National Institutes of Health Clinical Center
Nursing and Patient Care Services

Building the Foundation for Clinical Research Nursing

A CLINICAL RESEARCH NURSING MODEL OF CARE

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A Clinical Research Nursing Model of Care:

Nursing care is provided to participants in clinical research at the Clinical Center based on the requirements of the research protocol, the clinical needs of the participant, and the clinical needs that emerge in the context of research participation. Clinical research nurses have patient safety, comfort and continued informed consent during the research participation process as their top priorities. Nursing care is planned and provided based on an understanding of the goals of the protocol, the individual clinical needs of the participant, and participant and family involvement.

Purpose:

To define the scope and accountability of the nurse in a clinical research setting, in relation to research patients / participants, and in keeping with the Clinical Research Nursing Standards of Care (see Appendix 1).

Overview:

The NIH Clinical Research Nursing Model of Care provides a framework for the responsibilities related to the delivery of clinical care to research participants and the support of research protocols. These responsibilities include the overall management of a **group of research participants** on a single protocol or multiple related protocols across various care delivery sites, as well as the management of an **individual research participant** within a designated clinical area.

Clinical Research Nursing

Clinical Research Nursing is nursing practice with a specialty focus on clinical research. It includes care provided to research participants, as well as activities to support protocol implementation, data collection and research participant protection. In addition to providing and coordinating clinical care, clinical research nurses have a central role in assuring ongoing maintenance of informed consent, integrity of protocol procedures and accuracy of research data collection.

Nursing care requirements for research participants differ from care requirements for a patient coming to a health care setting for treatment of a clinical condition. Care received by research participants is driven by protocol requirements and the collection of research data. Protocol requirements must be coordinated with the care requirements indicated by the clinical condition of the participant. Protocol requirements may include administration of investigational drugs, use of a psychosocial intervention, detailed clinical assessment or phenotyping to characterize natural history and etiology of a disease, or an investigational surgical or radiological procedure. Data collection includes clinical observations, clinical measurements, specimen collection and/or documentation of research participant reported outcomes. Additional care requirements may be

imposed by the response of the participant to the investigational intervention and vary from education strategies regarding self monitoring to comprehensive physiological support in an intensive care unit. Clinical research nurses must continually balance the individual clinical needs of research participants and protocol requirements as they practice, while assuring consistency of baseline treatment and monitoring across participants within a study.

The NIH Clinical Research Nursing Care Delivery Model

Clinical research nurses serve as key collaborators in the implementation of clinical research. The *NIH Clinical Research Nursing Care Delivery Model* ensures the highest quality of clinical research care for each research participant. This model includes two central roles: the *protocol coordinator* for a defined specialty practice or protocol group, and the *primary clinical research nurse* who takes accountability for the processes and outcomes of clinical research care for individual participants. (See Appendix 2)

The protocol coordinator is primarily an indirect care role. A protocol coordinator is an experienced clinical research nurse who assumes responsibility as the nursing specialty team leader for a group of research participants based on a set of related protocols within a patient care unit or ambulatory program. The protocol coordinator determines the level and types of nursing involvement required and crosses clinical areas and discipline boundaries as a consultant on protocol and/or specialty specific clinical research nursing care. A protocol coordinator may also assume direct care responsibility for individual research participants as a primary clinical research nurse.

The primary clinical research nurse is a clinical research nurse with expertise in clinical research implementation who practices in a specific clinical care area. The basic tenets of practice for primary clinical research nurses are:

- **Expertise** in clinical research implementation and specialty clinical nursing practice
- **Accountability** for development, communication, implementation, coordination and evaluation of individualized research participant plan of care in collaboration with the patient, family, significant others, interdisciplinary and research teams
- **Continuity of care** based on **consistency** in care providers and approach to care
- **Advocacy** for the research participant and family

In collaboration with the research participant, family, and interdisciplinary research team, the primary clinical research nurse is accountable for the development, communication, implementation, coordination and evaluation of an individualized research participant plan of care which is driven by and compatible with the research protocol and clinical care requirements.

An associate nurse or the clinical research nursing team assumes responsibility for the implementation of the clinical plan of care and the research study during a given shift or visit. To the extent possible, primary clinical research nurses serve as the assigned CRN for their patients. Clinical research technicians are unlicensed clinical team members who work under the direction of a clinical research nurse to implement the research participant plan of care and support selected study procedures or data collection. The primary clinical research nurse works with assigned clinical research nurses, clinical research technicians, per diem nurses, and other interdisciplinary team members to implement and document the clinical research plan of care. Primary clinical research nurses may also serve as assigned clinical research nurses for research participants whose care is being (1) managed by a colleague or (2) managed through the use of a standardized short stay or ambulatory visit plan.

