Brigham and Women's Hospital

PGY2 Investigational Drugs and Research Pharmacy Residency

Brief Hospital and Pharmacy Department Overview

Brigham and Women's Hospital, located in Boston's Longwood Medical Area, is an 812-bed nonprofit teaching affiliate of Harvard Medical School and a founding member of Mass General Brigham (formerly Partners HealthCare). In 2022-2023, BWH was named the 14th best hospital in the United States by US News & World Report Honor Roll of America's Best Hospitals. The Department of Pharmacy provides services to inpatient, outpatient, and satellite clinic locations throughout the Boston area. The department is regarded as an innovator and leader in medication safety technology, clinical information systems, and clinical pharmacy services at the local and national level.





General Information

The Department of Pharmacy at Brigham and Women's Hospital offers a one-year, ASHP accredited specialized residency program in investigational drugs and research pharmacy practice. This one-year program is designed to provide advanced training in the area of investigational drug services and human subject research.

Program Fundamentals

The primary emphasis of the investigational drugs and research pharmacy residency is to develop pharmacists with expertise in investigational drugs, human subject research, and clinical trial management. Over the course of the year, the resident will gain experience in the management of human subjects enrolled in clinical trials, lead a comprehensive research project, strengthen their communication skills through formal and informal presentations and interactions with other healthcare providers in a variety of settings, and participate in human research and clinical trial interdisciplinary hospital committees. In addition, the resident will enhance their teaching skills by precepting pharmacy practice residents and students on investigational drug service pharmacy rotations.

Residents will rotate through all aspects of investigational drug services at Brigham and Women's Hospital, as well as rotations through the National Institute of Health and BWH Center for Clinical Investigation.

For additional information on resident learning experiences, additional required activities, application process, and other specific program details please see the Pharmacy Manual. You can also check us out on Instagram @BrighamIDSPharmacy or Twitter @BrighamPharmacy!

Brigham and Women's Hospital and **Investigational Drug Service Overview**

Brigham and Women's Hospital (BWH) is an 800+ bed, tertiary-care, academic medical center in Boston, Massachusetts. It is a nonprofit teaching affiliate of Harvard Medical School and a founding member of Mass General Brigham (MGB): a single, integrated health care system that consists of 16 institutions encompassing a range of health care organizations. MGB is one of the

largest hospital system-based research enterprises in the United States, and is a world-recognized leader in research. The hospital provides a broad range of clinical services and specialties.

The Department of Pharmacy Services is dedicated to placing a priority on patient care and safety, promoting research and education, and integrating technology innovation with clinical services. The department is composed of approximately 200 employees providing services to many different areas, including: inpatient and outpatient services, investigational drug services (IDS),

perioperative area, ambulatory infusion center, sterile products division, infectious diseases, renal, heart, and lung transplant clinics, anticoagulation management service, and emergency

department. The department offers an ASHP-accredited PGY1 general pharmacotherapy residency and six different PGY2 specialty pharmacy residences in infectious diseases, critical care, cardiology, investigational drugs & research, emergency medicine, and thrombosis and hemostasis.

> Investigational Drug Services (IDS) is a division of the Department of Pharmacy Services devoted to the coordination of human drug research activities at BWH. This includes developing procedures to ensure timely and safe drug dispensing, inventory management and accountability, blinding and randomization, meeting with principal investigators and study groups and reviewing protocols as voting members of the MGB Institutional Review Board

(IRB). IDS acts as an informational resource for other BWH pharmacists and clinicians in answering questions and solving dispensing issues with foreign drugs, orphan drugs, continued use of non-FDA approved agents from other institutions and emergency use investigational medications.

BWH IDS supports investigational drug research from 30+ different departments and divisions, managing over 300 active protocols for clinical trials and more than 10,000 clinical trial dispenses annually across all phases of care. Departments supported by BWH IDS include: cancer care, cardiology and heart surgery, infectious disease, endocrinology, gastroenterology, neonatology, neurology and neurosurgery, pulmonology, anesthesiology, rheumatology, urology, and women's and men's health.



PGY2 Investigational Drugs & Research

The BWH pharmacy residency programs are all one-year programs that provide diverse rotations in many areas of specialization and offer experience in the provision of adult patient-centered care. The scheduling of resident rotations includes a combination of required and elective rotations, including orientation, to ensure that the resident is exposed to a variety of patient populations, investigational medications, disease states, range of trial complexity, and interdisciplinary team members.

