



INVESTIGATIONAL DRUG SERVICES

ROLE OF OFFICE

The Investigational Drug Service (IDS) provides pharmacy support for research teams that are conducting clinical trials research. The research pharmacists and certified pharmacy technicians support inpatient and outpatient clinical research conducted by investigators from the Johns Hopkins Medicine entities, the Johns Hopkins University, the Johns Hopkins Bloomberg School of Public Health and the Johns Hopkins Clinical Research Network.

Leadership:

Janet Mighty, BS Pharm, MBA, Director of Investigational Drug Services

Jim Monolakis, Pharm.D., Johns Hopkins Bayview Investigational Drug Service Manager

PERFORMANCE IN THE PAST YEAR

Performance Metrics (July 1, 2018 – June 30, 2019)

Metric Description	Osler IDS (Non- Oncology)	Weinberg IDS (Oncology)	Bayview IDS	BPRU Pharmacy	Total
Number of protocols managed	264	389	99	24	776
Number of orders or prescriptions processed	6465	8182	4090	1219	19,956
Number of external monitoring visits	392	711	115	0	1218

CHANGES IN THE PAST YEAR

Investigational Drugs and Research Pharmacy Residency Program (formerly Investigational Drug Services Pharmacy Residency)

In June 2019, Leslie Anforth Pharm.D., the first resident in our Investigational Drugs and Research pharmacy residency program graduated from the program. This two-year, postgraduate pharmacy residency is the first program established in the country to address this unique pharmacy practice area. This training program was established to develop the knowledge, skills, and abilities required to support clinical trials research. The first year is dedicated to building strong clinical skills to provide care for patients, and the second year focuses on pharmacy operations and the infrastructure to support clinical trials research.

Our second resident, Jacqueline Saunders, Pharm.D., graduate of Ferris State University College of Pharmacy, has begun the second year of the program. Joining the residency program this year is Michelle Yu, Pharm.D., graduate of the University of Illinois at Chicago College of Pharmacy.

Research Expansion at Sibley Memorial Hospital

The expansion of oncology research at JH Sibley required the expansion and improvement of pharmacy services to support clinical trials research. A Research Pharmacy Manager, Lucy Chung Pharm.D. and a certified pharmacy technician, Ameha Aynalem joined the staff at Sibley. Over the past year, in addition to supporting the operations of the Investigational Drug Service, the new staff has successfully completed the onboarding process, developed standard operating procedures, and implemented Vestigo® (software for management of investigational products). Along with the other Johns Hopkins pharmacies, Sibley is finalizing renovation plans for compliance with USP <800> and USP <797> regulations. The staff are currently managing 26 active protocols with 12 pending activation within two months.

STAFFING CHANGES

The IDS staff supports research services from two distinct areas of the Johns Hopkins Hospital, Osler IDS supports non-oncology trials and Weinberg Oncology IDS staff supports the oncology trials. At Johns Hopkins Bayview, IDS operations support research from the Central Pharmacy and the Behavior Pharmacology Research Unit (BPRU) locations. Recent changes and appointments are listed below:

The Johns Hopkins Hospital

- Anne Delisa, Pharm.D. continues service to IRB-1 Committee as a voting member and Pharmacy & Therapeutics Liaison.

- Tyrell Schaffer, CPhT joined the Oncology IDS Team as an Inventory Specialist to manage and provide quality assurance activities for the investigational product inventory for that area.
- Dorinne Mettle-Amuah Pharm.D. clinical research pharmacist joined the Oncology IDS Team after completing a PGY1 Pharmacy residency at JH Sibley Memorial Hospital. Dorinne replaces Andrew Phan who relocated to Hawaii.
- Currently recruiting for 2 vacant positions

Johns Hopkins Bayview Medical Center

- Vitaliy Klimov, Pharm.D. joined the Bayview IDS in October 2018 after completing a one year fellowship with the FDA through the Oak Ridge Institute for Science and Education. At the FDA he worked with the Clinical Pharmacology Division II of CDER.

NEW DEVELOPMENTS FOR UPCOMING YEAR

Comprehensive IDS Plan

The expansion of research at the Johns Hopkins Medicine entities has resulted in the development of a comprehensive plan for Investigational Drug Services across the health system. The primary goal of the plan is to develop health-system services for IDS that optimize efficiencies, standardize processes and identify opportunities for achieving excellence. This plan aligns with the Department of Pharmacy strategic plan and the Johns Hopkins Medicine strategic plan FY 2019- FY 2023, *“Push the Boundaries of Science and Education”*. IDS operations, staff development and education, facility design, technology use, medication safety and quality assurance and financial management are all targets for improvements in service.

Renovations

The Osler IDS and Weinberg Oncology pharmacy (which includes Weinberg IDS) locations are finalizing plans for renovations in FY 2020. These planned renovations will expand the current space for operations and drug storage, as well as provide additional space for compounding of sterile preparations for compliance with new regulatory requirements of USP <800> *Hazardous Drugs- Handling in Healthcare Settings* and revised regulation requirements for USP <797> *Pharmaceutical Compounding- Sterile Preparations*. The projected start dates for renovations are November 2019 (Osler IDS) and January 2020 (Weinberg IDS). Post renovations, the Osler IDS Pharmacy that is currently located in Osler 100 will be relocated to the first floor of Blalock. The Weinberg renovations focus primarily on expanded space for compounding sterile hazardous drugs by acquiring additional space adjacent to the pharmacy. The renovations should not impact on how the research teams interact with the IDS.

Expansion of Research

With the expansion of Johns Hopkins at Greenspring, Pavilion III opened in May 2019. Pavilion III houses outpatient clinical and ancillary services and has provided space to add additional services and consolidate services on the Greenspring campus. Current review and analysis indicate an opportunity to expand oncology research at Greenspring. The Weinberg Oncology IDS Pharmacy has begun early phase planning to support operations for future expansion at Greenspring.

Another initiative is exploring the requirements and development of expanded pharmacy services to support Johns Hopkins investigators leading coordinating center activities. Changes in sponsor's operational procedures for management of investigational product supply have prompted the review of pharmacy operations to support clinical trials. This review of current operations also includes a review of regulations both state and federal that affect the management and transport of investigational products.

Johns Hopkins Clinical Research Network

The Director of the Investigational Drug Service is a member of the executive leadership committee of the JHCRN. Ms. Mighty facilitates collaboration and communications regarding operations and strategic priorities of the network. Each network site pharmacy is assigned a Johns Hopkins IDS liaison. A focus for the upcoming year will be site visits and improving collaboration with our pharmacy colleagues.

INCORPORATION OF SERVICES INTO GRANT AND CONTRACTS

Research teams should contact the IDS as they prepare budgets to make certain they incorporate costs of IDS into their grant applications.

BEST WAY TO WORK WITH PROGRAM

Daily interactions between IDS staff and the research teams occur by various means such as phone, email, Epic, and meetings. Staff are open to all forms of communication dependent on the need or urgency of the communication. Information regarding the Weinberg Oncology IDS is available on the CRO website (<http://cro.onc.jhmi.edu>.) The Department of Pharmacy intranet website is under revision and will be available in the future as a resource for additional information. Contact with an IDS pharmacist outside of standard hours of operations is available via CORUS/pager.