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

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

Course Outline

Day 1
Welcome to Winship – Training Schedule Overview
Orientation Complete
1st Chart
QM Review
Month 3
SOP Post-Test
Month 3
Mentor Guided - Competency Assessment
Week 4 - Month 3
Body System - Shadowing CRC/Mentor
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

Week 4 – Winship 2-Day Orientation Training Class
SOP Pre-Test
Day 1 - Week 4
Body System - Shadowing CRC/Mentor
Day 1 - Meet and Greet - Mentor
Receive an Orientation Binder
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)

Day 2
Welcome/Schedule Overview
CTRC Training
DSMC Training
How to Read and Understand Clinical Trial Protocols
SOP 5.2 Opening a Clinical Trial to Accrual Study Activation Checklist
SOP 3.4 Preparing a subject for a visit Assembling Lab Kits
PIMS Training
Research Tubes and Research Lab Policies
PowerChart Training
Cooperative Group Training
Screen Fails
QM Training - SOP Test
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