Category: Training & Quality Assurance – Work in Progress

Winship Clinical Trials Office CRC/CRN and Data Manager Orientation Program

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1. Background

Winship Clinical Trials Office (CTO) CRC/CRN and data manager orientation program was originally developed and implemented in December 2010. During years of leading the orientation program, the Quality Management (QM) Team has received extensive feedback from CRC/CRN. While some opinions of the program were positive, many CRC/CRN and data managers expressed stress and frustration due to the lack of practical training and support, and felt unprepared to perform independent research-related activities at the end of the orientation.

In August 2018, QM team revamped the orientation and training program by adopting a multidisciplinary approach, involving team supervisors and mentors, investigators and other experts from different research fields.

We have created a new flow for the orientation program. The new hires start with their team, are greeted by the mentor and receive an orientation binder. During the early weeks they complete mandatory online courses, shadowing their mentor. After being at Winship CTO for at least three weeks, they attend the 2-day Winship Clinical Trials Orientation Class that provides a comprehensive introduction to clinical research and the job functions of the CRC/CRN and data manager for cancer-related clinical trials. The course is conducted in the classroom setting. Winship clinical trials standard operating procedures, case studies, and research best practices are presented to emphasize how the learning objectives apply directly to the responsibilities of the CRC/CRN and data manager. After completing the class, they return to their team to shadow another team member followed by completing the mentor-guided competency assessment. If found competent, assuming they have completed all mandatory credentialing requirements, the new CRC/CRN or data manager can start consenting subjects independently. The first subject enrolled in any study by a new CRC/CRN will receive a real-time QA/QC audit until competency is determined.

We provide continuing education to our research staff in the form of educational seminars and training sessions, such as "Critical Updates for Clinical Research," "SOP Made Simple" sessions, "Oncology Educational Sessions," where staff can receive CMEs for attending.

2. Goals

Goals:

We hope to provide comprehensive support throughout the orientation process, verify competency before CRC/CRN and data managers can perform essential research-related activities independently. We expect to see an increase in job satisfaction and confidence and a decrease in deviations and errors that are due to new CRC/CRN and data managers' lack of basic oncology knowledge, basic clinical trials knowledge, Winship Clinical Trials SOP, and GCP.

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3. Solutions and Methods

Methods implemented:

- Orientation binder for the new CRC/CRN and data specialist
- "Winship Clinical Trials 2-day Orientation Class"
- Mentor-guided competencies
- Clinical trials "Post-Orientation Workshop" for New Hires
- "Oncology Educational Sessions" for Clinical Trials Office staff (CME credits available)
- "SOP Made Simple" quarterly sessions
- 1st Chart QM review of each new CRC/CRN
- 1st data entry case review of each new data manager
- Orientation tracker to keep up with progress of each new CRC/CRN and data manager
- Post-Orientation survey (confidential) to get feedback from each new hire

4. Outcomes and Future Directions

Future directions:

- Reference manual for the new Winship Clinical Trials Office Team Supervisors
- Widen the scope for an orientation program to include orientation for Winship Clinical Trials Office regulatory specialists