics

Status: Active
Not Required

Description:

Primary preceptor = Elyse A. MacDonald, PharmD, MS, BCPS

Active, elective rotation

Typical rotation duration = 4 weeks

Rotation Description:

A typical day in the IDS is driven by patient need, and the resident will receive a broad overview of the IDS. Experiences include the preparation and dispensing of study medications, review of protocols (new studies, amendments), inventory management, and leadership and management issues. The resident will attend some of the meetings that the IDS manager attends. Residents will also develop a good understanding of the role of IDS supporting research in the University of Utah at the Huntsman Cancer Institute and University of Utah School of Medicine. Residents will be introduced to study compliance, regulatory, and financial issues associated with conducting biomedical research and managing this service. Residents will complete projects to apply key concepts and to understand how an IDS pharmacy operates and is managed.

Site Description:

Investigational drug services have been available at the University of Utah since 1985. The IDS Pharmacy, a division of the Department of Pharmacy, is currently located in the Huntsman Cancer Hospital. The IDS pharmacy team currently consists of 6 clinical research pharmacists, 4 pharmacy technicians, and an IDS pharmacy manager. IDS exists to provide drug accountability (drug storage, handling, dispensing, and documentation of administration, return and/or destruction of the drug) for clinical trials throughout University of Utah Health (U of U Health) in order to promote maximum benefit and safety for those participating in each study. IDS currently manages approximately 450 studies. These studies are administered through Huntsman Cancer Hospital and the University of Utah Hospital and Clinics and associated satellites. Sixty percent of the studies are affiliated with malignancy disease states, whereas forty percent are affiliated with non-malignant disease states.
Role of the pharmacist:

The IDS pharmacy manager that the residents work with on this rotation provides the leadership for the service as well as contribute to the overall leadership of the department and organization. The role of the manager includes the following:

- Drive for strong operational performance including efficiency, financial strength, high value, and labor utilization
- Manage growth of the service to match the department and organizational goals.
- Manage change
- Prepare requests for new services and resources including FTEs, space, equipment, programs, and informatics resources
- Manage day to day operations
- Organize and prioritize tasks and projects
- Delegate work and engage team members
- Demonstrate strong problem solving skills. Examples of these situations include the following: urgent, emergent, and disaster situations; day-to-day activities; actions needed based on reported medication events; actions to improve and standardize processes; strategic decision making on the use of personnel and resources
- Facilitate team functions
- Manage service finances including capital and expenses
- Support employees by conducting HR functions including recruitment, onboarding, orientation, retention, motivation and engagement, coaching and development, and progressive discipline
- Advocate for the role of the profession of pharmacy both within the organization, the community, and at the national levels
- Strive for continued excellence in the quality of services provided
- Educate residents and students

Expectation of Learners:

**Expectations of the resident:** Residents are expected to come prepared for the daily activities, including meetings and any topic discussions. Residents will be meeting with research leaders in the organization, so they are expected to demonstrate executive presence, including the demonstration of emotional intelligence. Residents will demonstrate excellent communication, time management, and organizational skills. Residents are asked to be flexible because issues arise unexpectedly within IDS that need to be addressed more emergently. Residents will be involved with issue resolution as deemed appropriate by the preceptor.
Residents are responsible to schedule topic discussions and meetings with preceptor.

Residents will need to organize their time to be able to complete their projects within the rotation time block. This will involve being able to use small blocks of time effectively. Residents may need to use their own time to complete any rotation projects.

Residents need to demonstrate excellent sign-posting skills by keeping their preceptor appraised of the status of projects, activities, and the problem solving they are doing.

Residents will be attending many meetings with department, sponsor, and research leaders. As such, residents need to be actively engaged as appropriate for the meetings and generate questions to discuss with the leaders and preceptors. Residents are expected to identify and follow the progression of issues during the course of the rotation and will be able to make connections between sponsors, IDS stakeholders, and the pharmacy department to facilitate communication. Residents should bring up observations and questions with preceptors for discussion. Residents will keep a journal on rotation to capture their questions, observations, and insights.

Pre-rotation preparation: Residents need to contact the preceptor 2 weeks before the rotation starts to confirm the start date and provide the preceptor any scheduling situations (eg, vacation, appointments) as soon as the resident is planning it.

Readings and preparatory work: Prior to rotation, the resident is expected to read the American Society of Health-System Pharmacists Guidelines for the Management of Investigational Drug Products (Am J Health-Syst Pharm 2018; 75:561-73). A copy of the guidelines will be provided if the resident does not have access to AJHP. The resident should also review the institutional policies and procedures (available on Pulse at https://pulse.utah.edu/site/ids/Pages/default.aspx) related to IDS at University of Utah Health. Complete the review of the procedures and policies during week 1 if they cannot be reviewed prior to rotation.

