Winship Clinical Trials Office CRC/CRN and Data Manager Orientation Multidisciplinary Approach

Tatiana Kurilo Jacquis Presley
Quality Management and Education

Aim Statement

Goal: To provide a comprehensive, multidisciplinary value based orientation and training program for clinical research coordinators (CRC), clinical research nurses (CRN) and data managers who are involved in the management of subjects who participate in Winship cancer-related clinical research trials. To ensure subject safety, foster a culture of responsibility, and ensure high quality research in accordance with ethical principles, federal regulations and Institutional policies.

Winship Clinical Trials 2-Day Orientation Training Class

The 2-day CRC/CRN and data manager orientation class provides a comprehensive introduction to clinical research and the job functions of the CRC, CRN and data manager for Winship 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.

Learning Objectives

- Understand the roles and responsibilities of CRC/CRN and data manager
- Define essential processes involved in clinical research, such as informed consent process, eligibility, adverse events capture and reporting, deviations, etc.
- Understand the requirements for source documentation, case report forms, study tools, forms and logs, and SOP
- Discuss regulatory compliance and quality assurance as it relates to CRC/CRN and data manager practices

Who Should Attend

- New CRC/CRN and data managers who have been in Winship CTO for at least four weeks from the date of hire
- Non-CTO CRC/CRN and data managers involved in conduction of Winship cancer-related clinical trials

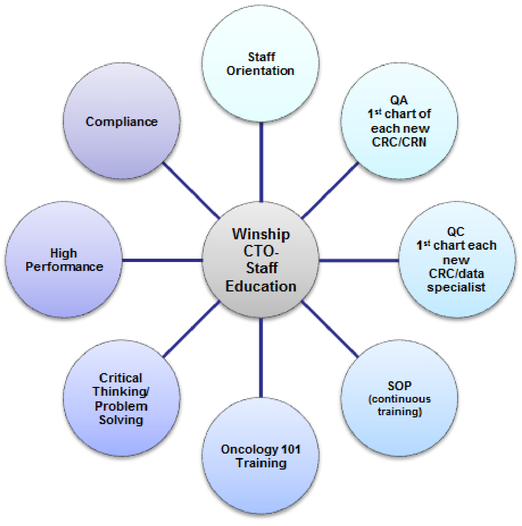
Tools

- Orientation binder (paper and electronic format)
- PowerPoint presentations, videos
- Webinars
- Case studies and discussion
- Role play

