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

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 procedures 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

<table>
<thead>
<tr>
<th>Traditional Roles</th>
<th>Less Traditional Roles</th>
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<tbody>
<tr>
<td>Principal Investigator</td>
<td>Manager/Administrator</td>
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<tr>
<td>Nurse Scientist</td>
<td>Educator</td>
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<tr>
<td>Research Nurse</td>
<td>Monitor</td>
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<tr>
<td>Direct Care Nurse</td>
<td>Regulatory Specialist</td>
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<td>IRB Administrator</td>
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<td>Director HSP Program</td>
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### 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 /Informaticists
- 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