*National Institutes of Health Clinical Center*
*Nursing and Patient Care Services*

# Building the Foundation for Clinical Research Nursing

## DOMAIN OF PRACTICE FOR THE SPECIALTY OF CLINICAL RESEARCH NURSING

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## Overview

The domain of practice for the specialty of clinical research nursing includes care provided to research participants, as well as activities to support protocol implementation, data collection and human subject protection. As the national and international clinical research enterprise expands, it is critical that investigators, health policy makers, regulators and sponsors of clinical research have an understanding of the important role that clinical research nurses play in assuring participant safety, integrity of protocol data and ongoing maintenance of informed consent, all within the context of effective and appropriate clinical care.

## Background

A role delineation project completed at the National Institutes of Health Clinical Center (NIH CC) in 2007, defined the scope of this specialty as including the practice of two nursing roles:

Clinical Research Nurses (CRN): clinical staff nurses with a central focus on care of research participants. They support study implementation within the context of a care delivery setting, such as the NIH Clinical Center, research units in Clinical Translational Science Award sites and the remaining General Clinical Research Centers (GCRC's), or specialty care programs with a clinical research focus.

Research Nurse Coordinators (RNC): nurses primarily responsible for study coordination and data management, with a central focus on managing subject recruitment and enrollment, consistency of study implementation, data management and integrity, and compliance with regulatory requirements and reporting

**Taxonomy Development:**

A taxonomy was developed to classify concepts and roles within the specialty domain of practice. The taxonomy consists of three levels moving from broad to more specific concepts (Figure 1). The domain, clinical research nursing, represents the specialty practice area for nursing. The dimension identifies distinct categories within the specialty domain. The activities are specific job descriptors within each dimension.

Figure 1: Taxonomy Structure

**Domain Development:**

It was proposed that the domain of practice for the clinical research nursing specialty encompassed five dimensions. Each dimension housed a cluster of activities which together describe the specialty practice. (Figure 2)

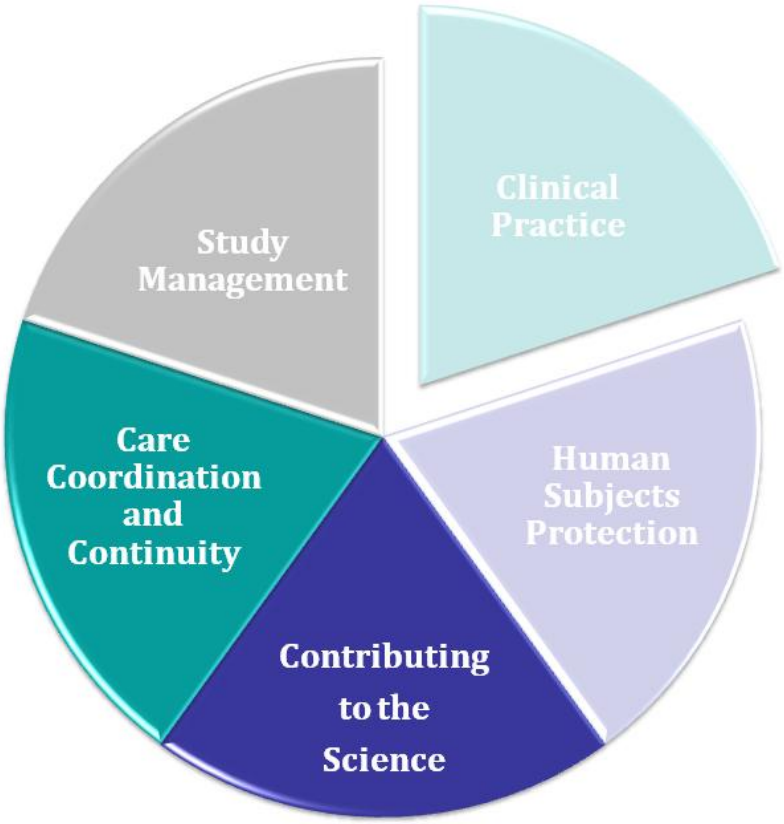


Figure 2: Clinical Research Nursing Domain Dimensions

**Domain Validation:**

An NIH CC Nursing Team was tasked with achieving consensus on the activities and descriptions of the work within the specialty. A purposively–selected national expert panel of nurses who actively provide or supervise clinical research care were recruited to participate in a Delphi survey to address the study objective. Expert panel members were from both the intramural and extramural NIH as well as clinical research sites across the country.

**Findings/Results:**

Thirty experts from across the United States verbally consented to take part in the survey rounds. The primary practice areas indentified most frequently were Clinical and Translational Science Award sites (29.6%), NIH Intramural Program [Clinical Center] (22.2%) and NIH Institute or Center (22.2%). Three survey rounds were distributed. Twenty-seven experts completed the first survey, twenty-four completed survey two and twenty-two experts completed all three survey rounds.

In survey three, agreement ranged from 77 – 100% for inclusion and placement of activities within each domain. The final number of activities per dimension was Clinical Practice (4), Study Management (23), Care Coordination and Continuity (10), Human Subject Protection (6), and Contributing to the Science (9).

The five proposed dimensions within the specialty domain were validated by the third Delphi Round. No new dimensions were identified by the experts. Fifty-two activities were confirmed across the five dimensions. Although activities were refined based on expert panel feedback, no new activities were added or removed. Feedback from the participants guided the final placement of each activity within one of the five dimensions. Appendix 1 includes the complete domain with activities grouped within the five dimensions.

