Implementation of a Competency Based Educational Program For Bedside Clinical Research Nurses at a Major United States Clinical Research Hospital

2014 IACRN Annual Conference

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Disclosure

I have no conflicts of interest to disclose with this presentation.
Objectives

1. Describe the current gap that exists for role specific standardized education, training, and competencies for the bedside Clinical Research Nurse

2. Discuss the framework that was used to develop the NIH Clinical Center Nursing Department Clinical Research Nursing Competency Based Educational Program

3. Describe the core components of the Clinical Research Nursing Competency Based Educational Program

4. Discuss evaluation strategies that were used to evaluate the educational program
NIH Clinical Center: America’s Research Hospital

- Supports intramural clinical research conducted by the Institutes and Centers of the NIH
- Creates and disseminates standards and innovations for conducting clinical research
- Creates and demonstrates models for clinical research training and career development for all disciplines
Nursing Practice at the NIH Clinical Center

- Acute care hospital and ambulatory care center with over 600 direct care CRNs
- An additional 230+ RNs work with investigators as research nurse coordinators
- Staffed at a level to support precision in patient care and data collection
- Clinical care requirements are protocol-driven
Validating the Clinical Research Nursing Domain of Practice

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Defining Clinical Research Nursing Practice: Results of a Role Delineation Study


Clinical research nursing: A critical resource in the national research enterprise

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Clinical Research Nursing
Domain of Practice
Competency Based Educational Program
Clinical Research Nursing
Domain of Practice Core Competencies

- Clinical Practice
- Study Management
- Care Coordination & Continuity
- Human Subjects Protection
- Contributing to the Science
### Competency: Study Management

Management of clinical and research support activities in order to assure patient safety, address clinical needs and assure protocol integrity and accurate data collection.

<table>
<thead>
<tr>
<th>Behavioral Indicators</th>
<th>Self-Evaluation</th>
<th>Assessment Method</th>
<th>Validator’s Initials/Date</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>1. Describe the following research terms:</td>
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<tr>
<td>a. basic / bench research</td>
<td>1 2 3 4</td>
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<td>b. clinical research</td>
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<tr>
<td>c. translational research</td>
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<tr>
<td>d. experimental research</td>
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<tr>
<td>e. random assignment</td>
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<tr>
<td>f. control group</td>
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<tr>
<td>g. blinding (single / double)</td>
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<td>h. dose-escalation</td>
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<tr>
<td>i. non-experimental research</td>
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<td>j. observational research</td>
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<td>k. therapeutic misconception</td>
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<td>2. Describe common types of protocols implemented at the Clinical Center:</td>
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<td>a. screening</td>
<td>1 2 3 4</td>
<td>T &amp; V</td>
<td></td>
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</tr>
<tr>
<td>b. natural history</td>
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<tr>
<td>c. clinical trials (I – IV)</td>
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<tr>
<td>d. pharmacokinetics / dynamics</td>
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<tr>
<td>e. training</td>
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<tr>
<td>3. Describe the process of protocol review and approval</td>
<td>1 2 3 4</td>
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<td>4. Describe what constitutes Good Clinical (Research) Practice</td>
<td>1 2 3 4</td>
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NIH Clinical Center
Nursing Department

Fundamentals of Clinical Research for the Clinical Research Nurse

January 29 & 30, 2014
CLINICAL RESEARCH NURSING
DOMAIN OF PRACTICE
COMPETENCIES
FACILITATOR GUIDE

WELCOME TO THE CLINICAL RESEARCH NURSING DOMAIN OF PRACTICE COMPETENCIES FACILITATOR GUIDE. IN THIS GUIDE YOU WILL BE PROVIDED THE INFORMATION AND ACTIVITIES NECESSARY TO HAVE A NURSE COMPLETE LEVEL III CLINICAL RESEARCH NURSING DOMAIN OF PRACTICE COMPETENCIES.

DEVELOPED BY THE CRN COMPETENCIES AND EDUCATION WORKGROUP
FOR QUESTIONS PLEASE CONTACT JULIE KOHN AT KohnJ@cc.nih.gov OR 301-451-1168
INDICATOR #7: DESCRIBE THE ESSENTIAL ELEMENTS OF A RESEARCH PROTOCOL AND THE IMPORTANCE OF EACH ELEMENT IN RELATION TO THE ROLE OF A CRN T & D

***NURSE AND FACILITATOR AGREE ON PROTOCOL SELECTION FOR PROTOCOL ANALYSIS WORKSHEET ACTIVITY.

☑️ For successful validation, the nurse must:

- Complete protocol analysis worksheet activity on their own time (facilitator reviews protocol worksheet with the nurse)
- Demonstrate the ability to retrieve relevant and accurate information from the protocol as it pertains to each section of the protocol worksheet
- Successfully answer the clinical research course test questions related to the concept above. May use the test questions for review or to revalidate individual in person.

