

**PGY2 INVESTIGATIONAL DRUGS AND RESEARCH PHARMACY RESIDENCY
UC DAVIS HEALTH
SACRAMENTO, CALIFORNIA**

**PGY2 Investigational Drugs and Research
Residency Program Director:**

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Program Overview:

The Investigational Drugs and Research Pharmacy Residency at the University of California, Davis Medical Center, is a one-year, PGY2 specialty residency in Investigational Drug Services and Research Pharmacy Residency. The residency is supported by the Department of Pharmacy.

The Investigational Drug Services (IDS) is a strong, well-established, and progressive center of excellence at the UC Davis Medical Center. The IDS manages investigational products for a robust portfolio of Phase I, II, and III studies which are conducted through the UC Davis Medical Center hospital, hospital-based clinics, Alpha Stem Cell Clinic, and UC Davis Comprehensive Cancer Center. UC Davis Medical Center is a Level 1 Trauma Center located on the main Sacramento health campus which also houses the CIRM awarded UC Davis Alpha Stem Cell Clinic, the Mind Institute, and the UC Davis Comprehensive Cancer Center. The UC Davis Cancer Center is an NCI-designated Comprehensive Cancer Center as well as a member of the National Comprehensive Cancer Network (NCCN). UC Davis Medical Center is home to the Sacramento Citywide Oncology Phase I Program (SCOPE) and is within the top awarded institutions for NIH funding, with individual researchers within the top percentage of recipients. At UC Davis Medical Center, Investigational Products are dispensed from various pharmacy locations including the main hospital IDS pharmacy, IDS Cancer Center Pharmacy, central IV pharmacy, Inpatient Oncology Pharmacy, outpatient pharmacies, and the UC Davis Cancer Center Infusion Pharmacy. The Investigational Drugs and Research Pharmacy Residency will provide each resident with a comprehensive training and educational experience in clinical trial pharmacy practices.

UC DAVIS HEALTH Pharmacy Department Mission:

UC Davis Health Pharmacy's mission is to provide the highest quality and most cost-effective pharmaceutical care in an environment that fosters efficient patient-focused care, education, and research. Pharmaceutical care services are designed to meet the needs of our customers (primarily patients, nurses, and physicians) in a way that constructively impacts all aspects of the medication use process (assessing, prescribing, dispensing, administering, and monitoring). We will be flexible and proactive in our responsiveness to opportunities and challenges in the dynamic health-care field.

PGY2 Program Purpose:

PGY2 residency programs build upon Doctor of Pharmacy (PharmD) education and PGY1 pharmacy residency training to develop pharmacist practitioners with knowledge, skills, and abilities as defined in the educational competency areas, goals, and objectives for advanced practice areas. Residents who successfully complete PGY2 residency programs are prepared for advanced patient care or other specialized positions, and board certification in the advanced practice area, if available.

Program Design:

The major area of focus is clinical trial management, with an emphasis on patient care, operations, education, research protocols and regulations, as well as leadership and management to support the

complex research enterprise. The care of clinical trial patients is provided in multidisciplinary settings. The PGY2 resident will interact with clinical pharmacists, pharmacy technicians, physicians, nurses, nurse practitioners, clinical research coordinators, business analysts, regulatory coordinators, laboratory technicians, patients, and caregivers to provide comprehensive care to patients enrolled on clinical trials. Daily activities will include coordinating investigational product dispensing, patient counseling, and adherence assessment activities, assessing patients' concomitant medications, providing drug information to physicians, nurses and patients, coordination of clinical trial medications for different phases of care, trial feasibility assessments and budget development, oversight of clinical trials as well as the set-up and the management of the pharmacy study portfolio.

The UC Davis Medical Center PGY2 Investigational Drugs and Research Pharmacy Residency is designed to meet the educational goals and objectives as outlined by the ASHP PGY2 Investigational Drugs and Research Pharmacy Residency Accreditation Standards.

