The Case for a Designated Clinical Research Educator

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Purpose

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.

Methods and Materials

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 and the development of Corrective and Preventative Action Plans.

Results

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 documentation practices. The monthly educational opportunities developed by CREs have made it easier for staff to obtain educational credits and maintain their research documentation practices.

Conclusions & Discussion

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.

Onboarding Curriculum

All Staff

- General topics (Weeks 1-2)
- Oncology and clinical trials basics
- General workflows and ancillary services
- The flow of a new study (e.g., Confidentiality Disclosure Agreements, Disease Oriented Team, Scientific Review Committee, DSMC, etc.)
- Training for the Clinical Trial Management System and other applicable software/databases
- Anatomy of a protocol and source documentation
- Documentation per GCP, FDA regulations, and internal expectations
- Review department Standard Operating Procedures and guidelines
- Preceptor assignment
- Shadowing opportunities (e.g., Translational Research Unit, Investigational Drug Services (IDS), research lab staff, etc.)

Clinical Research Assistants, Coordinators, and Nurses

- Electronic Medical Record training including oncology specific workflows
- IRB reporting
- Informed consent process
- Workflows for subject screening, enrollment, and study visits
- Workflows with ancillary departments (e.g., compliance, imaging, lab, IDS, etc.)

Regulatory Coordinators and Specialists

- New study submission process including:
  - IRB submission
  - Workflows with ancillary departments (e.g., safety committees, budget and contract team, compliance, etc.)
  - Informed Consent Form preparation
  - Execution of essential documents
  - Guidance in working with sponsors and Clinical Research Organizations
  - IRB submissions of amendments, annual reviews, and reportable events

Competency Evaluations

- 4-6 months into employment
- Review a subject shadow chart or regulatory binder completed by new staff
- Assess independence and proficiency of workflows and tasks covered during onboarding

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