Metrics

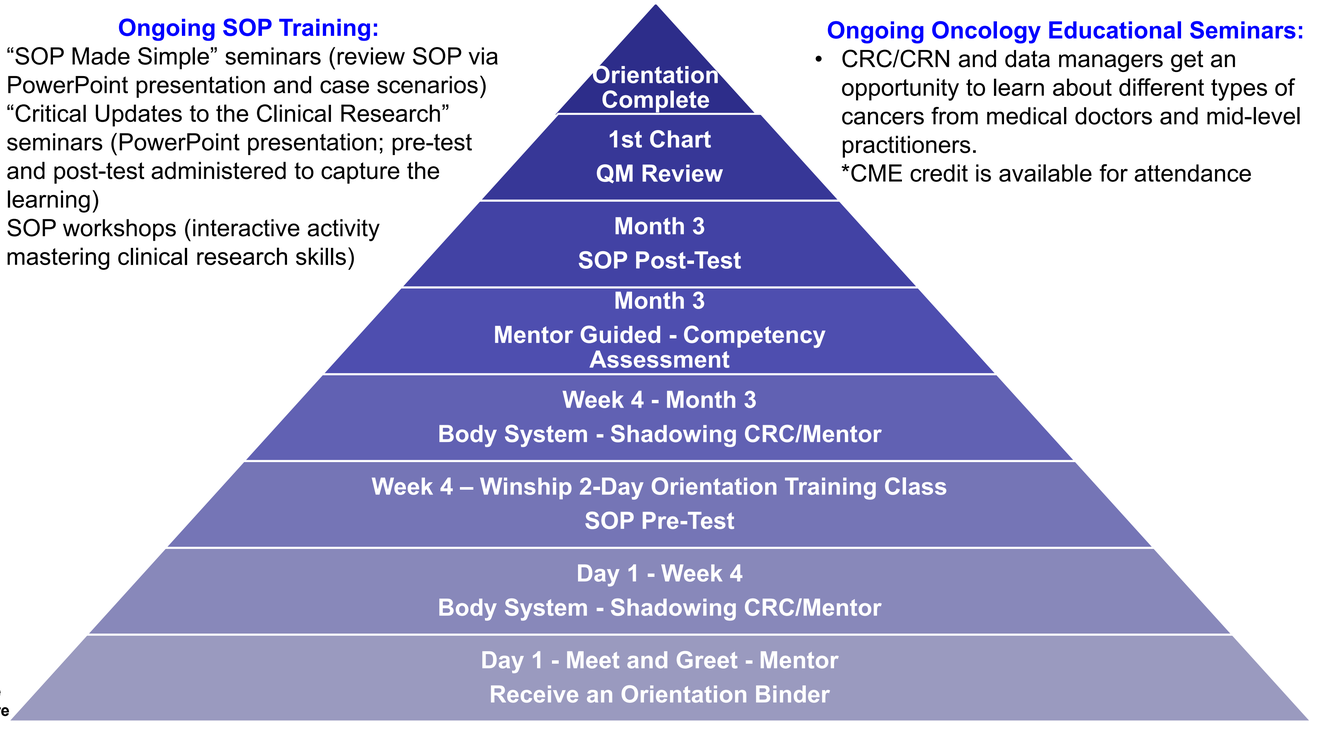
- Core competency skills assessment
- Mentor competency skills assessment
- Skills assessment testing
- Pre- and post-SOP training test
- Deviation prevention rate
- Staff retention

CRC/CRN Orientation Process



Ongoing SOP Training:

- "SOP Made Simple" seminars (review SOP via PowerPoint presentation and case scenarios)
- "Critical Updates to the Clinical Research" seminars (PowerPoint presentation; pre-test and post-test administered to capture the learning)
- SOP workshops (interactive activity mastering clinical research skills)



Ongoing Oncology Educational Seminars:

- CRC/CRN and data managers get an opportunity to learn about different types of cancers from medical doctors and mid-level practitioners.
  *CME credit is available for attendance

Course Outline

Day	Training
Day 1	Welcome to Winship – Training Schedule Overview
Day 1	Orientation Binder Review & Helpful Reminders
Day 1	SOP Review, Credentialing Application Requirements
Day 1	SOP 3.5 Reporting Unanticipated Problems/Adverse Events SOP 4.3 Protocol Deviations
Day 1	IRB/Regulatory Training
Day 1	SOP 2.1 Obtaining Informed Consent for Greater than Minimal Risk Interventional Trials SOP 2.2 Obtaining Informed Consent for Minimal Risk Interventional and Non-Interventional Clinical Trials
Day 1	SOP 3.13 Central Subject Registration
Day 1	SOP 3.2 Determining Eligibility for Clinical Trials
Day 1	SOP 4.1 Managing Research Records SOP 4.2 Data Completion Metrics
Day 1	OnCore Training
Day 1	SOP 3.0 Reproductive Status Assessment and Pregnancy Testing
Day 1	ECG Training
Day 2	Welcome/Schedule Overview
Day 2	CTRC Training
Day 2	DSMC Training
Day 2	How to Read and Understand Clinical Trial Protocols
Day 2	SOP 5.2 Opening a Clinical Trial to Accrual Study Activation Checklist
Day 2	SOP 3.4 Preparing a subject for a visit Assembling Lab Kits
Day 2	PIMS Training
Day 2	Research Tubes and Research Lab Policies
Day 2	PowerChart Training
Day 2	Cooperative Group Training
Day 2	SOP 3.8 Screen Fails
Day 2	QM Training - SOP Test