Program Structure:

Example Resident Schedule (subject to change):

Quarter 1	Quarter 2	Quarter 3	Quarter 4
July Orientation/training Intake assessment Establish residency goals/individualized development plan Selection of research/QI project topic Preparation of research/QI protocol Assign project for RPS Performance Improvement (SRC submission) IRB submission Selection of Grand Rounds topic Resident retreat 1 st committee: UC IDS PCT	October Rotation: IDSCC I Conduct data collection Pharmacy week Quarterly self and RPD assessments of longitudinal learning experiences and development plan 2 nd committee: Medication Error Reduction Committee	January Rotation: Elective (TBD; example: Alpha Stem Cell Clinic) Preliminary research/QI project data analysis Quarterly self and RPD assessments of longitudinal learning experiences and development plan 3 rd committee: HOPA IDS Special Interest Group	April Rotation: Protocol Management III Research Week Submit UC Pharmacy Conference abstract with final results Practice final UC Pharmacy Conference presentation Quarterly self and RPD assessments of longitudinal learning experiences and development plan 4 th committee: Clinical Trials Workgroup
August Rotation: IDS Practice Foundations 1 st committee: UC IDS PCT	November Research Week Rotation: IRB/Regulatory + Protocol Management I 2 nd committee: Medication Error Reduction Committee Grand Rounds Presentation	February Rotation: Rotation: Protocol Management II + Scholarship & Precepting Compile and analyze research project results Prepare and present draft research project to RPD & preceptors PGY2 interviews Present RPS Performance Improvement Project	May Rotation: Ambulatory Care (non-Oncology example clinics: Infectious Disease, Pulmonology) UC Pharmacy Conference Complete QI/research manuscript 4 th committee: Clinical Trials Workgroup

		3 rd committee: HOPA IDS Special Interest Group	
September Rotation: IDS I Conduct data collection Pharmacy Research Summit 1 st committee: UC IDS PCT	December Rotation: Cancer Center Infusion Conduct data collection 2 nd committee: Medication Error Reduction Committee Complete data collection Finalize RPS Performance Improvement Project Holiday/PTO	March Rotation: Elective (TBD) + BEACON Prepare UC PC presentation 3 rd committee: HOPA IDS Special Interest Group HOPA Annual Conference (<i>optional</i>)	June Rotation: IDS II or IDSCC II (resident choice) 4 th committee: Clinical Trials Workgroup Manuscript submission End of residency closeout and program improvement evaluation
Longitudinal Activities			
DPS Weekend Coverage		DPS Evening/Block Staffing	
Grand Rounds		Research/QI Project	
IDS BEACON		IDS Pharmacy Practice Management	
Protocol Development		Institutional Review Board (IRB) /Regulatory Affairs	
Research/QI Project			

UC Davis Medical Center PGY2 Investigational Drugs and Research Pharmacy Residency Learning Experiences

The residency learning experiences will primarily be divided into block rotations and longitudinal learning experiences. Most block rotations will be one month in duration. Some rotations may be in 2-4 week increments. Rotation schedules will be determined based on availability and resident interests. Rotation schedules may be adjusted and updated with the resident at each quarterly development plan.