**Invitation for Future Use/Testing:**

The domain of practice document has been configured as a template that can be adapted as a questionnaire or competency checklist. Nurses and others involved with clinical research are invited to download and use this template in their settings. Psychometric properties and a detailed description of the process of development and validation are available from the NIH Clinical Center Department of Nursing and Patient Care Services.

# Appendix 1: The Domain of Clinical Research Nursing Practice

## CLINICAL PRACTICE DIMENSION

*Provision of direct nursing care and support, using the nursing process, to participants in clinical research, their families and significant others. Care requirements are determined by the scope of study participation, the clinical condition of the patient and the requirements and clinical effects of research procedures.*

| | |
|---|---|
| CP 1 | Provide direct nursing care to research participants (Example: interact with research participants to provide nursing care, administration of research interventions, specimen collection, etc.) |
| CP 2 | Provide teaching to research participants and family regarding study participation, participant's current clinical condition, and/or disease process |
| CP 3 | Monitor the research participant and report potential adverse events to a member of the research team |
| CP 4 | Record research data (Example: document vital signs, administration of a research compound, participant responses, etc.) in approved source document (Example: the medical record, data collection sheet, etc.) |

## STUDY MANAGEMENT DIMENSION

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

| | |
|---|---|
| SM 1 | Participate in study development |
| SM 2 | Participate in research participant recruitment |
| SM 3 | Participate in screening potential research participants for eligibility |
| SM 4 | Coordinate and facilitate the collection of research specimens |
| SM 5 | Develop study specific materials for research participant education |
| SM 6 | Perform quality assurance activities to assure data integrity |
| SM 7 | Participate in the preparation of reports for appropriate regulatory and monitoring bodies/boards |
| SM 8 | Facilitate accurate communication among research sites |
| SM 9 | Facilitate communication within the research team |
| SM 10 | Contribute to the development of case report forms |
| SM 11 | Participate in the set up of a study specific database |
| SM 12 | Comply with International Conference on Harmonization (ICH) Good Clinical Practice guidelines |
| SM 13 | Collect data on research participant based on study endpoints |
| SM 14 | Facilitate scheduling and coordination of study procedures |
| SM 15 | Provide nursing expertise to the research team during study development and implementation |
| SM 16 | Protect research participant data in accordance with regulatory requirements |
| SM 17 | Participate in site visits and/or audits |
| SM 18 | Support study grant and budget development |
| SM 19 | Oversee human resources (people) related to research process |
| SM 20 | Record data on approved study documents (Example: Case Report Forms, research/study database, etc.) |
| SM 21 | Facilitate processing and handling (storage and shipping) of research specimens |
| SM 22 | Identify clinical care implications during study development (Example: staff competencies and resources, equipment, etc.) |
| SM 23 | Participate in the identification and reporting of research trends |

## CARE COORDINATION AND CONTINUITY DIMENSION

*Coordination of research and clinical activities to meet clinical needs, complete study requirements and manage linkage with referring and primary care providers.*

| | |
|---|---|
| CCC 1 | Facilitate the education of the interdisciplinary team on study requirements |
| CCC 2 | Collaborate with the interdisciplinary team to create and communicate a plan of care that allows for safe and effective collection of clinical research data |
| CCC 3 | Coordinate research participant study visits |
| CCC 4 | Provide nursing leadership within the interdisciplinary team |
| CCC 5 | Coordinate interdisciplinary meetings and activities in the context of a study |
| CCC 6 | Coordinate referrals to appropriate interdisciplinary services outside the immediate research team |
| CCC 7 | Communicate the impact of study procedures on the research participants |
| CCC 8 | Provide nursing expertise to community-based health care personnel related to study participation |
| CCC 9 | Facilitate research participant inquiries and concerns |
| CCC 10 | Provide indirect nursing care (Example: participation in clinical, unit, and/or protocol rounds; scheduling study related tests, etc.) in the context of research participation |

**HUMAN SUBJECTS PROTECTION DIMENSION**

*Facilitation of informed participation by diverse participants in clinical research.*

| | |
|---|---|
| HSP 1 | Facilitate the initial and ongoing informed consent/assent process |
| HSP 2 | Support research participant in defining his/her reasons and goals for participating in a study |
| HSP 3 | Collaborate with the interdisciplinary team to address ethical conflicts |
| HSP 4 | Coordinate research activities to minimize subject risk |
| HSP 5 | Serve as IRB member |
| HSP 6 | Manage potential ethical and financial conflicts of interest for self |

## CONTRIBUTING TO THE SCIENCE

*Contribution as a research team member to the development of new ideas for study, explorations of innovations arising for clinical research findings to practice.*

| | |
|---|---|
| CS 1 | Disseminate clinical expertise and best practices related to clinical research through presentations, publications and/or interactions with nursing colleagues |
| CS 2 | Serve as an expert in a specialty area (Example: grant reviewer, editorial board, presenter, etc.) |
| CS 3 | Participate in the query and analysis of research data |
| CS 4 | Generate practice questions as a result of a new study procedure or intervention |
| CS 5 | Collaborate with the interdisciplinary team to develop innovations in care delivery that have the potential to improve patient outcomes and accuracy of data collection |
| CS 6 | Identify questions appropriate for clinical nursing research as a result of study team participation |
| CS 7 | Mentor junior staff and students participating as members of the research team |
| CS 8 | Perform secondary data analysis to contribute to the development of new ideas |
| CS 9 | Serve as a resource to new investigator |