All PGY2 IDR residents will complete a two-week required orientation learning experience within the BWH IDS Pharmacy Department. This introductory training experience will be used to complete basic onboarding tasks similar to any new IDS staff member. This will also serve to provide administrative insights into the provision of pharmacy services within the hospital and to contribute to perspectives for subsequent participation in operational, clinical and/or administrative project activities.

The standard length of time for a learning experience is one month, with a few exceptions. The Human Research Affairs/Institutional Review Board rotation spans over the course of 6 weeks, and some elective rotations will range between 2 and 4 weeks. The eleven learning experiences listed on page 7 comprise the required residency experiences for the program. After completion of all required rotations, residents will choose 2 final elective rotations of their interest after discussion with program leadership. All required and elective learning experiences are listed on page 7.

For additional information on resident learning experiences, additional required activities, and other specific program details please see the Pharmacy Residency Manual. A full list of pharmacy residency preceptors, including photos and titles can be found here.





Positions Available

- One Domestic
- One International



Duration

One year



Stipend/Benefits

- ~\$66,000
- Health/dental/vision/life insurance
- 403(b) retirement plan
- Paid time off (PTO)

PGY2 Investigational Drugs & Research

Throughout the year, in addition to rotation learning experiences, the PGY2 Investigational Drugs & Research resident will have the opportunity to:

- Visit the National Institute of Health (NIH) headquarters in Bethesda, MD for onboarding and introduction to the Division of Allergy, Immunology and Transplantation. Residents will gain an inside view of how the NIH supports research at large academic medical centers across the globe
- Co-precept pharmacy students on advanced and/or introductory practice pharmacy experience rotations from area Universities
- Collaborate with disease groups and research study teams to provide the highest level of patient care to human research subjects
- Serve as a liaison between the pharmacy, study sponsors, and BWH study teams
- Gain exposure to Dana Farber/Harvard Cancer Center's workflow and research pharmacy management systems
- Choose their own longitudinal project if it fits the institution's needs. Alternatively, they may also pick from proposals that have been peer-reviewed by a pharmacy committee with research experience
- Present their research results at a national conference and and publish in a peer-reviewed journal
- Create or update an investigational drug service pharmacy guideline for BWH or Mass General Brigham (MGB)
- Work alongside the BWH Research Administration teams at the Center for Clinical Investigation where early stages of institutional clinical trial implementation begin
- Become an active, voting member on the Mass General Brigham Institutional Review Board
- Review, analyze, interpret, and implement new clinical trials
- Work with the Human Research Affairs Compliance and Education office to maintain ethical and safety standards for human research subjects and MGB quality assurance programs
- Join the Digital Health eCare (DHeC) team to learn the basics of pharmacy informatics and the important role that informatics pharmacists play in the maintenance of an enterprise EHR system





Current Residents



Donaciano Dominguez, PharmDPGY1: University of California Davis Medical Center
Sacramento, CA



Abdulrahman Jobran Khormi, PharmD
PGY1: University of Illinois Chicago College of Pharmacy
Chicago, IL

Investigational Drugs & Research PGY2



Kevin Zinchuk, PharmD, CCRP

Pharmacy Manager, Investigational Drug Services

PGY-2 Investigational Drugs & Research Residency Program Director kzinchuk@bwh.harvard.edu

Stephanie Manners, PharmD

Clinical Research Pharmacy Specialist, Investigational Drug Services PGY-2 Investigational Drugs & Research Residency Program Coordinator



Helen Karpov, PharmD

Clinical Research Pharmacy Specialist, Investigational Drug Services PGY-2 Investigational Drugs & Research Pharmacy Residency Coordinator

Past BWH PGY-2 Investigational Drugs & Research Residents



Kelly Zhou, PharmD 2024—2025

Clinical Research Pharmacy Specialist, Investigational Drug Services Massachusetts Eye and Ear Infirmary, Boston, MA PGY1: RWJBarnabas Health Jersey City Medical Center



Michaela Myerson, PharmD, BCPS 2023—2024

Manager, Investigational Drug Services NYU Langone Health, New York, NY PGY 1: Mount Sinai Beth Israel

