The Role of the Clinical Trials Nurse

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Objectives

• Discuss the clinical trials nurse’s involvement in protocol development.
• Discuss activities associated with study coordination.
• Analyze various activities related to oncology clinical trials management and what member of the research team may best be suited to carry out a specific activity.

CTN: Protocol Development

• Protocol review
• Protocol writing
• Protocol implementation
CTN: Protocol Review

- When to review - time points
- What to review
  - Implementation aspects
  - Discrepancies
  - Informed Consent document
- Impact of CTN input

CTN: Protocol Writing

- Use of templates
- What sections appropriate for CTN to write

CTN: Protocol Implementation

- Assist with screening, enrollment, and medical evaluations
- Review clinical laboratory findings and make correlations with clinical events
- Manage reporting of adverse events
- Oversee clinical aspects of study
- Conduct clinical rounds
- Direct patient care
What is a Clinical Research Coordinator (CRC)?

• Specialized research professional
  – Manages daily operations of a clinical investigation
  – Works with and under the direction of the PI whose research activities are conducted under Good Clinical Practice (GCP)
  – Plays a critical role in the study conduct
  – Has a wide range of responsibilities

Advantages of having a CRC

• Increase recruitment rate
• Enhancement of retention
• Good data quality
• Increases general study efficiency

Research Team Members

• Principal Investigator
• Associate, Sub, or Co-investigators
• Statistician
• Research Nurse/Clinical Trials Nurse
• Study Coordinator/Clinical Research Coordinator
• Data Manager
• Participant/Subject
• "Support" Staff
All staff involved in clinical research must adhere to the regulations and understand the guidelines that govern clinical research.

**CRC Responsibilities: Overview**

- Advocacy
- Feasibility assessment
- Informed Consent
- Study management
- Documentation
- Education

**CRC’s Role in Human Subjects Protection**

- Patient advocacy
  - Patient’s welfare
- Subject advocacy
  - Rights and welfare of individuals as research subject
- Study advocacy
  - Advancing research goals
  - Gather valid, clean data
- Roles must be balanced

Davis et al, 2002
Feasibility Assessment

- Review protocol while under development
- Review eligibility requirements
- Assess ability to meet study milestones
- Assess resources necessary to conduct the study (personnel, physical space, and materials)
- Assess financial feasibility

Informed Consent Process

- Interact with the investigator, sponsor (if appropriate) and/or IRB on informed consent wording issues
- Review informed consent document for quality and completeness
- Obtain informed consent
- Coordinate the re-consent process as needed

Study Management...

- Maintain integrity of the protocol
- Recruit, contact and screen potential subjects
- Schedule subject visits
- Prepare for each subject visit
- Assist investigator with study subject visits
- Collaborate with other departments as necessary and participate in problem solving
...Study Management...

- Documentation
  - Patient data
  - Deviations & violations
- Ensure that all necessary data are gathered and recorded in the appropriate case report forms
- Review case report form entries for completeness, appropriateness and logic
- Develop data QA/AC plan(s)

...Study Management

- Schedule sponsor visits
- Work with monitors during monitoring visits
- Ensure drug/device accountability
- Reorder study supplies as necessary
- Assist investigator with financial aspects of the trial, including budgeting/contracts, and payments to study subjects,
- Complete study closeout activities

Education...

- Patient/Subject
  - Disease
  - Clinical Trials & Research: phases, patient role
  - Importance of compliance with treatment and procedures
  - Specific protocol for patient
    - Study objectives
    - Schema: calendars & visual aids
    - Side effects & management
  - Expectations for patient
    - cure, control, palliation or no benefit?
...Education...

- “Support” staff
  - Schedule in-services for all appropriate nursing units
  - Present information in a concise manner focusing on what the clinical nurses need to know (drug administration and PKs)
  - Provide worksheets, as appropriate
  - Keep staff informed about amendment and general protocol progress

...Education

- Self
  - Know your protocol basics
  - Know your diseases being studied
  - Be your own advocate
    - Protect your time & get organized
    - Learn as much as you can about: clinical trials, oncology, your particular drug(s), your database/software programs
    - Know how/where to get training & do it
    - Join a professional organization & get involved