REQUIRED BLOCK ROTATION EXPERIENCES		
Rotation	Duration	Overview
Orientation and IDS Training	Block (1 month)	Orientation to UC Davis Medical Center, pharmacy residency program policies and the specific residency program. Training for IDS Pharmacy Coverage and Department of Pharmacy Service (DPS) Evening Support will occur during this time. Duration may be adjusted based on the resident's previous experience and knowledge of UC Davis Medical Center.
IDS Practice Foundations	Block (1 month)	This rotation provides the resident with a strong overview of the IDS pharmacy practice, including hands on learning for conducting trial feasibility, inventory management, dispensing workflows, set-up and maintenance throughout the trial lifecycle.
Investigational Drug Service I (IDS I)	Block (1 month)	Provides introduction to processes related to dispensing and managing investigational drugs, ERX development, and clinical trials in the non-oncology IDS Pharmacy.
Investigational Drug Service Cancer Center I (IDSCC I)	Block (1 month)	Provides introduction to processes related to dispensing and managing investigational drugs, ERX development, and clinical trials in the IDS Cancer Center Pharmacy. The resident will also attend at least one half-day of a medical oncology clinic (e.g. lung cancer clinic) with a PI to provide an overview of the ambulatory workflow in oncology and clinical trial patient care and observe the relationship to IDSCC operations.
Protocol Management I	Block (1 month)	This rotation immerses the resident in the day-to-day management of the internal medicine and surgery clinical trials portfolio. Areas of focus will include study start-up tasks such as feasibility assessments, fee schedule development, order set development, and ERX creation as well as participation in the maintenance of trials at various points in their lifecycle. Topic discussions will include the budgeting process, Medicare coverage analysis, budgets, contracts, and finance.
Protocol Management II	Block (1 month)	This learning experience builds upon Protocol Management I to provide the resident with experience in the start-up of oncology clinical trials and an introduction to oncology trial maintenance.

Cancer Center Outpatient Infusion	Block (1 month)	Cancer Center Outpatient Infusion will focus on the fundamentals of the Infusion Pharmacy workflow, with an emphasis on oversight of preparation and dispensing of chemotherapy and investigational drugs. The resident will be introduced to the process of reviewing and processing of chemotherapy orders; management and prevention of chemotherapy-related toxicities; medication safety/preventing chemotherapy errors; patient counseling.
Ambulatory Care Clinic (non-Oncology)	Block (1 month)	Ambulatory clinic rotation in a setting with robust pharmacy services and clinical trial study teams. Clinic experiences will be assigned based on the current clinical trial portfolio and ambulatory care service pharmacists to provide exposure to patient populations, clinic workflow, clinical pharmacist services, recruitment, retention, and treatment workflows, study team member roles, and clinical trials treatment. Clinic options may include, but are not limited to: Infectious Disease, Pulmonary Critical Care, Physical Medicine & Rehab, Neurology, or Transplant.
Protocol Management III	Block (1 month)	This learning experience builds upon Protocol Management I and II to provide the resident with a robust, focused experience on managing oncology clinical trials during their active life cycle as well as additional experience setting-up studies and IDS budgets.
Scholarship and Precepting	Block (1 month)	This rotation provides the resident with the opportunity to engage in precepting with other learners (students or residents) and to develop their precepting skills. To run concurrently with another learning experience.
Investigational Drug Service II (IDS II) or IDS Cancer Center II (IDSCC II)	Block (1 month)	The rotation will focus on the coordination and synthesis of activities in the IDS Pharmacy. The emphasis will be focused on review, implementation, modification, and feasibility of clinical trials and pharmacy workflow management while overseeing overall IDS pharmacy operations. This rotation is the capstone of the residency integrating all information learned throughout the year, allowing the resident to showcase their independence and practice autonomously as an IDS pharmacist.

