

## **Full integration of the Gynecology Oncology Research operations under the IU Simon Cancer Center Clinical Trials Office**

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### **1. Background**

The Clinical Trials Office (CTO) continues to coordinate services, share standard operating procedures (SOPs), and maintain standards of quality for clinical trials with cancer-related studies. Although the CTO services are available to all departments seeking to conduct Cancer related studies, some departments prefer to use their own departmental resources. The GYN Oncology model poses a challenge for accrual goals, maintenance of standardization and quality of clinical research. Full integration of the GYN Oncology research staff under the Clinical Trials Office with the support of GYN Departmental Leadership and new Principal Investigator allows for improvement of clinical research operations.

### **2. Goals**

Fully integrate GYN Oncology clinical trial operations under the direction of the Clinical Trials office:

- Develop a trusting relationship with GYN Oncology Leadership and PIs
- Provide regulatory, clinical and financial responsibilities under the CTO.
- Provide oversight of clinical research activity under the GYN Oncology program.
- Expand GYN Oncology Clinical Trial portfolio and increase clinical trial accruals
- Provide cross-coverage for staff support.

### **3. Solutions and Methods**

- Met with GYN Oncology leadership to understand vision.
- GYN Oncology PI participated in training and overview of the clinical trials office operations.
- Initiated quarterly meetings with GYN Oncology Leadership to review current research activity and address current issues.
- GYN Oncology PIs play key leadership roles within the IUSCC clinical research management and oversight.
- Hired research staff under the CTO and participated in our onboarding and orientation process, which allows us to train on current SOPs.
- Disease oriented teams (DOT) [PIs, Clinical Research Nurses, Clinical Research Specialist, Data Coordinators, Regulatory and Finance] meet on a weekly and monthly basis to review GYN Oncology portfolio.
- Share specific clinical trials metrics to PI and DOT on a monthly basis.

### **4. Outcomes and Future Directions**

- Since full integration the GYN Oncology research operations under the Clinical Trials Office, the clinical trial portfolio has expanded and therapeutic accruals have increased (multifactorial).
- Therapeutic accruals has increased 800% and patient's visits increased 485% for CY 2018.

*Category: Clinical Research Operations – Completed Project*

While we fully integrated the GYN Oncology research operations under the CTO, we continue to monitor clinical research activity on a monthly basis to address workload and expectations. With the support of GYN Oncology leadership and PIs this has allowed for a smooth transition for both departments. We continue to monitor progress and are excited for two new GYN Oncology physicians to join the department in CY2018 and 19 with the goal of exceeding 2018 accrual goals.