By the first day of rotation, residents need to complete everything on the, "Rotation Orientation Checklist for Preceptors and Residents." In particular, residents should bring a copy of the customized plan and resident's individual goals for the rotation.

Project/Presentation Description: The resident will have the opportunity to work on a wide range of relevant IDS administrative, quality, safety, or management projects during the rotation. Project opportunities will be driven by current events in IDS, the pharmacy department, or the organization. Presentations may be required depending on the project. Residents will be involved in numerous projects which may include the following:

- Conduct an audit of an area within IDS
- Participate in projects such as a CAPA, gap analysis, root-cause analysis, as needed
• Develop short instructions or update short instructions for a study
• Review and present a study at FAR

During this rotation we will have discussions concerning work-life balance. It is the responsibility of the resident to speak up if they feel they are overwhelmed, have too many projects, or have other things going on that may need adjustments of their schedule or activities. Preceptors want to support the residents, but they cannot always know what is needed unless told/requested.

**Typical Daily/Weekly/Monthly Activities:** Typical hours of operation for the IDS service are 0700 to 1730. The usual time for rotation is 0800 to 1700. However, the resident needs to be flexible based on what is going on in the service and with meetings: early (eg, 0700) or late in the afternoon or evening meetings are likely to happen during the rotation. The schedule will be reviewed every Monday morning to develop a plan for the week and will be adjusted daily (or hourly) as the need arises. Residents will also attend IDS-specific and pharmacy-specific meetings with the IDS pharmacy manager and other preceptors as the need arises. Residents may also observe investigational product logistics including drug accountability processes, participate in short instruction development, prepare for feasibility and administrative review (FAR), IRB and site-initiation meetings, and participate in the review of protocols, treatment plan template and/or investigational drug order templates. Residents may also be asked to notify the appropriate pharmacists via email for IDS medication administration that may occur on weekends or after-hours.

**Resident Progression:** The following describes the usual resident progression during the rotation.

**Time frame**

**Resident progression**

**Pre-rotation and Day 1**
1. Confirm with preceptor starting dates and time for first day.

Required readings: obtain readings and start working through them

- American Society of Health-System Pharmacists (ASHP) Guidelines for the Management of Investigational Drug Products (Am J Health-Syst Pharm 2018; 75:561-73) - complete reading prior to rotation
- Institutional policies and procedures related to IDS (available on Pulse at https://pulse.utah.edu/site/ids/Pages/default.aspx)

2. Come prepared to discuss resident progress to date, goals, and personal objectives for the rotation
3. Review rotation description with preceptor and orient to IDS
4. Check off rotation orientation checklist

**Week 1**
1. Attend selected meetings with preceptors
2. Complete review of institutional policies and procedures related to IDS (available on Pulse at https://pulse.utah.edu/site/ids/Pages/default.aspx) if not completed during prior to rotation
3. Discuss ASHP Guidelines for the Management of Investigational Drug Products
4. Set up additional topic discussions and evaluation appointments
5. Get project assignments as determined by needs of the service and IDS pharmacy manager
6. Apply readings to rotation activities

Week 2
1. Attend selected meetings with preceptors
2. Signpost on projects. Get additional project assignments as needed
3. Topic discussions with preceptor
4. Assess completion of goals for the rotation. Complete 30% or more of the goals for the rotation

Week 3
1. Attend selected meetings with preceptors
2. Topic discussions with preceptor
3. Apply readings to rotation activities
4. Signpost on projects

Week 4
1. Attend selected meetings with preceptors
2. Present selected projects to appropriate stakeholders, if required for project
3. Topic discussions with preceptor
4. Complete all projects and goals for the rotation. Work with RPD to develop a plan to address any areas that need improvement.

