



Investigational Drug Service (IDS)

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

Meghan Tolan, Pharm.D., MBA, Operations Manager, Oncology Investigational Drug Service

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

PERFORMANCE IN THE PAST YEAR

Performance Metrics (July 1, 2017 – June 30, 2018)

Metric Description	Osler IDS (Non- Oncology)	Weinberg IDS (Oncology)	Bayview IDS	BPRU Pharmacy	Total
Number of protocols managed	233	380	94	26	733
Number of orders and prescriptions processed	6133	8943	3652	387	19,115
Number of external monitoring visits	298	663	51	5	1017

CHANGES IN THE PAST YEAR

Investigational Drug Services Pharmacy Residency

July 2017 marked the beginning of the Investigational Drug Services Pharmacy Residency Program at Johns Hopkins Hospital. 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. Each new resident entering the program will be assigned a project, aligned with institutional or departmental goals, which will improve or expand pharmacy services for patients enrolled in clinical trials. Our first resident, Leslie Anforth, Pharm.D. began the program in July 2017 after completion of a Doctor of Pharmacy degree at the University of Maryland School of Pharmacy. Leslie has now transitioned into her second year of the program. Our second resident, Jacqueline Saunders, Pharm.D. has just started the first year of the program after completion of a Doctor of Pharmacy degree at Ferris State University.

Skip Viragh Outpatient Cancer Building

The Weinberg Oncology IDS staff, along with the Sidney Kimmel Comprehensive Cancer Center staff, prepared for the opening of the Skip Viragh Outpatient Cancer Building on May 14, 2018. Several months of strategic planning, meetings, and collaboration contributed to the successful opening and transition of pharmacy services for solid tumor patients in Viragh. The Viragh Pharmacy, located on the same floor as the infusion center in this building, serves as a pick-up location for outpatient infusions for research and clinical care patients, as well as for outpatient investigational prescriptions. Preparation and compounding of medications remains in the Weinberg building. Procedures and workflows were implemented to allow for smooth and efficient communication and delivery from the Weinberg building to the Viragh building, including the Advanced Clinical Evaluation (ACE) Program, which requires close collaboration between nursing and pharmacy.

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:

Johns Hopkins Hospital

- In July 2017, Anne Delisa, Pharm.D. was appointed to IRB-1 Committee as a voting member and Pharmacy & Therapeutics Liaison. She replaced Hye Kim, RPh, who served for five years in this position.
- In September 2017, Sasha Beselman, Pharm.D. joined the Osler IDS staff due to the departure of Esther Jeon, Pharm.D.
- Weinberg IDS recently received approval for the addition of an Inventory Specialist Technician to manage and provide quality assurance activities for the investigational product inventory for that area.
- Additional financial support was approved for IDS Pharmacist support for Epic research requirements.

Johns Hopkins Bayview Medical Center

- In September 2017, Sasha Beselman, Pharm.D. transitioned from the Bayview IDS to the JHH IDS.
- In January 2017, Laurie Bienert, RPh, MS, BCPS joined the Bayview IDS to fill a new position that was created to support the continued growth of research on the Bayview Campus.

Currently, one position remains open from Dr. Beselman's departure from Bayview.

NEW DEVELOPMENTS FOR THE UPCOMING YEAR

Strategic Plan

The Department of Pharmacy strategic plan, which aligns with Johns Hopkins Medicine initiatives, includes strategies focused on Biomedical Discovery. Past strategies focused on expansion of services, collaboration and improvement of quality of both research and clinical care. These strategies will be continued in the upcoming year. Due to the expansion of research at the Johns Hopkins Medicine entities, Research and Pharmacy leadership are engaged in the development of a comprehensive plan for Investigational Drug Services across the health system.

Due to expansion of research to Johns Hopkins Sibley Memorial Hospital collaboration has begun to support training, review of operations, implementation of Vestigo® (software for management of Investigational products) and other requirements to standardize and improve the operations of the Investigational Drug Service.

Renovations

The Osler and Weinberg IDS pharmacy locations have plans for renovations in the upcoming year. 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*. The effective date for USP <800> compliance is December 2019.

INCORPORATION OF SERVICES INTO GRANT APPLICATION

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.

Johns Hopkins Bayview Medical Center

Bayview, Investigational Drug Service

Location: 4940 Eastern Avenue, AA bldg. Rm 149

Hours of Operation: 8:00 am – 4:30 pm

Phone: 410-550-2747 / Pager# 410-283-0327

Johns Hopkins Hospital

Osler 100 Investigational Drug Service

Location: Osler 100, Johns Hopkins Hospital

Hours of Operation: 7:30 am - 5:30 pm

Phone: 410-955-6337 / Pager: 410-283-2936

Weinberg Oncology IDS

Location: 2430 Weinberg, Sidney Kimmel Comprehensive Cancer Center

Hours of Operation: 7:00am – 5:00 pm

Phone: 410-502-1036 / Pager: 410-283-8261

Additional information about the Weinberg Oncology IDS is available on the CRO website <http://cro.onc.jhmi.edu>.