REQUIRED LONGITUDINAL ROTATION EXPERIENCES		
Rotation	Duration	Overview
Research / QI Project	Longitudinal (12 months)	<p>Identification and completion of a research or quality improvement project in clinical interest or departmental need.</p> <p>This includes 10 days for research (divided into 2-5 day blocks) + 3 floating project days. Additional days may be granted at the discretion of the RPD. Attend the UC Collaborative Pharmacy Conference.</p>
Grand Rounds	Longitudinal (12 months)	The resident will provide a high quality and effective educational learning experience for participants in the form of an accredited CE presentation (or equivalent experience).
IDS Pharmacy Practice Management	Longitudinal (12 months)	<p>Longitudinal learning experiences that capture many of the global and leadership/management objectives of the PGY2 IDS & Research Residency training program, including but not limited to IDS service line management, metric analysis, and compliance with USP and BOP requirements. Committee assignments will be included in this LE as well as a process improvement project. The project (e.g. continuous medication use evaluation, or quality improvement initiative) allows the resident to step into the vital role that the IDS pharmacist plays in ensuring research pharmacy services (RPS) are striving for optimal workflows.</p>
Protocol Development	Longitudinal (12 months)	This longitudinal experience allows the resident to participate in the protocol development process with a focus on the pharmaceutical-focused and related portion(s) of the clinical trial.
IDS BEACON	Longitudinal (4 months)	The BEACON block LE offers the resident focused time working during Week 1 with the BEACON IDS pharmacist to develop the foundational knowledge as a precursor to the practical application in the remainder of the longitudinal experience: BEACON protocol development, reviewing content for accuracy, documentation for content development, and validation of the regimens and BEACON plans.
Institutional Review Board (IRB)/Regulatory Affairs	Longitudinal (9 months)	LE provides longitudinal opportunities for practical application of the concentrated IRB/Regulatory Affairs block rotation through attendance at IRB meetings once monthly with a

		<p>participating IRB pharmacist committee member.</p> <p>LE provides a concentrated exposure to topics of informed consent, ethics of human subjects, FDA inspections, the role of the IRB, clinical trial/research compliance procedures, privacy, and responsibilities as well as attendance at IRB with a participating IRB pharmacist committee member and learning about the role of the study team regulatory coordinator.</p>
DPS Coverage: Ambulatory Infusion Pharmacy Services	Longitudinal (12 months)	<p>The resident will provide coverage to a service line within the Department of Pharmacy Services IDS services. Staffing includes being a critical member of the weekend rotation and staffing at least one major and one minor holiday. 272 hours staffing commitment. Experiences may include staffing in the central unit dose area (CUDA), IDS, outpatient infusion services, and/or transitions of care (or other area identified as a service area of need).</p>
DPS Evening/Block Staffing	Longitudinal (12 months)	<p>Evening shifts will provide support to the DPS through experiences in the central unit dose area (CUDA), outpatient infusion services, inpatient oncology satellite pharmacy, the general medicine/surgery and/or transitions of care services (or other area identified as a service area of need). Assigned area may differ by residency year. 120 hour staffing commitment.</p>

ELECTIVE ROTATION EXPERIENCES		
Rotation	Duration	Overview
Protocol Development	Block (2 weeks)	This concentrated experience will provide the resident the opportunity to author the pharmaceutical portion of an oncology investigator-initiated clinical trial.
Alpha Stem Cell Clinic (ASCC)	Block (2 weeks)	This unique opportunity will be a focused learning experience on cellular therapies in which the resident will gain exposure to cellular storage and administration as well as direct patient care in the UC Davis Health California Institute for Regenerative Medicine.
Advanced ASCC	Block (1 month)	This LE provides the resident with an in-depth experience for study set-up, protocol management, and operations management for cellular therapy studies.
Cellular Therapy Service	Block (1 month)	Clinical rotation with the stem cell transplant team. Includes inpatient service and weekly SCT clinic. Focus will be on patients treated with clinical trial regimens.
Inpatient Medical Oncology	Block (1 month)	Clinical rotation with the inpatient medical oncology service. Focus will be on patients treated with clinical trial regimens when possible.
Drug Development	Block (1 month)	This rotation provides the resident with the opportunity to experience the workflows and processes associated drug development at the academic medical center (UC Davis Health).
Oncology Specialty Pharmacy	Block (1 month)	For residents interested in Oncology, this elective will provide opportunities to gain knowledge and practice in the management of patients prescribed at-home, self-administered cancer directed therapy by providers in the Oncology clinic. Residents will actively participate in direct patient care activities and oncology specialty pharmacy operations to provide patient care to adult Hematology/Oncology and Gyn/Onc patients.
IDS Pharmacy Practice Management	Block (1 month)	This learning experience is designed to enhance the longitudinal experience through focused time with the Oncology/ IDS Management Team. The resident will have the opportunity to participate in the day-

