*Category: Training, Career Development, and Staff Retention – Work in Progress*

**Adding to the Career Ladder of Clinical Research Staff at IUSCCC**

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**1. Background**

The original staffing model disease-oriented teams (DOT) of the IU Simon Cancer Center (CC) prior to its distinction of Comprehensive Cancer Center included patient facing research staff consisting of physicians and clinical research nurses (CRN). Within each DOT other research roles were non-patient facing focused. The Clinical Trials Office (CTO) has grown in the number of clinical trials overall for which the former staffing model of direct patient facing staff was no longer sustainable.

Staffing shortages and budget constraints during the COVID-19 pandemic left the CTO like many other institutions – short on qualified research nurses. IUSCCC CTO leadership met with leaders across multiple cancer centers across the United States and research units within IU to construct a solution for the use of non-nursing staff within the scope of subject care. The Clinical Research Patient Specialist (CRPS) model was created with the focus of relieving CRN tasks, dividing workload efforts, providing comprehensive care for subjects and efforts to improve staff retention.

**2. Goals**

- Have CRPS be protocol experts for non-therapeutic and therapeutic clinical trials in the clinical setting
- The CRPS and physician work together to accomplish study related assessments in real time
- Allow CRN to focus on high-risk, Phase I, and early development clinical trials
- Increase overall accruals to both non-therapeutic and therapeutic trials

**3. Solutions and Methods**

- Work closely with physicians, CRNs and CRPS to establish expectations and designated responsibilities of each role
- Office-wide source documents were updated to emphasize requirements of both CRPS and CRN/MD
- Standard operating practices (SOPs) were updated to include role-specific information
- Guidance documents and training materials were created for the CRPS role
- A CRPS-specific mentor was added to the Quality and Education Team with experience in the role to enable faster troubleshooting
- Collaborated with IU Health for training specific to the electronic medical record system
- Provide disease specific training and basic assessment skills for the CRPS

**4. Outcomes**

- Twenty CRPS positions have been integrated into DOT
- Over the past two years averaging an increase in accruals
- Successfully integrated the CRPS role into the daily workflow of multiple therapeutic trials at our satellite site
- CRPS managing research patients on non-therapeutic trials

**5. Lessons Learned and Future Directions**

The CRPS model has shown to be effective in relieving responsibilities of CRNs when implemented effectively. Education, training, and trust are imperative for a smooth transition. Across several DOTs the CRPS model have demonstrated to be effective in managing non-treatment/non-therapeutic studies.

Managing workload and integration of CRPSs into existing teams does have some difficulty. Many of the CRPSs have never been patient facing and therefore physicians and nurses must be preceptors. Existing CRNs who are used to managing every aspect of a subject's care are sometimes hesitant to delegate more than menial tasks to a CRPS. There are also limitations to what degree of documentation CRPSs are allowed to complete (collect adverse events [AEs], but not grade or assign relatedness of AEs). Teams who are reluctant to use CRPSs to their full potential will not see more than administrative relief, while teams who fully embrace these collaborations in workflow have a partner in the subject's care rather than an administrative assistant.