Category: Training & Quality Assurance – Completed Project

The Case for a Designated Clinical Research Educator

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1. Background

In a busy clinical trials office with more than 80 staff members, it may be daunting to onboard new staff with the goal of ensuring continued education of current regulations and best practices related to clinical research. This proves particularly challenging given that it is rare that new staff have any previous clinical research experience or a high level of relevant knowledge. Consistency in training (i.e., internal processes and expectations, best practices, etc.) is often also a hurdle. By having designated Clinical Research Educators (CREs), MCW's Cancer Center Clinical Trials Office has been able to provide uniform training across specialties leading to improved adherence to performance expectations and consistent best practices across teams.

2. Goals

The goal of implementing a model with designated CREs was for staff to receive consistent training and messaging. The Cancer Center hoped that staff would feel a sense of support during training, audits, and day-to-day operations.

3. Solutions and Methods

The cancer center CREs provide ongoing education to staff through an onboarding program, which is tailored by position; monthly education seminars; an annual symposium and other specific trainings, as applicable. Methods of teaching include didactic methods, as well as hands-on learning and simulation. The educators also create tools and checklists with the goal of developing uniform intra-department processes. Another unique duty of a cancer center CRE is to assist in distributing and developing learning opportunities that meet continuing education requirements for staff maintaining professional research certifications. This reduces a major burden for staff members (finding applicable courses, obtaining funding/reimbursement, dedicating travel time, etc.), and provides all staff with continued learning opportunities. The CREs also assist staff in preparation for audits.

4. Outcomes and Future Directions

Utilizing dedicated CREs has had a positive impact in the MCW Cancer Center Clinical Trials Office in many areas. For example, during the orientation phase, new staff feel supported by having a main contact and they experience a much smoother and consistent onboarding process when CREs coordinate a majority of the process. This simultaneously decreases the onboarding burden of our experienced staff and reduces variations in training. In addition, audit outcomes have improved significantly as departmental standards and best practices have been developed and enforced. This includes fewer major and minor findings and auditors praising the consistency of documentation practices. The monthly educational opportunities developed by CREs have made it easier for staff to obtain educational credits and maintain their research certifications. Educators also have become resources to our entire department beyond the onboarding process by developing standard operating

procedures and guidelines, and providing day-to-day assistance as needed (i.e., troubleshooting, facilitating questions regarding internal processes, required trainings, etc.).

The implementation of CREs has proven to be a successful model for the MCW Cancer Center Clinical Trials Office. Other departments have sought out the CREs as resources for their own staff training and education. Our CREs also have collaborated on campus-wide education initiatives. Having designated educators has promoted a consistent culture of clinical research best practices within the MCW Cancer Center Clinical Trials Office.