

Brigham and Women's Hospital

PGY2 Investigational Drug 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 drug 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 major teaching hospital of Harvard Medical School and part of Mass General Brigham (MGB), a single, integrated health care system that consists of 16 institutions that encompass a range of health care organizations. 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. Pharmacists provide clinical and distributive services through an integrated, patient-centered, unit-based, decentralized pharmacy practice model. The department offers an ASHP-accredited PGY1 general pharmacotherapy residency and five different PGY2 specialty pharmacy residencies in infectious diseases, critical care, cardiology, investigational drugs & research, 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, maintaining inventory of investigational drugs, blinding and randomizing drug studies, serving as an information resource regarding investigational drugs and study protocols, meeting with principal investigators and study groups, participating in protocols as co-investigators and reviewing protocols as members of the MGB Institutional Review Board (IRB)

IDS coordinates with research study teams from over 25 different divisions including: Infectious Disease, Hematology/Oncology, Cardiovascular, Pulmonary, Dermatology, Anesthesia, Endocrinology, Gastroenterology, Neurology, and Women's (OB/GYN) and Men's Health. The 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. IDS supports research in inpatient, outpatient and ambulatory setting. IDS also provides support services in conjunction with the BWH Center for Clinical Investigation (CCI). All research pharmacists practicing in IDS serve as active, voting members on the MGB IRB once per month.



PGY2 Investigational Drug & 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 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 except for the Human Research Affairs/ Institutional Review Board rotation, which is a standard six weeks. The eleven learning experiences listed on page 6 comprise the required residency experiences for the program. After completion of all required rotations, residents will choose the final 2 elective rotations of their interest. All required and elective learning experiences are listed on page 6.

For additional information on resident learning experiences, additional required activities, and other specific program details please see the [Pharmacy Residency Manual](#)



- Pre-Candidate Status



- One PGY2 position



- One year
- July 3rd - June 30th



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

PGY2 Investigational Drug & Research Specific Program Overview

Throughout the year, in addition to rotation learning experiences, the PGY2 Investigational Drug & 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 students on advance 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 team
- 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
- 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
- Review, analyze, interpret, and implement new clinical trials
- Understand the clinical trial phases and drug approval process
- Work with the Human Research Affairs and Compliance 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 Drug & 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 Drug & Research Rotations

Orientation	Kevin Zinchuk, PharmD
Investigational Drug Services Operations I	David Mellace, PharmD
Protocol/Project Management	Charles Kelly, PharmD
Hematology/Oncology Research Operations I	Kevin Zinchuk, PharmD
Disease State/Study Team Operations I*	Per Primary Investigator of chosen research division
Human Research Affairs/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 II*	Per Primary Investigator
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
Independent Practice	Kevin Zinchuk, PharmD
Hematology/Oncology Research Operations II	Kevin Zinchuk, PharmD
Investigational Drug Service Operations II	David Mellace, PharmD
USP (United States Pharmacopeia) Compounding Standards/ Investigational Drug Compounding and Safety	Caryn Belisle, BSPHarm, MBA, FASHP, FMSHP
Disease State/Study Team Operations III*	Per Primary Investigator
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)	Dana Farber/Harvard Cancer Center Neuro-Oncology
Gastroenterology Research Group	Nephrology (Dialysis) Research Group
Kidney and Pancreas Transplantation Research	COVID-19 Prevention Network (CoVPN)
HIV Vaccine Trial Network (HVTN)	HIV Prevention Trial Network (HPTN)
The Human Cardiovascular Endocrinology Research Group (CERG)	

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

- Successfully licensed as a practicing pharmacist in the state of Massachusetts by October 1st. If licensure not obtained within 90 days from the state date, the RPD will discuss disciplinary action with the resident.
- Successful completion of program and department orientation as appropriate per resident track as defined in learning experience description.
- Successful completion of all required rotation learning experiences:
 - Investigational Drug Services Operations I
 - Protocol/Project Management
 - Hematology/Oncology Research Operations I
 - Disease State/Study Team Operations I
 - Human Research Affairs/Institutional Review Board
 - Leadership in Investigational Drug Services
 - BWH Research Administration/Center for Clinical Investigation
 - Disease State/Study Team Operations II
 - NIG/NIAD: DAIT Clinical Research Operations
 - Digital Health eCare (DHeC) Pharmacy Informatics
- Successful completion of 1 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
 - IRB Membership
 - Teaching (Student Preceptorship)
 - Investigational Drug Services Residency Project
 - Pharmacy Committee Assignment
 - IDS Protocol Management Responsibilities
 - Pharmacy, Nursing and Physician In-Service Education
 - Staffing responsibilities and duty hours
- 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
 - Pharmacist Huddle - #3
 - Presentation of a clinical pearl at a local, regional, or national conference
 - 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
 - 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 EPIC 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