Resources:
- CRN Fundamentals Course Module: Basics of Clinical Research (binder tab 4)
- Protocol Analysis Worksheet, Appendix C

Study Management Indicator #7 Test Questions:

The section of the protocol that provides a brief description of what the research is about and includes a statement of significance is the:

a. Précis
b. Introduction
c. Design & Methods
d. Objectives

The section of the protocol that would provide the nurse with the procedures, labs and tests to be done on a research participant would be the:

a. Précis
b. Introduction
c. Design & Methods
d. Objectives
Appendix C: Protocol Analysis Worksheet

Nursing and Patient Care Services

PROTOCOL ANALYSIS WORKSHEET

This protocol analysis activity is meant to stimulate critical thinking to help nurses begin to understand how to read a protocol in order to retrieve important information related to the care of their research participants. Answers to items on this worksheet may not always be clear. The activity will generate discussion and possibly questions that can then be taken back to the research team for clarification and further dialogue.

*** If possible, an interventional research protocol should be used for this activity. If nurses in your patient care area do not provide care to patients on interventional protocols then please use an observational protocol.

<table>
<thead>
<tr>
<th>General Protocol Information</th>
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<tbody>
<tr>
<td>Protocol Title</td>
</tr>
<tr>
<td>Principal Investigator</td>
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<tr>
<td>Clinical Center</td>
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<tr>
<td>Protocol Number</td>
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<tr>
<td>IRR Consent Expiration Date</td>
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</tbody>
</table>

Research Classification:

- [ ] Observational
- [ ] Intervventional

Research Type:

- [ ] Training
- [ ] Screening
- [ ] Natural History-Disease Progression / Physiology
- [ ] Natural History-Sample Data collection or Analysis (Recruiting Patients)

If Interventional Research, choose:

- [ ] Prospective
- [ ] Retrospective
- [ ] Cross-sectional
- [ ] Case only
- [ ] Case-control
- [ ] Case crossover
- [ ] Cohort
- [ ] Randomized Controlled
- [ ] Non-randomized Controlled
- [ ] Single Blind
- [ ] Double Blind
- [ ] Open
- [ ] Single Center
- [ ] Multi-center

Supervisors' or Site: (If applicable)
Clinical Research Nursing Domain of Practice

Competency Program Overview

Clinical Research Nursing Domain of Practice Document

Clinical Research Nursing Model of Care Document

Publications

- Domain of Practice Delphi Study (746 KB)
- Role Delination Study (316 KB)
- White Paper (375 KB)

Resources

- Facilitator Guide (1.03 MB)
- Study Guide (1.02 MB)
- Competency Validation Process Checklist (302 KB)

Page last updated: April 1, 2013
Program Development

2009
• Working group created

2010-2011
• Developed 4 core competencies and introductory course

2011-2012
• Developed study and facilitator guides
Program Implementation

2011 Summer
- Nursing Department leadership completed course

2011 Fall
- Unit leadership completed course, including:
  - Clinical Managers
  - Clinical Educators
  - Senior nursing staff assisting with competency validation process

2012 Summer
- Unit Educators attended educational sessions on use of competency tools
Program Implementation

2012 December
- Clinical Nurse Specialists signed off on competencies by CRN Education Team

2013 January
- Unit Educators signed off on competencies by CNSs

2013 December
- All (600+) CRNs had completed course, protocol worksheet and were signed off on competencies
Kirkpatrick’s Evaluation Model

**Level 1: Reaction**

To what degree participants react favorably to the training

**Level 2: Learning**

To what degree participants acquire the intended knowledge, skills, attitudes, confidence and commitment based on their participation in a training event

**Level 3: Behavior**

To what degree participants apply what they learned during training when they are back on the job

**Level 4: Results**

To what degree targeted outcomes occur as a result of the training event and subsequent reinforcement

Evaluation Components

- Course Evaluations
- Test
- Facilitator Guide Feedback
Future Considerations

• Evaluate Study Guide Usefulness

• Consider ways to evaluate the CRN Domain of Practice Educational Program in relation to the 3rd and 4th levels of Kirkpatrick’s Model: Behavior and Results

• Continual review of introductory course based on change in regulations
Thank You

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