

Innovative and Inclusive Approach to Clinical Research Pharmacist Development

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1. Background

Investigational pharmacists are responsible for the proper maintenance, preparation, and documentation of hundreds of investigational drugs, yet post-graduate pharmacists typically do not have access to an in-depth cross-training environment with collaborating research-focused departments. Yale New Haven Hospital (YNHH) is currently one of the leading institutions in the nation for the development and implementation of research pharmacy training, which allows for an opportunity to standardize post-graduate research pharmacy training and cultivate a stronger partnership across all involved in the research endeavor, including integration with the Human Research Protection Program, Institutional Review Board, Yale Cancer Center Clinical Trials Office, Yale Center for Clinical Investigation, and sponsors. Focusing on a more comprehensive, hands-on, and inclusive research-based training for incoming research pharmacy residents will increase interest and engagement of research pharmacists. Additionally, integration and training across ancillary research groups will also improve the collaboration and communication between investigational pharmacists and research teams, thereby improving protocol compliance and patient safety.

2. Goals

There is a need to standardize the pharmacy residency training related to practical application of research. All existing research pharmacists have had onsite training but have not had access to a robust, comprehensive post-graduate program to support safe and compliant research practice. The goal of this partnership is to provide focused, post-graduate Research Pharmacy training with practical application of research, protocol compliance, and patient safety that will further cultivate relationships between researchers and YNHH.

3. Solutions and Methods

The Investigational Drugs and Research Post Graduate Year-2 (PGY-2) Residency offers a year-long, systematic education and training through the American Society for Health-System Pharmacy (ASHP) for new graduates to integrate into research pharmacy services, enabling them to provide highest quality of pharmaceutical care. Standard competencies from ASHP were utilized to address key areas of development for PGY-2 Residents and were addressed via a cross-functional, integrative approach with various stakeholders. Each resident in the year-long rotation spent four weeks in collaborative dedicated areas. At the end of the program, the resident completed an exemplar highlighting the work completed and lessons learned, demonstrating an “expert working knowledge of the clinical research study process, human subject protection, and national and local regulations governing drug research. They are responsible for providing information to the appropriate health care team members including pharmacy staff that may be unfamiliar with the investigational drug product, enabling them to correctly dispense it as described in the clinical protocol and ensure its safe use.” The cumulative experience was captured in PharmAcademic.

4. Outcomes

The pharmacy resident was able to adequately demonstrate a robust understanding of the research endeavor. The resident continued to support and guide study team members following the completion of the program, regularly integrating with the team. Of the two graduates of the program to date, both

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have accepted permanent research pharmacy roles utilizing their experiences from this program.

5. Lessons Learned and Future Directions

The PGY-2 Residency Program has been successful at our site thus far and plans for future pharmacy residents continue. Given the wide integration of the residents with the research teams, our site recommends implementing this program at other sites where available.