Evaluations: The resident will have discussions with the preceptor(s) multiple times per week. The weekly planning meeting (usually Monday morning first thing) will serve as a place for providing feedback to the residents and making adjustments to the rotation as needed. Residents also need to give feedback to the preceptor if anything can help make the rotation better for the residents. Evaluations in PharmAcademic include the following:

- Final summative evaluation (preceptor) - This evaluation will typically occur on the last day of rotation unless the date needs to be changed for various reasons.
- Final self-summative evaluation (resident) – Complete prior to the final evaluation meeting
- Evaluation of learning experience (resident) - Complete prior to the final evaluation meeting
- Preceptor evaluation (resident) - Complete prior to the final evaluation meeting

For all evaluations completed in PharmAcademic, the resident and the preceptor will independently complete the assigned evaluation and save as draft. The resident and the preceptor will then compare and discuss the evaluations. This discussion will provide feedback both on performance of the activities and the accuracy of the resident’s self-assessment skills.
<table>
<thead>
<tr>
<th>Goal R1.1</th>
<th>Lead departmental and/or interdisciplinary teams in the design, implementation, and/or enhancement of a health system's medication-use process.</th>
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</thead>
<tbody>
<tr>
<td>OBJ R1.1.1</td>
<td>Synthesis) Effectively represent the pharmacy perspective on an interdisciplinary team redesigning a selected aspect of the organization's medication-use system.</td>
</tr>
<tr>
<td>Taught and Evaluated</td>
<td>Attend and possibly present at multidisciplinary meetings with the IDS pharmacists or manager (eg, FAR) Help IDS manager set goals for the current and future fiscal years Identify opportunities within the medication-use system to help IDS and interdisciplinary team workflow.</td>
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<tr>
<th>Goal R1.2</th>
<th>Manage the medication distribution process in all locations within the health system where drugs reside.</th>
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<tr>
<td>OBJ R1.2.1</td>
<td>Evaluation) Based on one's own assessment of the pharmacy's drug control systems, contribute any needed recommendations for improvement.</td>
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<tr>
<td>Taught and Evaluated</td>
<td>Conduct a project such as a gap analysis, CAPA, root-cause analysis with preceptor(s) to address identified issues. Shadow IDS pharmacists and identify improvement opportunities within IDS. Update or write new short instructions for a study.</td>
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<tr>
<th>Goal R1.3</th>
<th>Manage a pharmacy's direct patient care services.</th>
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<tr>
<td>OBJ R1.3.1</td>
<td>Evaluation) Based on one’s own assessment of the scope of the pharmacy’s current services for its capacity to meet the needs of all patients served by the health system, identify any needed services.</td>
</tr>
<tr>
<td>Taught and Evaluated</td>
<td>Keep a journal during the rotation to capture questions and observations during meetings with IDS and key stakeholders. Plan for FTE expansion and defense in budget process as appropriate. Shadow IDS pharmacists and identify improvement opportunities within IDS. Update or write new short instructions for a study.</td>
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<th>Goal R2.2</th>
<th>Improve quality using contemporary performance improvement methodology.</th>
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<tbody>
<tr>
<td>OBJ R2.2.1</td>
<td>Synthesis) Participate in a formal performance improvement project utilizing the organization’s process for improving quality.</td>
</tr>
<tr>
<td>Taught and Evaluated</td>
<td>Conduct a project such as a gap analysis, CAPA, root-cause analysis with preceptor(s) to address identified issues.</td>
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<th>Goal R2.4</th>
<th>Understand how to assure pharmacy compliance with legal, regulatory, safety, and accreditation requirements.</th>
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<tr>
<td>OBJ R2.4.1</td>
<td>Comprehension) Explain the components of a departmental system that would assure compliance with applicable legal, regulatory, safety, and accreditation requirements.</td>
</tr>
<tr>
<td>Taught and Evaluated</td>
<td>Conduct a project such as a gap analysis, CAPA, root-cause analysis with preceptor(s) to address identified issues. Discussion of regulations associated with research and IDS. Keep a journal during the rotation to capture questions and observations during meetings with IDS and key stakeholders.</td>
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<th>Goal R2.5</th>
<th>Understand how to coordinate a health system's medication safety oversight program.</th>
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<tr>
<td>OBJ R2.5.1</td>
<td>Comprehension) Explain the components of an effective system for tracking, trending, and reporting adverse drug events (ADEs).</td>
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<tr>
<td>Taught and Evaluated</td>
<td>Attend meetings where part of the discussion focuses on reported RLs and measures taken to improve processes associated with the event Review RLs associated with an investigational product or IDS and define actionable steps, if necessary.</td>
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**Evaluations:**
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<tr>
<th>Evaluation Type</th>
<th>Evaluator</th>
<th>Evaluated</th>
<th>Timing</th>
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<tbody>
<tr>
<td>Summative Evaluation</td>
<td>All Preceptors</td>
<td>Each Resident Taking this Learning Experience</td>
<td>Ending and Quarterly if Needed</td>
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<td>ASHP Preceptor Evaluation</td>
<td>Residents</td>
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<tr>
<td>Management Rotations</td>
<td>All Preceptors</td>
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