		to-day activities associated with service line and practice management that are not feasible to experience during a longitudinal learning experience as well as to have dedicated time for practice management related projects.
Research Quality and Safety	Longitudinal (12 months)	Specialized intermittent experiences to explore incident reports and quality and safety initiatives related to clinical trials and enterprise practices at large.
Pediatric Oncology	Block (1 month)	Clinical rotation with the pediatric oncology outpatient clinic and infusion pharmacy services. The focus of this rotation will be the management of care for pediatric patients enrolled on clinical trials and patients treated per trial.

Elective length may vary if multiple learning experiences are scheduled to fulfill a one month period (e.g, two electives or one week of required rotation plus an elective). Additional elective rotations can be developed based on the clinical trial portfolio available at the time, and the interests of the resident. Any such modification will be noted in the customized development plan.

Additional Opportunities

Based on interest, the clinical trial portfolio, and current therapeutic and trial management advancements, the resident may choose to attend the quarterly Molecular Tumor Board, attend Clinical and Translational Science Center (CTSC) education courses as applicable, and shadow at the Clinical Research Center (CCRC) and the Office of Clinical Research (OCR). Other opportunities identified can be attended with approval from the RPD. These are optional experiences that may be incorporated into the residency year based on resident interest to increase their foundational knowledge and augment their self-driven, independent, professional development.

Assignment of Education Goals and Objectives to Specific Learning Experiences

See learning experiences and objectives outlined in PharmAcademic.

Topic Content:

The UC Davis Medical Center PGY2 Investigational Drugs and Research Pharmacy Residency is designed to provide the resident with a broad range of experiences in a variety of practice settings. Required learning experiences have been designed to meet the content requirements, as outlined in the ASHP PGY2 Investigational Drugs and Research Pharmacy Residency required competency areas, goals and objectives and to provide exposure to the key investigational drugs and research pharmacy residency topic references.

UC Davis Medical Center PGY2 Investigational Drug and Research Resident's Role in Teaching:

UC Davis Medical Center offers many opportunities for both clinical and didactic teaching. The resident will be responsible for assisting preceptors with clerkship teaching for University of California, San Francisco pharmacy students and UC Davis Medical Center PGY1 pharmacy residents. Should the rotations overlap, the resident will assume the primary preceptor role for any UCSF pharmacy students during their last IDS or IDSCC learning experience. The resident will engage in precepting and learning activities during the Scholarship and Precepting Learning Experience.

The PGY2 Investigational Drug and Research Resident can also participate in didactic teaching for clinical research coordinators, study teams, nurses, and pharmacist. In addition, the PGY2 Investigational Drugs and Research Pharmacy Resident may choose to participate in academic teaching, as requested by regional schools of pharmacy, with the approval of the PGY2 Investigational Drugs and Pharmacy Research Residency Program Director.

Residency Research Project:

All UC Davis Medical Center PGY2 residents are required to complete a research project during their residency and present their research at a regional, state, or national conference. In preparation for conducting their research project, the resident will be complete UC Davis Health IRB-required training and certification. The resident will prepare a project proposal, which will be reviewed and approved by the Pharmacy Research Oversight Committee. The resident may also submit their project to the Pharmacy and Therapeutics Committee, Scientific Review Committee (SRC) and the IRB for approval before embarking on their research. The resident will also be provided opportunities to present their research at one or more regional pharmacy residency conferences. Upon completion of the project, the resident will be required to summarize their research project in a manuscript and submit for publication. This will occur during the Research/QI Project Learning Experience.