Investigational Drugs & Research Rotations

Required Learning Experiences	Preceptor
Orientation	Kevin Zinchuk, PharmD, CCRP
Investigational Drug Services Operations I*	David Mellace, PharmD
Protocol/Project Management*	Charles Kelly, PharmD
Hematology/Oncology Research Operations I	Kenneth Tran, PharmD, BCPS
Infectious Disease/HIV Vaccine Trial Unit	Stephen Walsh, MD
Human Research Affairs Compliance and Education	Stephanie Manners, PharmD; Helen Karpov,
Office/Institutional Review Board*	PharmD; Benjamin Silverman, MD
Leadership in Investigational Drug Services	Kevin Zinchuk, PharmD, CCRP
BWH Research Administration/Center for Clinical Investigation	Opeyemi Talabi-Oates, MBA
Disease State/Study Team Operations I	Per Primary Investigator of chosen research division
NIH/NIAD: DAIT (Division of Allergy Immunology and Transplantation) Clinical Research Operations	Sanaz Hamrah, PharmD, MHSC
Digital Health eCare (DHeC) Pharmacy Informatics	Victoria Fisher, PharmD
Elective Learning Experiences	Preceptor
Industry	Kelsey Shaulsohn, PharmD
Disease State/Study Team Operations II	Per Primary Investigator of chosen research division
USP (United States Pharmacopeia) Compounding	Per program leadership discretion
Standards/ Investigational Drug Compounding and	
Safety	
Additional options to be determined annually after discussion with resident and program leadership	

Potential Disease State/Study Team Operations Opportunities

BWH AIDS Clinical Trial Group (ACTG)	Division of Allergy and Immunology
Asthma Research Center	Diabetes Clinical Research
Center for Alzheimer's Research and Treatment	The Human Cardiovascular Endocrinology Re-
(CART)	search Group (CERG)
Gastroenterology Research Group	Nephrology (Dialysis) Research Group
Kidney and Pancreas Transplantation Research	Pulmonary Vascular Disease Group
COVID-19 Prevention Trial Network (CoVPN)	HIV Vaccine Trial Network (HVTN)

^{*=} core rotation evaluated as part of longitudinal learning experience

Requirements for Successful Completion of the

- Successfully licensed as a practicing pharmacist in the state of Massachusetts within 120 days from start date.
- Successful completion of program and department orientation as appropriate per resident track (internal vs external residents) as defined in learning experience description.
- Successful completion of all required rotation learning experiences:
 - Orientation
 - Investigational Drug Services Operations*
 - Protocol and Project Management*
 - Hematology/Oncology Research Operations I
 - Infectious Disease/HIV Vaccine Trials Unit
 - Human Research Affairs Compliance and Education Office/Institutional Review Board*

- Leadership in Investigational Drug Services
- BWH Research Administration/Center for Clinical Investigation
- Disease State/Study Team Operations I
- NIH/NIAD: DAIT Clinical Research Operations
- Digital Health eCare (DHeC) Pharmacy Informatics
- Successful completion of 2 elective learning experiences
- Successful completion of all required longitudinal learning experiences:
 - Institutional Review Board
 - Teaching (Student Preceptorship)
 - Investigational Drug Services Residency Project
 - Pharmacy Committee Assignment

- Protocol and Project Management
- Pharmacy Continuing Education Presentation
- Investigational Drug Service Operations and Staffing
- Successfully meet and document the completion of progress of each quarter with residency program director electronically in PharmAcademic
- Successful reached 80% Achieved for Residency with required objectives. Must include required objectives: R1.1.1, R1.3.1, R1.3.3, R2.1.1, R2.2.2, R3.1.2, R3.2.1, R3.2.3, R3.3.1, R4.1.1, R4.2.4, R5.1.1, R5.1.3
- Successful completion of required formal presentations
 - Continuing education program
 - Department or multidisciplinary presentations—#5
 - Presentation of year-long project
- Successful completion of professional practice requirements:
 - Completion of IDS staffing requirements
 - Completion of committee assignment and associated work
 - Documentation of duty hours as appropriate in PharmAcademic
 - Documentation of Benefit Time/Time off in PharmAcademic and/or StaffReady
- Successful completion of year-long protocol management
- Successful completion of Institutional Review Board (IRB) Membership
 - Successfully submitted for membership within 45 days of start date
 - Successfully attend one monthly IRB meeting as a voting member and document meeting date in IRB spreadsheet
- Successful completion of all required documentation:
 - Initial assessment
 - Quarterly self-assessment as part of the Resident Development Plan
 - All learning experiences and preceptor and learning experience evaluations
 - Final assessment of residency and feedback
 - Completion of electronic residency binder with all required documents uploaded into the IDS residency folder and/or PharmAcademic
- Successful completion of other requirements:
 - Attend one regional or national research summit/conference
 - Obtain both Basic Life Support and Advanced Cardiac Life Support certification by the end of residency year
 - Completion of ASHP IDS and/or Teaching Certificate Program
 - Completion of program appendix