

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 specialized residency 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 drug 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 Residency Manual](#). You can also check us out on Twitter [@BrighamPharmacy!](#)

Brigham and Women's Hospital and Investigational Drug Service Overview



Brigham and Women's Hospital (BWH) is an 812-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 including cancer care, cardiology and heart surgery, endocrinology, gastroenterology and GI surgery, geriatric care, obstetrics and gynecology, neonatology, nephrology, neurology and neurosurgery, orthopedics, pulmonology, rheumatology, transplantation, and urology.



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 residencies in [infectious diseases](#), [critical care](#), [cardiology](#), [investigational drugs & research](#), [emergency medicine](#), and [thrombosis and hemostasis](#).

IDS is a division of the Department of Pharmacy Services devoted to the coordination of BWH human drug research activities. 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 Mass General Brigham 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 25+ different departments and divisions, managing over 400 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: Infectious Disease, Hematology/Oncology, Cardiovascular, Pulmonary, Dermatology, Anesthesia, Endocrinology, Gastroenterology, Neurology, and Women's and Men's Health. Study teams are comprised of a principal investigator (PI), co-investigator physicians, clinical research coordinator's (CRC), research nurses, and a primary IDS senior research pharmacist.



PGY2 Investigational Drugs & Research Specific Program Overview

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, medications, disease states, range of complexity, and interdisciplinary team members.

All PGY2 IDR residents will complete a two-week required orientation learning experience with the Brigham and Women's 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 IDS Operations I and Protocol and Project Management will be covered in a single learning experience over the course of 8 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 resident and 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](#)



ASHP Accreditation

- Candidate Status



Positions Available

- One PGY2 position



Duration

- One year
- July 1st — June 27th



Stipend/Benefits

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

PGY2 Investigational Drugs & Research Specific Program Overview

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 PGY1 pharmacy residents and pharmacy students on advanced or introductory practice pharmacy experience rotations
- Collaborate with disease groups and 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 and they are passionate about a particular topic. 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/or 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 the early stages of institutional clinical trial implementation begin
- Become an active, voting member on the Mass General Brigham Institutional Review Board (IRB)
- Review, analyze, interpret, and implement new clinical trials
- Understand the clinical trial phases and drug approval process
- 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



Investigational Drugs & Research PGY2 Residency Leadership Team



Kevin Zinchuk, PharmD

Manager, Investigational Drug Services
PGY2 Investigational Drug & Research Pharmacy Residency
Program Director
kzinchuk@bwh.harvard.edu

Stephanie Manners, PharmD

Senior Research Pharmacist, Investigational Drug Services
PGY2 Investigational Drug & Research Pharmacy Residency Coordinator

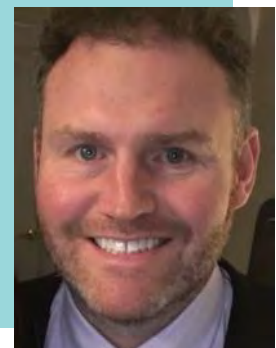


David Mellace, PharmD

Senior Research Pharmacist, Investigational Drug Services
PGY2 Investigational Drug & Research Pharmacy Residency Preceptor

Charles Kelly III, PharmD

Clinical Pharmacy Specialist, Investigational Drug Services
PGY2 Investigational Drug & Research Pharmacy Residency Preceptor



Jon Silverman, PharmD

Director of Pharmacy, IDS & 340B Drug Pricing Program
PGY2 Investigational Drug & Research Pharmacy Residency Preceptor

Investigational Drugs & Research PGY2 Current Resident



Michaela Myerson, PharmD

2023—2024

PGY 1 Mount Sinai Beth Israel New York, NY

Investigational Drugs & Research Rotations

Required Learning Experiences	Preceptor
Orientation	Kevin Zinchuk, PharmD
Investigational Drug Services Operations I*	David Mellace, PharmD
Protocol/Project Management*	Charles Kelly, PharmD
Hematology/Oncology Research Operations I	Kenneth Tran, PharmD
Infectious Disease/HIV Vaccine Trial Unit	Stephen Walsh, MD
Human Research Affairs Compliance and Education Office/Institutional Review Board	Benjamin Silverman, MD
Leadership in Investigational Drug Services	Jon Silverman, BSPHarm, PharmD
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	Jamie Van Kleeck, 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 Standards/ Investigational Drug Compounding and Safety	Caryn Belisle, BSPHarm, MBA, FASHP, FMSHP
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 (CART)	The Human Cardiovascular Endocrinology Research 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)

*= may be completed in a single, combined learning experience

Requirements for Successful Completion of the PGY2 Investigational Drugs & Research Residency Program

- Successfully licensed as a practicing pharmacist in the state of Massachusetts within 120 days from the start date.
- Successful completion of program and department orientation as appropriate per resident track (internal vs external)
 - Orientation
 - Investigational Drug Services Operations I*
 - Protocol/Project Management*
 - Hematology/Oncology Research Operations I
 - Infectious Disease/HIV Vaccine Trial 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
- residents) as defined in learning experience description.
- Successful completion of all required rotation learning experiences:
 - IRB Membership
 - Teaching (Student Preceptorship)
 - Investigational Drug Services Residency Project
 - Pharmacy Committee Assignment
 - IDS Protocol Management Responsibilities
 - Pharmacy Continuing Education Presentation
 - Staffing responsibilities and duty hours
- Successful completion of 2 elective learning experiences
- Successful completion of all required longitudinal learning experiences:
- Successfully meet and document the completion of progress of each quarter with residency program director in the IDR Training Program Spreadsheet
- 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 (#5 total)
 - 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
- Successful completion of year-long protocol management:
 - Create medication entry in Pharmacy Dictionary
 - Adequately build a protocol in IDSIS
 - Request a new or change of IDS medication entry in ServiceNow
- 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
- 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
- Successful completion of other requirements:
 - Attend one regional or national research summit/conference
 - Obtain Basic Life Support and Advanced Cardiac Life Support certification by the end of residency year

*= may be completed in a single, combined learning experience