The primary clinical research nurse also serves as an advocate and resource for the research participant and family within the interdisciplinary research team and assures a seamless transfer of care to another clinical area or community when appropriate. The primary clinical research nurse is responsible for the continual balancing of research and clinical care requirements and for assuring that protocol integrity and data quality are maintained within the context of clinical care. See Appendix 2 for a summary of roles and responsibilities of clinical research staff in the care of research participants.

Both primary clinical research nurses and protocol coordinators are integral members of the interdisciplinary clinical research team and participate actively in protocol development and implementation, clinical care and research outcomes dissemination. They collaborate closely with **research nurse coordinators** (research nurses) working within the institute or center research team to assure protocol integrity, data quality and research participant protections. They contribute actively to the development of a dynamic professional practice climate through discussion of various research participant case studies, engagement in clinical scholarship including dissemination, and education and mentorship of other staff.

Appendix 1- Clinical Research Nursing - Standards of Care

Every research participant can expect the following from nursing at the Clinical Center:

1. Research participants can expect to receive evidence-based nursing care consistent with the accepted professional standard related to their particular condition or therapy.

2. Research participants can expect that their care and treatment are consistent with the research protocol guiding their participation, and that valid data are being collected by the nursing staff

3. Research participants can expect that treatment and monitoring will be individualized to accommodate individual needs, to the extent allowed by the protocol, and that in *all cases* participant safety, comfort and well-being will be placed *above* research requirements.

4. Research participants can expect prompt assessment and appropriate response to changes in condition or untoward responses to research procedures.

5. Research participants can expect to know which nurse is accountable for their care and how to contact that person.

6. Research participants can expect that nurses will communicate and collaborate effectively with members of the clinical research team to assure coordinated, high quality care.

7. Research participants can expect that information about their care and condition is discussed and communicated with confidentiality, and that care is being appropriately documented.

8. Research participants can expect that while in the Clinical Center they will have a sense of being cared for as an individual and that they will receive prompt, courteous and individualized services from nurses and patient care staff.

9. Research participants can expect to develop an understanding of their condition, research participation and treatment, and be able to manage self care as appropriate after discharge.

10. Research participants can expect to be involved with discussions and decisions about their plan of care and research participation.

Appendix 2 – Clinical Research Nursing - Roles in the Care Delivery Model

Scope of Activity	Protocol Coordinator Role	Primary CRN Role	Assigned CRN Role	Clinical Research Tech Role
Focus of Work	Group of participants on a given protocol	Individual participant who requires continuity for care spanning more than one day or visit	Individual participant	Individual participant or unit tasks (i.e. setting up research bloods)
Time Frame	Duration of Protocol or long term program of care	Episode of Care (inpatient admission or one or more protocol related visits)	Shift/Visit	Shift/Visit
Assessment	Overall impact of protocol, level of nursing care required, clinical needs of patient population (group assessment)	Health status, needs and responses over an episode of care – presenting and as they evolve during participation (individual assessment).	Immediate presenting needs, follow-up based on prior caregiver report, new or emerging needs based on changes in therapy or health status	Immediate needs and responses to care; participant initiated requests or concerns
Planning	Plan and standards for specific protocol-based care and patient population-based care that become part of the protocol implementation plan.	General and specific goals and plan for episode of care (to be achieved by the end of the episode	Priorities for care during shift, including delegation of appropriate activities. Review of existing plan; recommendations for changes based on shift-to-shift observations	Priorities for care during shift
Implementation	Education of staff; preparation of protocol specific forms and research participant educational materials; ongoing participation in research team coordination of care	Implementation of nursing plan of care, medical orders and protocol procedures, incorporating participant feedback and adjusting as indicated by participant response	Implementation of nursing plan of care, medical orders and protocol procedures	Implementation of delegated care per plan of care and protocol
Evaluation	Quality monitoring to assess consistency in implementation; assessment of patient feedback and need for change as protocol progresses; evaluation of participant outcomes assessing for trends and needs for changes in protocol implementation plan	Assessment of patient responses over entire episode, movement towards identified goals and effectiveness of protocol procedures with feedback to clinical research team and modification of plan as appropriate	Assessment of patient responses during shift with feedback to clinical team and recommendations for changes as appropriate	Monitoring of specific patient responses and reporting g to covering CRN