Grand Rounds: The resident will be required to prepare an ACPE accredited pharmacy grand rounds (or equivalent) presentation on a topic pertaining to emerging therapies, clinical trials, or investigational drugs, based on the resident's interests and per department needs assessment. A presentation, to an external department or entity, that is deemed to be equivalent may be permitted as an alternative with RPD approval. This will occur during the Grand Rounds Learning Experience.

Committee Assignments:

The PGY2 Investigational Drug and Research residents will rotate in quarterly assignments through at least four (4) of the following UC Davis Health Committees: 1) Data Safety Monitoring Committee (DSMC); 2) Medication Error Reduction Committee (MERC); 3) UC IDS Pharmacy Collaborative Team; 4) Hematology Oncology Pharmacist Association (HOPA) IDS Special Interest Group (SIG); 5) BEACON Clinical Trials Workgroup; 6) Society of Research Clinicians (SRC). Committee assignments may be extended or repeated based on resident interest. The resident will be assigned various activities and projects during each committee rotation. Activities may include specific projects, coordinating agendas and minutes, and reviewing documents. The purpose of the resident's committee involvement is to ensure the resident gains exposure to the IDS pharmacist's role in activities related to quality-improvement, study management on a site level, practice standardization, understanding the impact of clinical trials in standard of care practice, medication safety, safe handling of hazardous drugs, guideline development, and assessment/implementation of technology and automation within the institution and pharmacy department. This is part of the Longitudinal IDS Pharmacy Practice Management learning experience.

Professional Development:

The PGY2 Investigational Drug and Research resident is encouraged to maintain an active role in pharmacy professional organizations. The resident is required to attend the Research Pharmacy Summit (RPS), complete the ASHP Investigational Drug Services Certificate, and attend a second professional conference to further develop their clinical interests and areas of research. The resident is also strongly encouraged to join a professional organization with a mission, initiative, or concerted effort to further research pharmacy services (RPS) or Investigational Drug Services (IDS) practices. The resident will be provided with some financial support from the institution and professional leave time to facilitate participation in professional development activities. RPS is captured in the Investigational Drug Service I or Investigational Drug Service Cancer Center I depending on the dates and the ASHP IDS Certificate is captured in the Longitudinal IDS Pharmacy Practice Management learning experiences.

Department of Pharmacy (DPS) Service:

The PGY2 Investigational Drug and Research resident will be expected to provide approximately 400 hours of pharmacy department service. This expectation will be met primarily by providing weekend DPS pharmacy coverage (272 hours) approximately every 3rd weekend plus one major holiday (Thanksgiving,

Christmas Eve, Christmas Day or New Year's Day) and one minor holiday as well as providing 120 hours of evening Department of Pharmacy support. This is accomplished through the DPS Pharmacy Coverage and DPS Evening/Block Staffing learning experiences in the assigned areas.

Required Competencies:

Residents function as licensed pharmacists in patient care activities. As such, minimum knowledge in a variety of areas must be assured. Within one month of starting the Residency, the resident must complete competencies required of all clinical pharmacists, including Basic Life Support (BLS) (and if required for staffing requirements, Advanced Cardiac Life Support (ACLS)). For residents who completed their PGY1 Pharmacy Residency at UC Davis Medical Center, renewal during the PGY2 year will be as outlined by the institution renewal cycles and requirements for competency.

Resident Portfolio:

Each resident must maintain a portfolio containing all information from the residency year including but not limited to: copies of papers and projects done during rotations, lectures given, and other miscellaneous deliverables. The portfolio shall be maintained in PharmAcademic and in the resident's folder on the Pharmacy Department shared drive.

Resident Personnel Policies:

The following policies are located in the Pharmacy Resident Personnel Manual located at <https://health.ucdavis.edu/pharmacy/Residency/>

- Resident Qualifications
- Early Commitment Policy
- Pre-employment drug testing
- Health insurance and benefits
- California pharmacist licensure requirement
- Moonlighting
- Duty hours/tracking of duty hours
- Professional, family, and extended leave policies
- Dismissal policy and consequences of failure to progress