POSITION STATEMENT: General Clinical Research Center Nurse Managers Position on Clinical Research Nursing

ABSTRACT:
The purpose of this paper is to describe the unique role of Clinical Research Nurses and to articulate the requisite knowledge and skill necessary to succeed in the clinical research environment. The General Clinical Research Center (GCRC) Nurse Managers’ Association is committed to the parallel growth and development of both the clinical research enterprise and the specialty of clinical research nursing. The content of this paper represents the long history and rich experiences of clinical research nurses who have contributed to improvement and innovation in American health care through their practice in GCRCs across the US. Clinical Research Nursing is at an important juncture as the Clinical Translational Science Awards (CTSA) provides the opportunity for institutions to create innovative infrastructures for research that best suit their individual strengths. As these innovations move forward, it is important that the wisdom and experience gleaned from 45 years of clinical research nursing in GCRCs be incorporated and innovatively reengineered, with the best interest of patient safety and the highest standards of research conduct in mind. Clinical Research Nurses are at
the bedside monitoring patient responses and intervening to protect patient health while maintaining the integrity of the research protocol. However, duties of these nurses relative to the research enterprise have not been clearly defined, nor has the unique knowledge and skill required to fulfill this role been articulated. In this paper we describe the important contributions of Clinical Research Nursing to the clinical research enterprise thus far, and propose key elements that will be integral to any clinical research program in the future.

INTRODUCTION:
Historically, hospitals were created as places to provide nursing care to patients. They were, and continue to be, dependent upon the nursing staff to provide consistent, continuous, coordinated, quality patient care. For the past 45 years a significant amount of clinical research has been carried out in GCRCs. Creation of the GCRC units is tacit evidence that persons volunteering to be clinical research subjects require quality nursing care as any other patient does. Nurses working in these units have been charged with (1) safeguarding human research participants throughout their continuum of care despite their disease acuity and (2) maintaining the integrity of the clinical research enterprise. Today, the
role of the GCRC Clinical Research Nurse is a key element in infrastructure that promotes excellence in clinical research.

The GCRC program has demonstrated that a dedicated site for the study of human subjects is a successful model to provide maximum protection of research volunteers while supporting quality clinical research. With the introduction of the NIH Roadmap and implementation of the new CTSA, institutions are being provided the opportunity to reexamine their clinical research infrastructure and are being encouraged to create different models to encourage a higher volume of translational clinical research. The retention of dedicated sites for clinical research is essential in order to maintain the standards of excellence and level of expertise, which are key elements within the infrastructure of the current GCRC system.

It is anticipated that there is potential for dispersion of research subjects into the general clinical population in these new models. This will dilute research nursing leadership oversight and will have an impact on the integrity of data gathered by nurses inexperienced in research practices. When a nurse, who might or might not be a clinical research nurse, cares for a clinical research volunteer outside of a clinical research unit, the primary practice concern becomes clinical in nature, thereby losing the
unique blend of *clinical and research* currently found on a GCRC. By virtue of practicing at the interface of patient care and the implementation of research protocols, Clinical Research Nurses have expanded responsibilities that require a unique body of knowledge and skill that characterize their specialty practice.

Unique characteristics of the Clinical Research Nurse role include:

- Possesses expert clinical judgment and critical thinking skills shaped by the needs of the human subject as “patient/client” and by the specialized needs of clinical research.
- Possesses expert clinical skills that ensure reliable and accurate specimen collection and processing.
- Provides education and discharge planning that supports subject compliance with the protocol and enhances the quality of the data collected.
- Expert in the continuous assessment of “patient/client” understanding and willingness to continue in volunteer role.
- Collaborates with members of the interdisciplinary team to coordinate the multifaceted aspects of protocol implementation.
• Possesses the ability to identify trends across various studies that identify the need for intervention such as procedural variances, issues related to standards of practice, need for staff or patient education.

• Is a leader in establishing excellence in the standards of patient care in the conduct of clinical research within their respective institutions.

Clinical Research Nurses operate at the interface of two complex and sometimes conflicting practice arenas, research and clinical, each having specific regulatory requirements and professional obligations. They are charged with assuring excellence in both domains while protecting the health and wellbeing of persons who volunteer to serve society as human research subjects. Within the clinical practice arena, nurses and nurse leaders of GCRCs are well integrated into patient care operations where the practice expectations are well known and in fact mandated by their licensure as Registered Professional Nurses. Within the research arena, investigators who hire Clinical Research Nurses or who implement protocols in GCRCs understand the role research nurses play in the implementation of research protocols, but may not fully recognize the clinical mandates that impact their practice including tasks that cannot be
delegated in accordance with state nurse practice acts and institutional policies. Registered nurses carry out research protocols based on standards of excellence and provide patient care that is consistent with the highest standards of nursing practice; they make a unique contribution to the clinical research infrastructure of institutions, especially academic health centers.

FUTURE DIRECTIONS

The future of clinical translational science is intimately associated with and dependent upon the professional contributions of Clinical Research Nurses. Within the clinical research nursing community, the GCRC Nurse Managers’ Association promotes the development of best practice guidelines, creates policies and procedures to enhance the safety and efficacy of clinical research, and disseminates this information to its membership. These activities dovetail with the goals outlined by the NIH Roadmap initiative and the opportunity exists for the development of innovative and creative ways to continue these activities. The CTSA will create incentives for continuing education among clinical research nursing staff, just as clinical research nurses will contribute to the overall educational initiative of the CTSA by providing essential, practical, and theoretical knowledge to the entire interdisciplinary team. Clinical
research nurses functioning within these newly established centers will continue to serve as a resource for other professionals in the community.

CONCLUSION:

The specialty practice of the clinical research nurse cuts across the entire clinical research process. It begins with the development of a protocol implementation plan, follows through to patient care and data collection, and ends with refining and supporting the implementation of practice standards based on the findings of clinical research. The clinical expertise of the nurse in this specialty practice spans the spectrum of care from the healthy volunteer to the critically ill volunteer. As institutions embark on the implementation of the NIH initiative for human and translational research it will be critical to structure an environment that supports the safe care of patients and maintains the integrity of the research protocol. Institutions that provide a clinical research infrastructure that includes specialty research nursing practice will benefit from the unique contributions of the Clinical Research Nurse. Such a clinical research environment will safely support novel translational research protocols with outcomes that will shape clinical practice and health care of the future. The specialty practice of the Clinical Research Nurse is vital to this success.