Roles and Responsibilities of the Research Team Module
Part 2: Clinical Trials Team Members

Slides from: Elizabeth Ness, RN, MS, Nurse Consultant (Education); Maureen Edgerly, RN, MA, Senior Research Nurse Center for Cancer, NCI
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Agenda

- Research Participant
- Research Nurse
- Study Coordinator
- Data Manager

Research Participant Responsibilities…

- Respect research staff and other participants
- Read the consent form and other documents
- Ask questions if they do not understand something about the study, their rights and responsibilities
- Carefully weigh the risks and benefits when deciding whether to participate in the study
- Refrain from signing the consent document until they understand its content and feel comfortable with their decision to participate

Resnik & Ness (2012)

… Research Participant Responsibilities…

- Follow directions for all protocol related procedure include those associated with self-administered study medications
- Know when the study begins and ends.
  - Particularly important for an intervention trial that has a follow-up period after the intervention is completed
- Show up at scheduled appointments on time, and inform the staff within a reasonable time if they need to reschedule

Resnik & Ness (2012)

… Research Participant Responsibilities…

- Provide truthful answers to questions asked throughout the study
- Inform staff if other medical care is needed while on the study
- Inform the staff if there are questions they would rather not answer
- Report pain, discomfort, nausea, dizziness and other problems and symptoms they experience during the study.

Resnik & Ness (2012)

… Research Participant Responsibilities

- Keep information about the study confidential, if asked to do so
- Keep staff informed when contact information changes
- If they decide to withdraw from the study, inform the staff and follow the procedures for withdrawal

Resnik & Ness (2012)

Nursing Roles in Clinical Trials

Traditional Roles

- Principal Investigator
- Nurse Scientist
- Research Nurse
- Direct Care Nurse

Less Traditional Roles

- Manager/Administrator
- Educator
- Monitor
- Regulatory Specialist
- IRB Administrator
- Director HSP Program

Research Nurse Responsibilities…

- Licensure responsibilities
- Coordinate study:
  - Recruiting
  - Screening and scheduling patients
  - Securing informed consent
  - Study conduct
  - Initiation, monitoring and close-out visits
  - Coordination of lab pick-ups, supplies
- Maintain integrity of protocol
- Maintain regulatory files

…Research Nurse Responsibilities…

- Assist PI in preparing protocols & consent for initial review, continuing review & amendments
- Report adverse events expeditiously
- Maintain participant records & documentation
- Clinical care, drug prep & administration
- Data management & QA

…Research Nurse Responsibilities…

- Teach participants
- Teach staff
- Abstract, analyze & publish findings with PI
- Stay informed of new information regarding investigational agent
- Prepare & facilitate monitoring of trials
  - Resolve discrepancies, common goals/time lines

…Research Nurse Responsibilities

- Anticipate the deadlines & data needed
  - IRB
  - FDA
  - Professional meeting abstracts
  - Audit/monitoring visits
- Review previous publications & reports
  - Data tables, charts, graphs, scan images
- Mentor other research nurses

Clinical Research Coordinator (CRC)

- Similar to the Research Nurse minus the licensure responsibilities
- Will vary, often more regulatory versus clinical

Clinical Data Management Activities

- Data acquisition/collection
- Data abstraction/extraction
- Data processing/coding
- Data analysis
- Data transmission
- Data storage/security
- Data privacy
- Data quality assurance

Clinical Data Management Staff

- Biostatisticians
- Database programmers /Iformaticists
- Research Nurses/Study Coordinators
- Investigators/Medical monitor
- Monitors
- Support personnel
- Clinical Data Managers

Clinical Data Manager (CDM) Responsibilities

- Collects source documents needed for data abstraction
- Assists in the development of case report forms (CRF)
- Abstracts research data from patient's medical record/source documents to the CRFs
- Assists in preparation for audits/ monitoring visits

Pharmacist Responsibilities

- Prepares drugs as per protocol
- Stores investigational products as per protocol
  - For multiple studies using same IND agent, needs to provide separate/distinct storage in pharmacy
- Maintains accurate drug accountability records
  - Receipts of drug shipment/invoices
  - Drug accountability record forms/database

Regardless of Your Role: Be Your Own Best Advocate

- Protect your time & get organized
- Learn as much as you can about:
  - clinical trials
  - Disease/condition
  - your particular drug(s)/device
  - your database/software programs
- Know how/where to get training & do it
- Join a professional organization & get involved